## **NWX-HHS FDA**

**Moderator: Lesley Maloney** August 26, 2010 1:30 pm CT

Coordinator:

Welcome and thank you for standing by, at this time all participants are in a listen only mode. After today's presentation we will conduct a question and answer session. To ask a question at that time, please press star one on your touchtone phone. Today's conference is being recorded, if you have any objections, please disconnect at this time.

I would now like to turn the call over to Ms. Pat El-Hinnawy, ma'am, you may begin.

Pat El-Hinnawy: Thank you, (Charissa) and good afternoon everyone. This is Pat El-Hinnawy with the FDA press office. I'd like to welcome you to this joint FDA and CDC media briefing on the latest updates for the salmonella enateritidis outbreak involving the recall of shell eggs from the Wright County Egg and Hillandale Farms of Iowa.

> Since our first call a week ago, there have been several updates, which we will attempt to summarize during this one hour briefing. Today our speakers are Dr. Jeff Farrar, FDA's associate commissioner for food protection, Sherri McGarry, emergency coordinator at FDA's Center for Food Safety and

Applied Nutrition and CDC's Dr. Christopher Braden, who's the acting director in the Waterborne and Environmental Diseases.

Because of the level of interest in today's topic and the number of reporters taking part in this call, we will for today limit each reporter to one question with no follow up. I would also like to mention to you that we have established a dedicated media mailbox for this recall. If you have any questions please send them to FDA@eggs, E-G-G-S as in Sam@FDA.hhs.gov.

With that I will turn this over to Dr. Farrar to make an opening statement.

Dr. Jeff Farrar:

Thank you, Pat, we appreciate everyone joining us today. As Pat mentioned the purpose of our call is to keep you updated on the progress of our investigation of this large increase in SE illnesses throughout the United States.

We do have some important new information to share with you today and without further ado I think we'll get right into that. Sherri McGarry from SFSAN will be providing that new information. Sherri?

Sherri McGarry: Thank you, Dr. Farrar, as you know FDA investigators have been at Wright County Egg in Iowa and Hillandale Farms of Iowa collecting samples and conducting environmental assessments.

> Nearly 600 samples have been taken from about 24 different sources, sources such as manure, feed, surfaces and barns and other environmental areas. While the majority of these samples are still undergoing processing and testing, we'd like to share with you as Dr. Farrar mentioned the first set of positive samples that we believe are significant.

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These positives were collective from two barns associated with the initial

Wright County Egg recall. And the FDA has confirmed salmonella findings

with a DNA fingerprint, also known as PFGE that matches the outbreak

fingerprint from environmental samples collected at two of the Wright County

Egg Farms.

Additionally, we've received confirmation of salmonella positive again with a

DNA fingerprint that matches the outbreak fingerprint from feed samples that

were provided (to pull) at Wright County Egg Farms and also at Hillandale

Farms.

The feed samples again were positive for salmonella with a DNA fingerprint

that matches the outbreak fingerprint in this outbreak. Although this particular

DNA fingerprint is fairly common for SE finding, this finding was a matching

DNA fingerprint in the feed indicates first that Wright County Egg Farms and

Hillandale Farms of Iowa are other likely sources of the contaminated eggs.

And second that feed and other feed ingredient perhaps were the sources but

maybe not the only sources of the SE. We will certainly keep you posted as

we receive additional information and sample results in this ongoing

investigation. And as I mentioned, a good portion of those samples are in

process.

Dr. Farrar?

Dr. Jeff Farrar:

Thank you, Sherri, we expect follow up questions on that at the end of the

briefing. We'll certainly take those questions. Before we turn it over to our

colleagues at CDC, I'd like to just walk through a little bit of an overview of

the timeline of the investigation.

There have been some questions regarding that but I want to make clear my discussion's going to be at a fairly broad level. And at this time we're not prepared to go into, you know, daily or hourly details on the timeline. We understand that is of interest and we will be addressing that issue.

But right now our focus is on protecting the public health, getting these eggs effectively recalled and trying to figure out what exactly happened on the farm and put measures in place to prevent it from happening again.

So broadly, let me say a few things about investigations in general and this investigation specifically. The first phase is what we're kind of referring to as the initial investigation. And my colleagues at CDC can add to this but sometime in early May CDC was aware of a significant increase in the cases of salmonella.

