NWX-HHS FDA ORA

Moderator: Anita MacMullan
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Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen only mode until the question and answer session of today's conference. At that time you may press star 1 to ask a question. I would like to inform all participants that today's conference is being recorded.

If you have any objections you may disconnect at this time. I would now like to turn the conference over to Mr. Joe Reardon. Sir, you may begin.

Joe Reardon: Thank you (Jennifer). And I want to welcome everybody to the call this afternoon and good morning to those of you on the West Coast. And I thank everyone for joining our call today. Again I am Joe Reardon, the senior advisor for Federal/State Relations in ORA FDA.

And today is really a very special call and something that I'm really proud that we're doing today. It's a little bit of a different call than we've had in the past, a type of hot wash type call and we really hope that this call will be very engaging.

And so we want everyone to think and listen through this call today and identify your questions or concerns are.

This is really one of the first times that I can remember when we at FDA have actually held a call in combination with our partners at CDC to provide not only an overview of the investigation of the farm investigation as it would relate to the listeria that was identified in the cantaloupes form Jensen Farm in Southeast Colorado.

But also an opportunity to talk about the investigation, the laboratory findings, the product recall.

And then following the presentations that we're going to have at the beginning of the call, we're going to open this call up for everyone to give us some thoughts and comments and suggestions on how to move forward.

And so this is one of the first calls but I hope it - and have been reassured that it will not be one of our last calls that we do. And so this call is going to be a little bit different than we normally hold but I think a very good beginning and an extremely important call.

We have several speakers with us on the call today and we have Dr. Barbara Mahon, the Deputy Branch Chief, for the enteric disease branch of CDC. And she's going to share some information with us today. Dr. Kathleen Gensheimer. She's our Chief Medical Officer with FDA CORE Network.

And we're really exciting about her being at FDA and what she has brought and the management that she's going to provide the leadership and direction to CORE as we move forward and looking to better understand what the

vehicle is and some of the illnesses that we have had and outbreaks in - as we go forward.

And then Sherri McGarry, the Senior Advisor for FDA's CORE Network is on the call with us as well today. But to get us started we're going to ask Dr. Mahon to provide us with an overview of the epidemiology associated with the investigation.

And then Sherri McGarry is going to provide us with a review of the environmental investigation, the timeline of events, the laboratory findings and the post response. And so I'd like first to turn it over to Dr. Mahon to give us an overview from the CDC perspective. Dr. Mahon?

Dr. Barbara Mahon: Hi. Thanks so much Mr. Reardon. I'm Dr. Barbara Mahon, the Deputy Chief of the Enteric Diseases Epidemiology branch at CDC. This outbreak has ended and thanks to rapid and effective public health and regulatory action that ended substantially sooner than it otherwise would have.

Nonetheless it was the deadliest food borne outbreak in the United States in more than 90 years. And it was also the first outbreak of listeriosis linked to cantaloupe in the United States.

The peak in illnesses occurred in late August to the middle of September and we were back to baseline by the end of October. In total, CDC received reports of 146 cases and 30 deaths from 28 states as well as one miscarriage in a pregnant woman.

These numbers will be posted in a final outbreak Web update on www.cdc.gov within a few days. In all seven cases were associated with six

pregnancies. In addition to the miscarriage one mother and her infant were both infected.

Two other positive cultures were reported from ill newborns but not from their mothers. One positive culture was reported from a pregnant woman who gave birth to an uninfected newborn.

And one positive culture was reported from a pregnant woman who was treated and whose pregnancy is still being monitored. In an outbreak response our first goal is always to bring the outbreak to an end as rapidly as possible.

And in this outbreak the rapid and successful investigation not only prevented more cases and deaths it also identified a new food vehicle for listeria, cantaloupe, that we did not know about in this country before.

The outbreak was first reported to CDC by the Colorado Health Department on September 2nd. Within ten days and with only 13 cases reported CDC issued a national consumer warning. The specific producer was identified and the company recalled their cantaloupe on September 14th.

Listeria outbreak investigations typically take months so this is a real success. And one of the major keys to the success was the listeria initiative.

So I'd like to take a few minutes to talk about it and about how it helped to solve this outbreak in record time and also to encourage all state health departments to participate fully in it.

The enteric diseases epidemiology branch started the listeria initiative in 2004 in accordance with a CSTE position statement to improve the speed and effectiveness of listeria outbreak investigations.

In listeria outbreaks finding appropriate controls can be a major challenge because listeriosis usually affects only a small, higher risk segment of the general population. That's older adults, persons with immunocompromising conditions and pregnant women and their newborns.

In an outbreak investigation identifying people to serve as controls who were at similarly high risk, can be even more resource intensive than in other case control studies and can really slow down the investigation.

Through the listeria initiative states routinely report food consumption histories from patients with listeriosis to CDC as illnesses occur without waiting for an outbreak to be identified.

Interviewing patients as soon as they're diagnosed can help reduce recall bias which could be another big problem in listeriosis investigations because of the long incubation period for illness and because many patients can be so severely ill.

Then when a cluster or outbreak of listeria infections is identified which usually happens through PulseNet, epidemiologic data on food exposures from the listeria initiative database are linked with PFGE information.

This allows us to identify outbreak related illnesses and sporadic illnesses for rapid case/case analysis. Case/case studies are similar to case control studies except the controls are patients with sporadic cases of illness, that is patients who are not associated with the outbreak.

Using patients with sporadic listeriosis is control solved the problem of finding controls from higher risk groups because these patients are by nature in the higher risk groups for listeriosis.

They can be batched by age, pregnancy status or other factors as needed for the outbreak under investigation. And since their food consumption histories are already available analyses can be conducted and results obtained very quickly.

The listeria initiative more than proved its worth during this outbreak. As Colorado public health officials received the reports that led to their recognizing the outbreak, they rapidly conducted patient interviews using the listeria initiative questionnaire.

Using those interview data we conducted a case/case comparison of the foods eaten by outbreak patients and patients with sporadic infections. And within one day we were able to convincingly show that cantaloupe was strongly associated with the outbreak.

For the epidemiologists on the call the odds ratio on that first day was 8.5 and was statistically significant. And as information on other cases came in later and was included in the analysis, it became even higher.

Cases in other states were also quickly identified and linked to the growing outbreak by comparison of their PFGE patterns through PulseNet. The listeria initiative depends on state health departments for two things.

First, routine interviews of all patients with listeriosis using the listeria initiative questionnaire as soon as possible after the case is reported. And

second, routine PFGE of all listeria isolates with upload to PulseNet as soon as possible after isolation.

Since the listeria initiative started in 2004 the number of states reporting cases to it has increased from about 20 to more than 40. And the percent of all listeriosis patients interviewed has increased from about 15% to about 70% which is great progress and it's really paid off.

But there's still room for improvement and we encourage all state health departments to participate fully. The listeria initiative really can dramatically decrease the time from outbreak detection to public health intervention.

Another key to the success of the investigation of this outbreak was the excellent collaboration and fast work by investigators from state public health agencies and FDA to conduct rapid trace back and to collect cantaloupe from patients' homes, from the stores where they shopped and from farms that supplied those stores.

The culture of those cantaloupes yielded the four outbreak strains. This work was critical in rapidly identifying the source farm and in allowing a detailed investigation of the root causes of the outbreak. And Sherri McGarry from FDA will discuss this work in more detail next.

Although the public health response to this outbreak clearly kept it from being as bad as it could have been it's still a tragic situation. We need to learn all we can from this experience. This call to discuss the lessons learned is an important part of that.