And by the end of July states had identified investigations of 26 distinct clusters. The issue of note in those clusters was that there was a wide range of theories for what could have been behind the outbreak. Various food commodities, possibly food workers and shell eggs were possibilities at that point in those initial investigations.

On approximately July 26, FDA joined CDC and states in a call to discuss these various hypotheses. At which point the investigation moved into kind of a second phase if you will, a process of narrowing down the potential suspects, suspect foods or food ingredients and really trying to identify the source, definitive source of the outbreak.

FDA, CDC and states worked very closely in that endeavor to determine the source. And conceptually at this point, investigations can take several

different routes when there are multiple sources involved, multiple possible

sources involved.

One approach to outbreak investigations of this type are to pursue really massive recalls of all foods under consideration as a possible source. And I don't think anyone would agree that this is a smart option, it's just - that would be confusing and resource - very wasteful of resources. And FDA and other

agencies would be crying wolf all the time and just confuse everyone.

On the other extreme is to require or wait until there is confirmed laboratory tests before moving forward with recalls. Now I think most folks would agree that's not a reasonable approach either, although in past years we have to be

honest that that was more or less the approach that FDA required.

However that is not the case today, that approach can cause obviously unnecessary delays, significant delays as well. In this case we tried as we do

in every investigation to find the appropriate middle ground.

From July 26 to August 11 there were more than a dozen FDA investigators working with state and other federal officials to confirm the source of the eggs and confirm the epidemiological connection to the illnesses.

It's important to note that by August 11 we did not have any confirmed laboratory tests at the farm. Some of this information is really coming to light

today, this morning as you heard from Sherri McGarry.

But at that time, August 11, FDA believed that the evidence was clear enough that we obviously wanted to err on the side of protecting public health. We did not have proof positive but yet we initiated, we urged the firm to initiate the voluntary recalls that began at Wright County Egg Farm.

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We then began our third phase of investigations at the facilities to determine

and identify all the suspected food that may be contaminated to ensure the

scope of the recall was adequate and our inspection on the facilities to try and

determine the source of the contamination and ensure that adequate preventive

measures would put in place to prevent future outbreaks.

We took these actions before having definitive SE evidence or definitive lab

evidence in this case. We can't assure you enough that every individual in

FDA and CDC and state health agencies understand the critical importance of

being timely in our approach and response.

We have to strike the balance between being timely and being accurate and

that is what we do in each and every investigation.

It is certainly a fair question whether anything could have gone faster. This is

obviously a question we ask after every outbreak and we would be the first to

admit that there's always room for improvement and we strive to improve

after each and every investigation.

It's also important to note that there are some specific provisions of the food

safety legislation in Congress that could have sped up this investigation. One

of those pieces was the area that talks about establishing or improving

traceability of foods. If this investigation had there been a improved

traceability system that could have sped up the investigation.

Second, the proposed law provides for improved access and prompt access to

records. Although the firms were cooperative mandatory access two records

could have helped this investigation.

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Third, another important area of the pending legislation is mandatory recall

authority. In this case we found the companies to be generally cooperative.

However, we do not believe that those decisions should rest with the private

companies.

And one last point before we go to our colleagues at CDC. It's with - Pat

emphasized today. We did establish a searchable data base on our Web site

that will facilitate searching for the correct, you know, recall products this is

an important consumer tool. So with that I think I'll turn to Dr. Braden for the

(EPI) update. Dr. Braden.

Coordinator:

Mr. Braden did disconnect. One moment please.

Dr. Jeff Farrar:

I'm sure he'll be dialing right back in.

Coordinator:

Mr. Braden has joined.

Dr. Chris Braden: Hello.

Pat El-Hinnawy: Hello Chris welcome back.

Dr. Chris Braden: I'm sorry I hit the disconnect instead of the mute button. This is - am I open to

the audience?

Pat El-Hinnawy: Yes you are.

Dr. Chris Braden: Okay, thank you. This is Dr. Chris Braden I'm at the Centers for Disease

Control. Again I'm the Acting Director for the Division of Foodborne,

Waterborne and Environmental Diseases. Thank you everybody for your

interest.

All right the CDC continues to collaborate with public health officials on multiple - in multiple states. And to monitor laboratory confirmed cases of salmonella enteritidis infections with the outbreak strain reported through Pulsenet. Pulsenet is the national sub typing network made up of states and local public health laboratories and federal food regulatory laboratories that perform molecular surveillance of food born infections.