The CDC's committed to continuing to work with all of you as well as with FDA and our other partners to do everything we can to prevent food borne illnesses and deaths. Thank you and I'll turn it over to Sherri McGarry now.

Sherri McGarry: Thank you doctor and again this is Sherri McGarry with FDA's CORE Net (unintelligible) response and evaluation group and I'm the senior advisor with that group.

And I again want to extend appreciation for everyone being on the call today to really share some of our lessons learned from this outbreak and again I don't want to spend too much time on the presentation part.

I really want to hear from our state partners, colleagues on what went well and how we can improve in the future. But I think to have that dialogue might be helpful to give a little bit of a recap of some of the significant events.

And as Dr. Mahon pointed out, some of the excellent work, proactive rapid work that was done by Colorado state officials and local official CDC and FDA working together in other states as well when we get, you know, beyond the initial kind of investigation part, working on the recall and other aspects and communication.

So let me kind of give a little bit of a recap on the timeline to give us a context. And I know you - hopefully you all have that timeline that Mr. Reardon and his group have sent out. So let's just do a quick review to kind of jog our memories a little bit, of some of the key events.

So FDA working with Colorado state and local officials and CDC and again we work in this way on all outbreaks, trying to find exposure information, the best exposure information of the best - what we call cases, to trace back.

So Colorado collected the initial information on trace back and share that with FDA. And we collectively continued that work with Colorado officials and also cooperating with CDC on exposure information as well.

And as we conducted that trace back we identified early on a couple of growers that appeared to be in common in the trace back.

And I think one of, again the successes here is the proactive step particularly by Colorado and FDA in this instance, to go to those farms before we even had completed the trace to identify a single farm in common.

And so September 10th Colorado officials and FDA visited Jensen Farms which in the end turned out to be the common farm. But we were at that farm before we even completed the trace to find out it was the single common farm.

And conducted basically an inspection on the 10th, FDA and Colorado working together in a joint inspection. So we completed that investigation inspection on the 10th, collected samples as part of that investigation.

And while those samples were in process we were basically learning more on the trace back.

And through the sample information as well as the trace back findings, Jensen's as the commonality, we decided that it would be worthwhile to go back to Jensen's Farms and that was on the 22nd and 23rd with a multi disciplinary team to conduct the environmental assessment.

And I know that there's quite a bit of information on FDA's Web site about the environmental assessment, how it's done and, you know, when we

conduct an environmental assessment we're using expertise in many different areas - veterinarians, epidemiologists, microbiologists and investigators with expert information and knowledge.

And again, kind of looking at this multidisciplinary approach and of course that was again a joint effort between Colorado and FDA to conduct the assessment. Another key success to this is that those joint investigational efforts and findings.

So as you know, from probably reading the reports, we did identify all four, actually Colorado was the fourth of the outbreak streams in samples collected either through retail samples or through samples collected - environmental samples primarily.

But we also did get cantaloupe positive samples though that matched the outbreak streams. So that really kind, you know, added another piece of that to really solidify that Jensen's Farms was the commonality from the trace.

And then we also kind of had the sample of results matching the outbreak stream that pointed us to Jensen's Farms and conducted that environmental investigation to really identify how might this contamination have occurred?

And so the environmental assessment looked at both growing production sites as well as packing operations.

We looked for kind of the root causes of how this may have occurred, looking at different aspects of packing and cold storage, again the growing fields looking at, you know, (ivory) coastal waters, soil, growing and harvesting practice, potential animal intrusion, adjacent land use, employee health and hygiene, mostly at the production end.

And then of course on the facility end looking at sanitary design, cleaning and sanitizing practices, washing, drying including storing and transporting of cantaloupes so kind of looking at all of those aspects with the multidisciplinary team.

As you know, I'm kind of jumping back a little bit in the timeline. There was a recall that was done on September 14th by Jensen's Farms to recall the cantaloupe that was contaminated.

So that was again a proactive step that occurred just shortly after the infection that had occurred jointly with Colorado and FDA. And then of course the environmental assessment after that.

And some of the findings - again a lot of this information is on the Web but just again to remind folks, to kind of jog their memory of some of the things that we did find on the environmental investigational side is where we had - from the production end a truck that is used to haul a cold cantaloupe to a (cattle) operation was parked very close to the packing facility.

If you think of kind of the environment on a packing facility, certain could have introduced contamination into the packing facility. We're looking at the packing facility, the design, kind of allowed person pooling of water on - was on the packing facility for and near equipment.

And also where walkways - there was access for employees and grading stations.

So you can also envision that there could be a spread of that contamination just by the design - the packing for - the facility that was constructed in a

manner that wasn't easily cleanable. Some of the equipment wasn't easily cleaned and sanitized.

Some of the washing and drying equipment used for the cantaloupe packing had been used previously for another commodity and then there was kind of on the cooling side of things kind of a different approach to cooling where there really wasn't a pre-cool step to remove the (fealty) from the cantaloupes before cold storage.

And, you know, certainly we can talk about some of the findings but I think the main focus today is really to learn what went well and where we can approve in this process, working with our state partners. And I'm going to say we did have quite a few media conference calls to share some of the findings.

And I'd say one of our lessons learned on FDA side already that we know, is I think we certainly could have improved upon some of our communications with our state partners that maybe weren't directly - when I say directly what I mean is the investigational part of it as affected.

And so I think we already have some lessons learned. That's part of our process in FDA is to make sure we look back and see where we can improve.

But I think one of the things that we can certainly say collectively is that we were very proactive in this investigation, all of our partners, in that the key work done by Colorado in particular, really made a huge difference.

The proactive steps by our district office and those that are on the environmental assessment team both from CORE and from our produce safety staff and from the district office in Colorado, really have some excellent

findings that we were able to share with industry and with our state partners here.

So hopefully this contamination event won't occur in the future. And that's really why we conduct environmental assessments so we can prevent it in the future. And of course that is one of our main focuses in the Food Safety Modernization Act.

And our goal here at FDA is to prevent outbreaks like this from happening in the future. And again if it wasn't for some of the excellent work by Colorado, CDC, other states as well and FDA, I'm not sure that we would have had the findings that we have right now.

But really kudos to Colorado and other states as well in this outbreak investigation protecting public health. We really truly did prevent additional illnesses by the proactive steps and partnerships.

So I think - let me just make sure I touch on some of the key points - one other point I wanted to share with you is we did issue a letter to industries highlighting some of our findings.

But more importantly is reminding our industry partners that there is existing guidance out there that actually addresses some of the findings in this outbreak, particularly in the area of packing and cooling.

So we did issue a letter to the industry - the cantaloupe industry reminding them of that guidance. It is guidance. It is voluntary. But as we look to the future in (SISMA), there are certainly going to be more efforts from a preventive standpoint, that will be requirements down the road.

So I think with that I'll turn it back to Mr. Reardon right now to take us through the next steps.

Joe Reardon: Well thank you Sherri and thank you Dr. Mahon for this summary. This is a great representation of the work that we can do in building an integrated food safety system.

I mentioned earlier that Dr. Kathleen Gensheimer had joined us at FDA as our Chief Medical Officer. And Dr. Gensheimer, prior to us taking questions from our listeners on the phone, is there any additional comments you would like to make here?

Dr. Kathleen Gensheimer: I can't really add much more. I think that this is an incredible, exciting investigation. It shows what early detection can accomplish. It shows what full integration between feds and states and locals can accomplish.

And I'm just really excited to be a part of this whole initiative. Thanks Joe.

Joe Reardon: Well thank you Dr. Gensheimer. And again, I want everyone to be thinking about some comments and questions that you have relative to the investigation, product recall, communication or information sharing either right in the Colorado area or across the United States.

This is going to be a hot wash, one of the very first we've ever done. We want to hear from you - suggestions, recommendations, what went right, what wrong and what can be improved.

We're also very excited today to have representatives from the Colorado State Department of Public Health and Environment. Alicia Cronquist and Susan Parachini are on the phone from Colorado.

And Alicia or Susan, are there any comments you'd like to share before we go to the open call here - we surely want to give our partners at Colorado State Department of Public Health and Environment an opportunity here with the great work that you all have done in combination with FDA and CDC and our district partners there in Colorado? Any comments?

Alicia Cronquist: Hi. This is Alicia Cronquist and I'm here with Susan Parachini and I think that both of us feel that we have nothing further to add.

Joe Reardon: Okay. Fantastic. And again, joining us on the call today is Dr. Jim Gorney which is our Senior Advisor for Produce Safety. We have several other people that have joined us, even (David Meiser), the supervisor in the Denver District Office.

We have (Katie Berrick) with CORE. We have a lot of FDA officials that have joined us on the call today. But we really- as Sherri and Dr. Mahon and Dr. Gensheimer said- we're here to hear from you.

And so (Jennifer), I know you're in charge of opening these lines up and so we want as much participation in this call - we're going to take time to listen. We're going to try to respond to the things here. They may be things that you ask of us that we need to respond in writing. We're going to do that too.

Again, it's one of the first calls that we've ever had as a hot wash and interactive type call. I applaud everyone for their willingness to participate. And I'm thankful for the 180, nearly 200 or more people on the line today that hopefully will give us some feedback.

So Sherri, if you will, let's take some questions, some comments as it would relate to the investigation, the product recall, communication, information sharing, things that went right, things that could have been improved, and recommendations to how to move forward.

Jennifer if you'll open the lines up, we look forward to hearing that information.

Coordinator: Thank you. If you would like to ask a question please press star 1 and record your name clearly. To withdraw your request you may press star 2. Once again to ask a question or make a comment please press star 2. Just one moment for our first question.

And our first question comes from (Charla Haley). Ma'am, your line is open.

(Charla Haley): Thank you. Hi. We had a little bit of an issue here in Utah finding out if we had any of the product here and it turned out that we eventually did find some.

And I'm just wondering if there's anything that can be done to help us be able to communicate an accurate message rather than waiting until somebody happens to find out that we actually did have some of the cantaloupe here.

Joe Reardon: Sherri, do you want to take a stab at that?

Sherri McGarry: I will. This is Sherri McGarry. And I think (Roberta Wagner) may be on the phone as well. But I think this is an area - I'm actually really glad you asked that question. One of the challenges that we face at FDA is some of our legal restrictions with sharing some information. That's one piece.

The other piece is we rely so much on the industry information to let us know where that product was distributed. And we also know that there can be sub distribution. So we may not know right away where that product ultimately went because there may be several steps before we know the end point.

And sometimes we don't know the retail point, we know the step or two down and again because of the - just because of the nature of sub distribution. So there are all those inherent delays that occur because of that sub distribution.

And the information we receive from the firm typically is the one step forward. And so we do have those challenges in trying to find out ultimately where products went and it takes a bit of time. That's one piece to try to explain why you may not know right away.

And we don't know right away the final point at which a product may have reached. The second aspect is the sharing of information, distribution lists which are commercial confidential information.

I think Mr. Reardon is maybe going to broach this topic a little bit towards the end and say some encouraging words of whatever can be done.

And I'm speaking to this not just to Utah really because you may already have this established, but other states as well in having agreements in place so FDA, due to our legal restrictions, we need those agreements in place with our state partners in order to share a commercial, confidential information which is distribution information.

And we have been working for a good period of time to try to find ways to make that information be shared faster, quicker but we do have those legal constraints and so we really do encourage commissioned officers in this off

space or other types of agreements that can be made to share commercial confidential information.

And hopefully that - I'm hoping that addresses your question maybe not as efficiently as you might like, but any comments back are much appreciated.

(Charla Haley): Thank you.

Coordinator: Our next question comes from Doug Saunders. Sir, your line is open.

Doug Saunders: Thank you. This is Doug Saunders, Virginia Department of Agriculture and Consumer Services. And I would just like to share along with what the State of Utah just shared, I think, you know, it's good that, you know, this investigation into this outbreak has gone as well as it has.

And I think that's very encouraging, you know, however I think we all need to be cognizant of the importance of appropriate communications because here in Virginia we ran into a situation also where, you know, we didn't find out that we were on the recall list until it actually showed up on the list.

And only to find out once we had done some investigation that the cantaloupes really had not been distributed within this state.

And my main reason for mentioning this is just to; once again stress the importance of verbal communications, you know, so that if a state is going to show up on a recall list that they are made aware of it, you know, before they actually read the list when it comes out.

So, you know, not trying to point the finger at anybody, just once again just stressing the importance of appropriate communications between all of the necessary parties.

Joe Reardon: Doug, this is Joe and I want to thank you for those comments because that's really what we want to hear from all across the country over the next little while that we're on this call is those very candid comments that you're making and that we had heard from Utah as well.

So thank you for those comments. And at the end of the call we are going to provide information on how we can move forward to make that process more effective. But we do need that type of conversation today. Sherri?

Sherri McGarry: Yes, if I could add to that and echo what you said Joe as well, I appreciate Doug's comments there and I absolutely agree that you shouldn't find out about it when it's posted. So we do need to work on that.

One thing that I want to share with you that we encountered and I know this affected more than in Virginia, again the information that we received is from the firm. And at that time we're moving quickly to try and get the information out.

And so what happened early on is the firm gave us information about distribution. And we didn't know at the time that some of those addresses were not actually where the product was physically shipped but more or less either a broker of some kind or a - just a mailing address of sorts.

And I know (Alan Gelfius) is on the phone as well as (David Meiser) if they want to kind of clarify what I said or correct what I said. But that was one of

our challenges early on in trying to get information out quickly. We didn't know at first that that wasn't the physical shipment of the product.

So again I apologize for that confusion. But in the effort to try and get information out we didn't have those particulars and - but we were able to clarify and correct our Web site as quickly as we possibly could.

Doug Saunders: Who's going to be on the list before you publish it?

Sherri McGarry: Joe?

Joe Reardon: Yes, thank you Sherri and thank you Doug for those comments. (Jennifer), do we have some additional questions?

Coordinator: Our next question comes from (Caroline Picard-Bombat). Ma'am, your line is open.

(Caroline Picard-Bombat): Good afternoon. Thank you all for your comments. And to go along with what Joe said, as well as Utah and Doug Saunders, from the State of Louisiana's standpoint I do understand this commercial confidential information that was previously mentioned.

However these are permitted, regulated facilities in the State of Louisiana. We were - we stood ready to go out and gather all of the products that could have been contaminated.

And we did not receive, for the two cases that we had in Louisiana, information until after the people had already been infected with the product. And so I think that's a major issue that needs to be addressed, you know, just to go along with what Utah and Virginia stated.

It's a major issue that needs to be addressed. And this commercial confidential information that was previously stated, I did not agree with that.

We need to be able to have the information of where this product is coming, if it's coming into our state, so that we can make people aware and remove the product from the shelves in a timely manner.