We also continue to look for new clusters of illness that could be investigated. Clusters occur at restaurants or events for more than one person what the outbreak strain has eaten. As we anticipated we have received new reports of illnesses with this outbreak strain since the last Thursday's announcement.

Between May 1 and August 25, 2010 a total of 2403 illnesses were reported. However some cases from this time frame have not been reported yet and some cases may not be related to this outbreak.

Based on previous five years of reports at Pulsenet we would expect approximately 933 illnesses total during this same time period. Illnesses that occurred after July 23 might not have been reported due to the time that it takes between when a person becomes ill and when their illness is reported through the public health system. Plus it takes an average of two to three weeks for salmonella to traverse those systems.

In addition no new clusters of illnesses at restaurants or events have been reported to CDC and there have been no reports of associated deaths. This outbreak represents the largest salmonella enteritidis outbreak reported since the start of outbreak surveillance in the late 1970s.

The next largest one was in 1994 due to a commercial ice cream product that was contaminated by raw eggs which had a total of 743 reported illnesses.

As we continue to review and analyze the data we currently have available we

have some good news. To date we have no reported cases or clusters of

illnesses among elderly persons living in nursing homes, a group that is

especially vulnerable to severe illnesses from salmonella infections. In past

experience with salmonella enteritidis outbreaks due to eggs nursing homes

have been involved.

Recall also that the questions that have been identified with restaurants and

events were small. We believe that this could be attributed to improved egg

safety practices in restaurants and other commercial kitchen facilities

including the use of pasteurized egg products.

Many people may not know that there are pasteurized shell eggs and other egg

products at grocery stores which was another option for reducing risk of

getting salmonella infection from eggs.

Other important choices include thoroughly cooking eggs and thoroughly

cleaning utensils including preparation surfaces that may have come into

contact with unpasteurized raw eggs. Of course consumers should be

reminded to discard recalled eggs.

Those who develop systems of SE infection which include fever, abdominal

cramps and diarrhea beginning 12 to 72 hours after consuming a potentially

contaminated egg should contact a medical provider.

More information is available at FoodSafety.gov, FDA and CDC Web sites

and by calling 1-800-CDCINFO. CDC continues to collaborate with our

partners to monitor outbreak related cases and clusters, to provide technical

advice and on hand assistance in investigations and conduct advance testing at

CDC laboratories reaching out to educate consumers about the important actions they can take to protect themselves.

Later today we will be updating our investigation Web site with the latest counts of illnesses which could be found at www.cdc.gov/salmonella. Thank you. Back to you (unintelligible).

Pat El-Hinnawy: Thank you Dr. Braden. Operator we're now ready for the questions.

Coordinator: Thank you and if you would like to ask a question please press star 1 on your

touchtone phone. To withdraw your question, please press star two. Again, to ask a question, please press star one. One moment please for the first question.

Pat El-Hinnawy: Operator, are there no questions?

Coordinator: There is a question. One moment please.

Pat El-Hinnawy: Thank you. Operator, could we just begin with the first question.

Coordinator: Sure.

Pat El-Hinnawy: Thanks.

Coordinator: William Neuman, your line is open.

William Neuman: Hi, this is Willy Neuman with the "New York Times". I wanted to ask please if you could clarify a little bit what you told us about the positive tests. You said that there were two (unintelligible) positives from barns at Wright County. It sounds like those are environmental swabs. And they need to you

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said you had a positive from feed given to pullets. So is that three total

positives?

And you said the pullet feed was at Wright County and Hillandale but we'd

previously been told that the pullet rearing was being done by Wright County

and then the birds went into laying barns in Hillandale. So just clarify, please.

Sherri McGarry: Sure, I'm happy to clarify. This is Sherri McGarry. The samples that we have

positive at this point, we have swabs that are positive collected at Wright

County Egg from two of the farms that are indistinguishable from the

outbreak strain.

We also have feed samples or feed ingredients that were collected as part of

the Wright County Egg investigation. And those feed samples, one was for the

pullet chicken feed and the other is an ingredient in feed.

So the feed samples were not collected at Hillandale. What we were saying is

that the feed does go to the pullets at both Wright County Egg and Hillandale

Farms of Iowa.