Joe Reardon: Let me share - you may want to weigh in on the specifics here but again I think there's a common theme here. And so we've got to have a path forward and at the end of this call we're going to talk about it.

The Food Safety Modernization Act - a very good Act and we're all going to be working on building this integrated food safety system. One of the elements of that is that we are directed to share information with our state and local partners in a timely way.

The Act didn't go far enough to provide us any latitude to go beyond what we currently have legally in the code of federal regulations.

And so what we're going to do, and you're going to hear this at the end of the call in a little bit more detail, is put a process in place immediately where we can ensure that in each of the states across the country we have the right people under the right agreement so that we will not be bound by not being able to share this information with our public health partners immediately.

And there are several provisions to do that. We spent the last two years working on the infrastructure to support this process.

And so at the end of the call we're going to lay out some of the steps to take that barrier down and put a process in place that Sherri or (Roberta) or the districts will not be impeded in their ability to share information with our state and local partners in a timely way.

So we do have a path forward and we're going to go over that a little bit later in the call. But we still need this kind of feedback that we heard from Virginia, we heard from Louisiana, we heard from Utah and so we welcome other comments as well.

Sherri McGarry: And Joe, this is Sherri. I'm glad we're going to have that conversation at the end. I think it's really important. It's a theme that has been echoed several times. One thing I want to mention that in many states we do have these agreements and again it is a legal limitation that FDA has.

We do have these agreements with many on the food regulatory side of the house. But more and more as we learn, it's just so important that maybe we also have some of our epidemiologists or on the health side of the house, have some agreements in place as well.

And that the communication between the health officials as well as the food regulatory officials, and I know this is a theme we've been talking about with our state partners for a period of time and whatever we can do to encourage, enhance those communications we stand willing to facilitate it in any way, shape we can. Joe?

Joe Reardon: Thank you Sherri and thank you for those comments. Operator, any additional questions or comments? We want as many as we can get.

Coordinator: As a reminder, if you would like to ask a question please press star 1. Our next question comes from (Patrick Guzzle). Sir, your line is open.

(Patrick Guzzle): Thanks and Joe, you know this - I'm going to echo some of the same communication issues that we had in Idaho. But our situation was a little bit unusual I think and I would urge other states to see if they may be in a similar situation or hopefully avoid a similar situation.

In our situation we were not initially impacted by the recall. However, there was a truckload of product that was shipped to a neighboring state before the recall took place. The retail outlets at the neighboring state rejected the truck because the product was too ripe.

And so it ended up back in the State of Idaho whereupon the shipping company decided to donate the melons at large to the community. We unfortunately in Idaho did not become aware of that until a couple of weeks after an FDA consumer safety officer had that information.

I am commissioned and credentialed and I spoke with our regional office about this and we worked with it in the region to try to make sure that this kind of information gets flowing correctly in the future.

But it was a little bit disconcerting that we had - or FDA had -information that the melons were in the community at large, had been donated through this shipping company.

And we didn't get that from the state level until we actually did our own investigation of that and contacted the shipping firm directly. And that's how we were able to get that information. So I would just I guess throw that out there for consideration.

Joe Reardon: So (Patrick) that's very important and we really appreciate you providing that feedback to us. Sherri, any comments on that? I know we want to get as many comments as we can from the people across the country.

Sherri McGarry: No. Just that, you know, we're all after really the same thing. We want public health protection so we need to make some improvements so again it doesn't happen again so we'll work on that.

Joe Reardon: Thank you.

(Patrick Guzzle): Thanks.

Joe Reardon: (Jennifer), let's go back to the questions.

Coordinator: Our next question comes from (Patrick Kennelly). Sir, your line is now open.

(Patrick Kennelly): Good morning Joe.

Joe Reardon: Good morning.

(Patrick Kennelly): You know, just to kind of echo what Doug and Sherri were talking about, California also had been listed as receiving the product and we were actually one of the states that had the billing address and the product was never shipped to the distribution center here.

And we had already cleared that with the district a number of days before that actually got posted.

To echo Doug's comments on communication, I think is really important that we make sure that we're sharing that information across the board so that as things are being developed that information and part of the investigation that's going on gets to be fed into that process.

But I think the frustrating point here as much as we worked with (Alan) and with (Roberta) to try and quickly resolve that, it took more than 24 hours before the Web was able to be updated on the FDA site. You know, and as they were explaining to us it was really outside their control.

It was kind of within the internal workings of FDA and the approval process to do things. But I think if there's an error that's been identified on the Web site we've really got to work harder to find a way to quickly resolve that within an hour or two hours, not 24.

That's really what kind of stood out to me. I think everyone had the best interest of trying to get it fixed once we put the information back out there. But the reality of the functional elements of trying to get that done seemed to get in the way in some form or fashion.

Joe Reardon: Thank you (Pat). That's a very good point. And I know that Sherri and (Alan) both heard you so we're going to put that in our minutes to address that. But thank you for that feedback. Operator, any additional questions? We want questions or comments - we want as many as we can get.

Coordinator: And our next question comes from Roshan Reporter. Ma'am, your line is open.

Dr. Roshan Reporter: Hello. I wanted to shift over to the consumer. Apparently the thing that's new is that listeria can survive on the outside of cantaloupes and is the theory that people did not wash the cantaloupes before cutting them?

I mean it's not unusual for cut fruit to have listeria on it because it's stored in refrigeration and it becomes contaminated but what is the theory about why people became sick from this? Listeria can survive on the outside of the cantaloupe, can it survive even if people wash with water?

Are there some recommendations for consumers?

Joe Reardon: Sherri, I think that's a good one for you.

Sherri McGarry: I do and but actually I think Dr. Jim Gorney who is one of our produce experts would probably be in a better position to answer the question. Jim, would you like to answer the question for - and I didn't quite catch the name and organization. Could you repeat that again?

Dr. Roshan Reporter: This is Dr. Roshan Reporter from Los Angeles County Department of Public Health.

Sherri McGarry: Thank you. Jim, are you able to address that? I know we do have some information on the Web and also a lot of research that you've been involved in.

Dr. Jim Gorney: Yes, sure. The issue is basically that once fruits or vegetables really become contaminated on the outside whether it's LM or salmonella or E. Coli, there's nothing really that consumers can do to make that product 100% safe.

It is encouraged that they do wash the product under cold, running water and it will reduce potentially the amount of contamination present but it'll certainly never completely eliminate it.

And in this case, when we did the enumerations of the cantaloupe that were taken from the cold storage shed, it had tremendously high LM levels. I don't know what was going on there but it had very high LM levels. And even if they'd washed that product they probably still would have gotten sick.

So yes, consumers should wash their fruits and vegetables immediately before consumption but it's not a fail safe.

Joe Reardon: That's perfect Jim. Any additional comments from the doctor relative to Jim's comments?

Dr. Roshan Reporter: Hi. Yes, how about the - some kind of organic fruit wash? Would that remove more of the listeria?

Dr. Jim Gorney: There's been a tremendous amount of studies done on various aqueous based solutions to improve the washing process. It doesn't matter what you add - chlorine, chlorine dioxide, any type of acids, because the bacteria can reside in places that are these hydrophobic areas where water can't reach.

It really doesn't matter what you put in the wash water. So yes, it will reduce it again but you'll never completely eliminate the pathogens.

Dr. Roshan Reporter: And how about use of a vegetable brush or something like that to wash the surface?

Dr. Jim Gorney: Yes, that can be used. It's actually one of our recommendations. It's posted on the FDA Web site with regard to safe handling by consumers for fresh fruits and vegetables. For some very firm fruits and vegetables like cantaloupe you can use a brush. It would be helpful.

The mechanical action helps loosen up those cells and potentially reduce a little bit more the pathogens.

Dr. Roshan Reporter: Thank you.

Coordinator: Our next question comes from (Bob Cab). Sir, your line is open.

(Bob Cab): Thank you. This is (Bob Cab) from West Virginia. The one thing - I may be jumping ahead but if you have your certificate of commission from the FDA does that entitle you to have this information in a timely manner and have, you know, all the legal pieces in order?

Joe Reardon: (Bob), this is Joe. It does. Basically once you're commissioned by FDA you're able to share that information as if you were a federal employee.

So whether it's a credential or a commission we're able to share that CCI or commercial confidential information as freely with you as we would someone that was working for FDA.

If you have that then that allows us to seamlessly share that information in a timely fashion.

(Bob Cab): Okay. That being the case and I happen to have a commission, is everyone that has those credentials - are they notified by email or what other means,

when something like this happens? Or do we have to go online somewhere to check in to see what's there?

Joe Reardon: No. What we want to happen, and Sherri I want you to help me with a little bit of this, is that whenever a parent district is made aware of an investigation and they're made aware of the distribution patterns or the projected distribution of those products into these neighboring states, we want to be able to then communicate to those other states, our awareness of the possibility of that product moving into those states.

So you, as a public health official, can give us additional information. You're going to know what is going on at the ground level, where the rubber meets the road that simply we're not going to know in Rockville, Maryland or College Park, Maryland and the other districts may not know as well.

And so the framework we want to build is that the collective knowledge of the district and the state collectively, far exceeds the knowledge that the state would have or the district would have independent of each other. We want to build an integrated system.

We want information to come from the investigative district to the district that would represent the State of West Virginia. And then immediately from that district they then communicate to our state partners in those states represented by the district such as West Virginia.

That is our goal and what we've got to build is a technological platform that assists us with it.

But in the absence of some of the technological platforms we've got to build those processes and relationships to make sure that this happens without any hesitation so we can collectively do what's best for public health.

That means that we do this as fast as humanly possible. So (Bob) that there is no impediment in sharing. We've got to build those processes to make that happen.

(Bob Cab): Okay, so the issues that came up on the egg issue where West Virginia was told we didn't have it and in fact we did, have those types of problems been looked at and resolved to where we don't get - I mean sometimes you - I would rather get misinformation that we possibly did with them saying that absolutely we don't when in fact we did.

Have those issues been addressed?

Joe Reardon: Well, I wish I could say every one of them has been resolved but we're not there at that place yet.

But what I can say is that there is a full commitment of Mike Taylor with the Office of Foods, Dara Corrigan with the Office of Regulatory Affairs and obviously Sherri and Dr. Gensheimer, thus we are holding this call today that we're going to hear where those issues are.

And we heard it from Utah, West Virginia; obviously we heard it from some other states close to Colorado where this information is simply not transferring as quickly as we would want it to be transferred. And in some cases the legal framework may be in place.

We're going to talk about that at the end of the call. The information has to go both ways from the state to the district, the district to the state and headquarters to the district.

So are we there yet? No. Are we - do we have the commitment at the top of this organization to get this right? One hundred percent.

We have started the process, thus this call today – The very first time in my 30 years of working at the state level or now at FDA, that we've held a national call where we can get on the table what went right, what went wrong and how to get it better.

This represents a step forward. And so, we're not there yet (Bob). I wish we were. But we're committed to the cause.

(Bob Cab): Thank you.

Coordinator: Our next question comes from (Oscar Garrison). Sir, your line is open.

(Oscar Garrison): Good afternoon everybody. Joe, I really want to thank you all for hosting this call. It's a major part of building an integrated food safety system. As we move forward to work out the communication issues that have frustrated so many for so long, I think this is a great step in getting us on the right path.

You know, one piece that's still lacking and, you know, really Georgia had very little involvement in the outbreak or in the products coming through our state, but we are a major producer of cantaloupes, is still the early notification of state Departments of Agriculture as these food products are identified in the early stages of the investigation.

I didn't realize there are concerns out there with states jumping the gun and other issues.

But I still maintain that the state Departments of Agriculture have a major piece of knowing the movement of these products, knowing the brokers, knowing the farmers, knowing the packing houses and even some diverters that can be involved in repackaging and other activities that really seem to keep making it very frustrating for identifying the source of the product and exactly what states received which products.

And, I don't know how we're going to get that piece nailed down but, any early information that can be passed along of suspected foods and outbreaks I think is going to help us move from a reactive system to a preventive system and get these things under control a whole lot quicker.

Joe Reardon: Thank you (Oscar). Sherri, any comments there?

Sherri McGarry: Yes. Actually I'd love to comment on that. And that's a really terrific point for bringing up and thank you for that. I think there are a couple of ideas. And this topic has come up more recently on how we can get that notice out to some of our agricultural officials in the state.

And Dr. Mahon maybe able to comment as well, but CDC hosts calls of course with the epidemiologists early on as we're doing the epidemiological studies and trying to sort out the food involved.

And one of the things at FDA that we have talked about is that FDA might, and particularly with maybe our new group, CORE, what we might think about doing is having a similar call with a more focus to - and of course we invite CDC in the states that are epidemiologically most involved.

But hold an FDA call that has more of our food regulatory partners on the phone to talk more about the product aspects, to share the epidemiology and where it's headed and to get the intel from the food regulatory and agricultural officials in the states, understanding that we may be bound by certain, you know, information sharing aspects but we want to share as much as we can.

So what's your thoughts on having kind of that we don't want to duplicate efforts but there does seem to be a bit of a void on that other side where CDC's hosting the calls with the epidemiologists.

Maybe we need to, FDA kind of have a call earlier on for some of our agricultural partners and also share some of the epi. What's your thoughts on that, the official from Georgia?

(Oscar Garrison): Yes, I think that's a great piece. We've maintained for years through several issues that we've had down here that although we've had a very active relationship with our state epidemiologists and our public health partners to build an integrated food safety system and an integrated system focused on protecting public health, we have to have the interaction of the regulatory body over these products.

And the knowledge that's carried across the country, whether it's a (Steve Stich) in New York or a (Pat Kennelly) in California or a Doug Saunders in Virginia, when you tap into the resources out there of what's being produced in their states, the distribution flow of those products, you can really cut- not hours but days- off some of the tracebacks in the very early stages and get ahead of the game.

The key to that comes down to where you're not making a knee-jerk reaction but we're using these as educational opportunities to learn from each other and to learn about the movement of the commodities and the food products not only on a regional approach but also on a national approach as well.

Sherri McGarry: Thank you for that. Joe I'm sure will capture that and I also - I do want to encourage - just echo what you said.

It's so important to have the health officials speaking to the ag officials within the state as much as possible because, you know, we can't really take that kind of food regulatory step without the epidemiology to help guide us in what direction to go.

So that partnership within the state and among the FDA and CDC is so important to all of us for those proactive steps. Dr. Mahon, did you want to add anything?

Dr. Barbara Mahon: Yes, I did. Thank you. And what you have just said was the first point I was going to make is that those - in Colorado and - Colorado did such a superb job with this outbreak and it appeared from where we're sitting, that the very close relationship between the epidemiologists in Colorado and the ag groups in Colorado was really critical for doing the rapid trace back, the collection of product from homes, from stores, from the farm that led to such a quick result for the outbreak.

So certainly everything that could be done to encourage those kinds of relationships, that kind of communication both within states and from state to federal is - could only be helpful. So it sounds like a, you know, excellent idea to me.

Joe Reardon: Okay. Thank you Dr. Mahon and thank you Sherri and thank you (Oscar) for your comments.

These comments were just spot on and I think we've identified something that we either can pilot or rollout even in a larger way is what Sherri shared with us about hosting this call with our regulatory officials similar to what CDC does with the epidemiological side.

So we have got to build that communication within the states as well. So (Jennifer) do we have any additional questions?

Coordinator: We do from Ben Miller next. Sir, your line is open.

Ben Miller: Hi there. Good afternoon. Ben Miller, Minnesota Department of Agriculture. Hi Joe, Sherri. I think as the conversation matured here it captured some of the thoughts that I think we had at the Minnesota Department of Agriculture.

But maybe to follow in that concept of investment and the integrated food safety system that (Oscar) was talking about.

You know, I think there may be an opportunity too to look at some of the rapid response states as they exist and maybe leverage some of those resources that exist relative to determining product distribution more quickly as it gets out there.

I know we contacted Colorado directly to try to get a lean on where that product may have gone early on in the investigation and followed up accordingly.

But I think there is an opportunity for a more coordinated effort there, you know, kind of using the infrastructure that we've invested in some of these rapid response states. Or that we may continue to do so in the future.

And the other question that I had was completely unrelated but more to - more in line with the microbiology, is - I know there are four different strains of - or not strains but types of listeria monocytogenes associated with this outbreak.

Is there a thought as to why the pathogenicity was so significant in this particular outbreak? Was it level of contamination or something unique to those strains of LM or don't we know yet?

Sherri McGarry: Ben, good question. And I think maybe a combination of Dr. Mahon and Dr. Gorney, I think can address that question. And if they don't want to I can give it a shot as well. So Jim, do you want to start?

Dr. Jim Gorney: Yes. I don't think it's uncommon to find multiple strains of LM during an outbreak that, you know, causes illness. I think that we did have a tremendously high dose that was being ingested by the ill individual based on our sampling from the cantaloupe that we sampled out of the cold storage.

Whether it was, you know, particularly pathogenic I really can't impress that and maybe CDC can address that portion.

Sherri McGarry: And before Dr. Mahon does Jim, I think there was some other thinking as well as (unintelligible) kind of a bug that likes to have environmental niches. We're not all that surprised to see, you know, a couple of different subtypes so to speak.

Dr. Jim Gorney: That's right.

Sherri McGarry: Okay. Dr. Mahon?

Dr. Barbara Mahon: Yes, thank you. Regarding the pathogenicity, you know, we have much the same questions and this work that's ongoing right now, looking at the strains involved in this outbreak to try to understand better, you know, exactly why they might be different from other strains.

And that work will take some time but will be made public when it's completed. I do think it's - this could be a bit speculative but it was really striking in this outbreak that there was such a very low proportion of pregnancy associated cases.

Typically in the listeria initiative database we see, you know, around 20% of cases reported are pregnancy associated.

And in this outbreak it's much, much less. About six out of 146 - a very, very low proportion and - which makes us wonder whether there are different, you know, differences in the strain itself - pathogenicity of the strain might explain that or whether it might have to do with the dose.

And we noticed that the median age is very high for this outbreak. Even leaving aside the pregnancy associated cases, the median age of the nonpregnant patients is very high, which may indicate that there was an extremely high dose - listeria can grow on cantaloupe at refrigerator temperatures.

And we keep hearing stories about older adults who would slice up a cantaloupe and keep it in the refrigerator and eat one slice a day over a number of days.

So one possibility and there certainly - this is absolutely speculative but one possibility could be that by, you know, day seven or day eight eating cantaloupe that had been refrigerated but that listeria initially in a high inoculum on the rind and then, you know, whether it was internalized beforehand or put on the flesh during cutting that by the time it had been refrigerated for several days or a week or more it could have amplified to very high counts.

So it's a thought but we don't really have definitive information to answer the question at this point.

Joe Reardon: Okay. Thank you Sherri. Thank You Jim and thank you Dr. Mahon. Anything else Ben, on your point regarding the virulence of this particular strain?

Ben Miller: No. I think that covers it. I was just curious and those were all very good responses. I think it'll be interesting to see what the microbiology kind of finally confirms from CDC.

Joe Reardon: Thank you Ben. Thank you for those comments. Operator, any additional questions?

Coordinator: Yes. We have a question from (John Tilden). Sir, your line is open.

Dr. John Tilden: Hi. John Tilden from the Michigan Department of Ag and Rural Development. Joe, it's really encouraging to hear all of the progress that's being made on the trace back parts of the investigation.

And my question kind of focuses on prevention and converting what we've learned from this, into how to prevent contamination in the first place.

I looked through the environmental assessment and there's a long list of observations of conditions that aren't in line with one or more guidance documents and I'm wondering what's FDA's ideas on how to determine to what extent the conditions present in the outbreak associated facility are the same or different than in non outbreak associated packing operations.

That, you know, if we could get that kind of better defined it might help both the agencies and the private sector set priorities for prevention.

Joe Reardon: That's a very good question and we heard some of those same comments from other states as well. Sherri, do you want to take a stab at that?

Sherri McGarry: Yes. I'll start and then I'll ask Dr. Gorney to add here. I've been - myself have been on quite a few cantaloupe investigations both outbreak related and non outbreak related. And for my experience have not, you know, have not seen what we saw here as typical so to speak, practices.

So I would say that it's not something that we're expecting to see routinely. And then on the flipside of that is in the last I'd say year and a half or so FDA has been taking greater steps and more frequently visiting packing facilities of agricultural commodities and gathering more information on those practices.

So I think it's something that we're kind of building that information pool. But from what I've seen anyway and I think what other have seen this is not your norm so to speak. But, you know, I can't speak for every facility out there. So this - I'll turn it to Dr. Gorney to add here.

Dr. Jim Gorney: Yes. I think you're right on target Sherri. I think these were fairly atypical packing practices with no pre-cooling, with using equipment that really wasn't designed for cantaloupe packing or handling.

And I think what we've got to look forward to are the new regulations with regard to our Food Safety Modernization Act, regulations for preventive controls and for fresh produce which will clearly set, you know, implementing regulations which will set a standard of conduct or care which is really going to be needed in facilities that pack fresh fruits and vegetables.

So we've taking those - these learnings into account in drafting both of these proposed rules which will be coming out shortly.

Joe Reardon: Thank you Jim and thank you Sherri. Any additional comments John, related to that?

Dr. John Tilden: No. I think that's right. It's just we have to have a really good understanding of what's "normal." Clearly the load of LM on these was not normal. And it'd be great to understand which parts of the practices that were in place in that facility were what was driving that. Thanks.

Joe Reardon: Thank you John. And I think it really speaks to one of the primary roles of CORE.

You know, to go in now and do an environmental assessment to see if they can identify what the vehicle - what the processes were or the lack of processes, whether it is facility generated, employee practices or whether it's associated with the commodity itself and the growing, harvesting practices.

This really gives us an insight to what went right, what went wrong and what can be learned and then how we can - as we've heard from you and heard from other states - institute and implement those processes to mitigate or eliminate the opportunity to have the same type of issues due to some of those very systemic practices - the growing, harvesting or packing practices that are out there.

(Jennifer), any additional comments here - questions?

Coordinator: We do have one last question from Keith Roehr. Sir, your line is open.

Dr. Keith Roehr: Thank you. Joe, this is Keith Roehr. I'm the Colorado State Veterinarian. And I had an opportunity to work with you in the past in some of the food protection efforts. So I've had a lot of interest in this outbreak.

There's been a lot of discussion ongoing for a long period of time about one health/one medicine concepts. In investigating zoonotic diseases or in this case of potential animal exposure into food production or food protection investigations.

I'd just like to point out that (Paul Teitell) with FDA was very effective in communication and collaboration involvement of our animal health professionals here in the State of Colorado.

When we were approached we were able to send a veterinarian medical officer who resides in the Rocky (Forward) areas. But in private practice done in that area for over 22 year and he had extensive - has extensive knowledge of livestock production systems in the area.

So I think he was able to help with that team. And in the event that there had been a more direct exposure to livestock of enteric pathogens from livestock I think he would have been instrumental in lending an aid in that investigation.

So I'd just like to say that I was very pleased with that collaborative nature of the investigation. And I think it was just a very applicable use of the one health/one medicine concept.

Joe Reardon: Thank you Keith. And I think that's something that we've heard increasingly over the last ten years - this whole concept of one health/one medicine.

And the work that (Paul Teitell) did there in working on the food side, the veterinary side and the animal side of that, is just so important. And you putting that back on the table today again in this call, is extremely important as well.

And so we've got to bear that in mind. And I know Dr. Gensheimer will as we think about this from a global aspect or in a larger community- this one health/one medicine approach, whether it's the human or animal side and the coordination between those two.

So thank you for putting that on the table again. It's a very important point here and we want to capture that. (Jennifer), any additional questions?

Coordinator: We did have another question from Jill Ball. Ma'am, your line is open.

Jill Ball: Hi. This is (Jill) from Wisconsin Department of Agriculture. And I did want to say I appreciate all the work that was done prior to the recall announcement. But I think the consensus is, is that there is some catch up that needs to be done after the recall announcement.

And one of the things that we ran into here was one of the distributors here in Wisconsin issued their own press release on September 16th in conjunction with discussing with FDA what that press release looked like. And it identified that they were removing all of the cantaloupe from their US stores.

But then it utilized in the body of their recall only those states that were identified in the Jensen Farms recall. So the other stores - their other store locations in other states outside of that, didn't pick up on that recall announcement.

So Wisconsin could have known as early as September 16th that we had the cantaloupe here in Wisconsin. Instead we didn't get confirmation on that until September 30th. And then the FDA came out again with that announcement that the three other states were identified on September 30th.

And we also did not receive any prior information from FDA that that announcement was coming out, that again came through our email.

So we found out - actually we were running through that because some consumers notified our Department of Health that they reported purchasing the recalled cantaloupe in that specific retail store. So we were following up on our end and at the same time FDA was in the distribution center.

And then the announcement came out so there was a lot of duplication of effort in addition to the - what I considered- misinformation in that September 16th press release by that retailer.

And so there's a two week lag time there that we could have had that information out to our local partners as well as the rest of the state.

Joe Reardon: Well that is just absolutely good information Jill and we're capturing every bit of this in the minutes and the transcripts. And so thank you for sharing that. Sherri, I'll give you an opportunity if you want to react or anyone, to the information that Jill from Wisconsin has provided.

Sherri McGarry: I'll give it a start and then I don't know if again Joe from ORA might want to comment. I'm not sure who's joined from possibly headquarters or (David Meiser). But I think again we have - we're holding this call to hear from you and we need to find solutions together. So it's good to raise these.

It's so important to raise them and then let's figure out a solution. And I don't have the answer right now and I think no one person does. We need to collectively come up with a solution.

And but as Joe said, we are committed to finding the solutions and to work on this and getting that information to you as quickly as possible. So let me just ask if there's anyone from ORA headquarters or other ORA representative that wants to add anything.

Coordinator: And they may do that - do so by pressing star 1.

Sherri McGarry: Okay. Then I think again we'll add this to the communication challenges. And again where the primary goal is public health protection. So we've got to find solutions because we don't want this to happen the next time.

Joe Reardon: Thank you Sherri. And Jill, thank you for those comments. And we still want to continue to get those comments. We've got about 15 more minutes left on this call. I want to take the last three minutes of it to talk a little bit about a path forward on some of the communication issues.

So we'll take the next ten minutes to continue to get those comments. We want to hear from you. So (Jennifer), do we have anybody in queue?

Coordinator: I show no questions at this time.

Joe Reardon: Let me just talk a little bit about a path forward on some of the communication issues that we've heard from across the country. And while I'm doing so if you have any additional comments we want you to go ahead and call in and we'll go to those questions before we wrap up.

As Sherri indicated earlier, there's no question that the Food Safety Modernization Act gives us the legislative mandate to build this nationally integrated system that the Doug Saunders and the Joe Corbys and those that had worked all their lifetime to understand. And to build an integrated process that our states, locals and FDA have to build-a new system of sharing and communicating in a timely manner.

And the Food Safety Modernization Act says that we shall do that.

So we've been, for the last two years, rebuilding some infrastructure at FDA to be able to handle more people being commissioned, credentialed, with 20.88s in place, not only in ag and public health, to support this process of more seamlessly, timely and effectively sharing information.

And so we will, in combination and working with our regional directors, the RFDDs at FDA, our district directors, our district investigators and compliance branches, we're going to put together a process to rapidly look at the regions and the districts to make sure that we have the right people in one

of those frameworks, either commissioned, credentialed or with a 20.88 in place.

This gives the FDA the ability to share information with a state or local official as if they would be sharing it with another FDA official. It gives us the freedom to share that information. And so we will be rolling out a process to make sure we have that in place.

As Sherri indicated earlier in the call, we have for some time, been putting a lot of people in the manufacturing regulatory programs across the states, under this process. We will take the same effort on the public health community as well - the epidemiologists and the public health officials.

And so you're going to this process coming forward and it's going to come forward pretty quickly. There have been some events over the last 90 days; 120 days that have helped pushed that process forward.

FDA has also released Field Management Directive 50 to provide some guidance on building SOPs between the district and the states in three categories - emergency communication, routine communication and work planning.

But we know that we've got to carry that even further. The Food Safety Modernization Act is going to ensure that we have a framework for national work planning with our state and local partners and to share this information and all of these processes in a more systematic and seamless way.

And so we are committed to that and you'll be seeing some initiatives coming forward very, very shortly. And we're going to need your help. We're going to need help to make sure we've got the right people in these processes.

We're going to need feedback from you if there's someone new or a change in staff that should be receiving this information. We share an operational report now with commissioned officials in the state.

We may expand on some of that. But we're going to need to make sure that this information comes from FDA to the states but likewise we've got to provide a process for sharing the information.

We will do this and this is something you'll see coming out -a rollout of the process in the very near future.

(Jennifer), do we have any additional questions?

Coordinator: We do just one moment. Our question comes from Jim Jones.

Joe Reardon: Thank you.

Jim Jones: Am I on?

Joe Reardon: You are Jim.

Jim Jones: Okay. Was there any role of water quality? Did that play a role in this contamination of this cantaloupe - either irrigation water used to irrigate the fields or used to wash the cantaloupes before they were packed?

Was it a potable drinking water source or was it a regulated drinking water source or was it an irrigation well or any comments on that?

Joe Reardon: Sherri or Jim, either one?

Sherri McGarry: Jim?

Dr. Jim Gorney: Yes. Certainly from our environmental assessment the water quality in the field did not seem to be indicated as an issue. Nor - they used also city water or municipal - not city water but municipal water was incoming into the packing shed and so that did not seem to be an issue.

Certainly water could have helped spread the contamination around and it was not - there was no wash water disinfectant present to help prevent that contamination from being spread around.

Sherri McGarry: And then I - this is Sherri. I'd just like ask (Katie Berrick) and (David Meiser) or somebody from the Denver district if they want to add anything. (Katie) and (David)?

(Paul Teitell): Hi. This is (Paul Teitell) in the Denver district office. As Jim alluded to, throughout the course of both our visits to the farm water - extensive water sampling was conducted both in the packing shed and during the environmental assessment from the field.

And while, you know, that's only a snapshot in time none of those water samples revealed any contamination with listeria.

And I would reiterate also what Dr. Gorney said is that the water used in the packing shed was in fact city water, however the process did not include any additional disinfection either before, during or after the use of the city water.

(Katie Berrick): Hi. This is (Katie Berrick). Thanks Jim and (Paul). I have nothing else to add.

Joe Reardon: Thank you (Paul). Thank you (Katie) and Jim and Sherri on that. And hopefully - any additional questions on that Jim?

Jim Jones: It seems to be answered. It seems like you answered it. But I was just curious if the city water was - added chlorine residual and was disinfected or if it was unchlorinated.

Joe Reardon: (Paul), do you want to answer that? I think you did a little bit but do you want to expand on that?

(Paul Teitell): Yes. The city water for that particular location is in fact a chlorinated water system.

And the chlorine was present in, you know, at levels that you would expect from any, you know, any chlorinated water system coming out of the processing equipment or out of, you know, out of a normal, you know, point of use tap.

Joe Reardon: Okay.

Alicia Cronquist: This is Alicia Cronquist from Colorado. May I add a comment too before the end of this call?

Joe Reardon: Please do Alicia.

Alicia Cronquist: Okay.

Joe Reardon: We'd love to hear from you.

Alicia Cronquist: So I wanted to comment on your discussion about commissioning and is it credentialing, and sharing of information going forward. And I just want to add one additional suggestion as you think about this process.

It seems to us here we have several people who are credentialed and are commissioned and who can receive information. But it's been very unclear to us about which pieces of information we receive from FDA are subject to those restrictions and which pieces are not.

And so one thing I'd like to suggest during the process in which you're going to look at all of this would be to clarify exactly what pieces of information fall under the requirements that they only be shared with (unintelligible) commissioned people and which pieces of information can be just shared with people who are not.

In addition, I'd like to propose that it would be very helpful for state health departments to have a list or some sort of guideline document about which types of information FDA feels are confidential because of the laws that I know you fall under and which are not.

I think that it's an ongoing source of confusion for us that we saw in the epidemiology side to understand what we can and cannot expect from FDA in terms of information based on your laws. That having some sort of list would be incredibly helpful to us.

Joe Reardon: Alicia I think that's a very good comment and we need to provide clarity to you on what is considered CCI information so it will help you in protecting that or thus sharing information more fully within your own staff.

And it's information that we also need to provide internal to FDA as well so that there's clarity inside and outside of the FDA. And so your point's well taken. We have taken the effort of drafting a white paper that begins to define that and makes it easy to understand.

What we found is that we've got to then revisit it to make sure that anyone reading it can understand it and it's not written in legal talk to the point that you don't understand it.

And so we've got some work to do to provide something that is more easy to understand and then utilize. So your point's well taken. Thank you Jim for your question and Alicia, thank you for those comments. And so we will work on that.

(Jennifer), any additional questions?

Coordinator: We do have a question from (Heidi Kassenborg). Ma'am, your line is open.

(Heidi Kassenborg): Thank you. This is more of a comment and suggestion. If you're going to start the regulatory epidemiology meetings - calls that we move from the oral tradition of the calls that are - (unintelligible) with the epidemiologists on some of the people in this investigation.

And there's not a lot of pieces of data that are shared. So orally even though it's frustrating, they do get done. But I think if there's a lot of information, you know, rapid response team states we've been doing a lot of the trace backs.

And the amount of data is such that it needs really a visual platform to be useful. So I would encourage sort of modern electronic technology when you start to look at those calls.

Joe Reardon: Sherri, any comments there while we've got (Heidi)? I think it's a very good point.

Sherri McGarry: Yes. It's right on target. And you're right particularly when it comes to trace back but other data as well. And that's where we are moving towards, you know, funding permitted.

But we completely agree and have been collaborating with CDC but also exploring as well technological platforms and potential contractors that can help us with the sharing of information. So you were right on target and we are exploring it.

And right now I think to some degree we have a system that we can share more through a more confidential way and that's Food Shield. But I think we're exploring other platforms that may enable us a little more flexibility and knowledge management.

But you're - again we will add this as something that - to continue to explore and look at as we advance hopefully beyond the century that we've been working.

Joe Reardon: Thank you Sherri. (Heidi), any additional comments on that? I think that's very well taken. We've got to move to some type of technology platform to share this information more seamlessly.

(Heidi Kassenborg): Thanks, thanks for the efforts in that.

Joe Reardon: Okay. I think we are down to a couple more minutes. We'll take one more question and then we'll wrap up and give Dr. Gensheimer an opportunity to say a few things as we close this call out. Any additional questions? We'll take one more (Jennifer).

Coordinator: And I show no questions at this time.

Joe Reardon: Okay. Absolutely perfect. First, before we go to Dr. Gensheimer to help wrap us up I want to thank everybody - Colorado being on the call today with us. It's just so important to have the State Department of Public Health and Environment, Alicia Cronquist and Susan Parachini on the call today.

And our district with (Paul Teitell) and (David Meiser), having them on the call, Jim Gorney with CFSAN, Dr. Gensheimer and Sherri McGarry from CORE and Dr. Mahon from CDC. It's especially exciting to me to see us have this kind of open call where we can identify the path forward.

We identified where it worked well and then cases where we can work more collaboratively to be more effective, to share and communicate in timelier manner.

And again, the common goal- it's all about public health and protecting lives and being able to prevent as many illnesses as possible. Well Dr. Gensheimer, as our Chief Medical Officer, I know you have a passion about overseeing CORE's work here.

This gives you a firsthand perspective of what we did so well and the areas we can work to improve on. Any final comments on your part?

Coordinator: And Dr. Gensheimer has disconnected.

Joe Reardon: With that this will wrap up our call today. Sherri, I pass to you or Dr. Mahon, any final comments? If not we will wrap this up.

Sherri McGarry: Oh no. Just again I thank you to everybody for their participation and honesty. And we mean to move forward with solutions. Thank you.

Dr. Barbara Mahon: And for my part, just echoing your thanks Sherri and thanks to FDA for setting this call up.

Joe Reardon: Okay. Well thank you all very much. And again, thank everybody for taking time out of your schedule today across the country, to be on this call, to provide the feedback and the honesty to speak of the things that we need to correct to move forward.

So this will conclude our call today. There will be a transcript available. If you'd like to contact DFSR we can make that available to you if you want to share it with other folks that were not on the call today. That email is dfsr@fda.hhs.gov. So I thank everyone for being on the call.

And this will conclude our call today. Thank you.

Coordinator: Thank you for your participation. You may disconnect at this time.

END