William Neuman: OK. Thank you.

Pat El-Hinnawy: Next question, please?

Coordinator:

Next question comes from (Philip Frazier). Your line is open.

(Philip Frazier):

Yes. Just to follow-up on that, could you - you say - was the - was it the feed

that was going to the pullet houses infected, because that would suggest - or

does that suggest that all of the - that more than just the two farms were

contaminated?

And could you say what the farm - the numbers of the two farms that where you found positive samples just finally - does this - does this mean these positive samples, you only found them on two farms. Does that - does that

suggest that only those two farms are contaminated? Could you address that?

Sherri McGarry: The - certainly what I can hear in the question is the concern for the feed potentially going to firms other than Wright County Egg and Hillandale Farms of Iowa. And in reviewing records and in our investigation, we have not found that to be the case. So that's one piece I think to the question.

> Additionally, the feed - one of the feed samples was feed that was going to the pullet rearing facilities. In the pullet rearing facilities, the pullets themselves go to both Hillandale Farms of Iowa and Wright County Egg.

I believe that that was all the questions.

(Philip Frazier):

No. But what - clarify what I was trying to - you found positive samples at two farms about the pullets, the feed going to the pullets was contaminated. Can you limit the contamination just to the eggs from those two farms based on what you know?

Sherri McGarry: Of course with any investigation we're trying to narrow down the source of contamination. We have believed that these results certainly indicate that contamination was likely at Wright County Egg involving potentially the feed. There may be other possible sources onsite as well as we continue our investigation.

Pat El-Hinnawy: Thank you. Our next question, please?

Coordinator: Our next question comes from Elizabeth Weise with USA Today. Your line is

open.

Elizabeth Weise: Thanks for taking my call. A question about the feed. Can you tell us what the

ingredients in that feed were and which of the ingredients you found to

contain the salmonella strain?

Sherri McGarry: At this point we are reviewing all the information for the components of the

feed and we'll be providing additional updates as that information becomes

available. Dr. Farrar, did you want to add anything to that?

Dr. Jeff Farrar: This is Jeff here. One of the positives was reportedly from a bone meal

ingredient that went into the pullet feed and that's the extent of the

characterization that we have. As Sherri mentioned, we're going to be digging

a little bit deeper into that.

Pat El-Hinnawy: Thank you. Next question?

Coordinator: Your next question comes from Bill Thompson with Dow Jones. Your line is

open.

Bill Thompson: Yes, hi. Thank you. I just wanted to - it sounds like the - you answered this

but maybe not. The infection looks like it took place at the feed mill where the

feed was made. But you're saying that feed was then only sent to these two -

these - the farms involved? I want to make sure I'm understanding that right.

Sherri McGarry: This is Sherri McGarry. As part of the investigation, we're always looking to

determine how the - how the product that's become contaminated occurred. So

we're certainly as part of this investigation looking at how the feed may have

been contaminated and are looking at our investigational findings to determine

and evaluate again where that contamination may have occurred such as at the feed facility.

Pat El-Hinnawy: Next question.

Coordinator: Jennifer Corbett with Dow Jones. Your line is open.

Jennifer Corbett: Yes, hi. I'm sorry. I just had a question on the feed again. You mentioned

earlier that is was found at Wright County but it was also the feed - was it found at Hillandale or is it just feed that was - it was actually found at

Hillandale or was it just feed that's used by both farms?

Woman: Feed that is used by both farms.

Jennifer Corbett: So it hasn't been linked yet to Hillandale. Is that right or...

Woman: Well, if we look at it from the feed is used - the feed is used for the pullet-

rearing at the pullet-rearing facility and those pullets then go to all of the

farms at Wright County Egg and all of the farms at Hillandale Farms of Iowa.

Certainly we see a connection there.

The feed sample was not collected at Hillandale Farms of Iowa. But if we

look at it again where the feed goes we see the connection at that point and the

potential source of contamination though there may also be others.

Jennifer Corbett: OK. Thank you.

Pat El-Hinnawy: Next question, please?

Coordinator: Question comes from Molly Peterson with Bloomberg News. Your line is

open.

Molly Peterson: Yes. Can you tell me, have you all determined where exactly the feed came

from? I believe in the previous briefing you had mentioned that one of the

feed sources was with Quality Egg. Was that the source of this feed and if not,

have you determined what the source was?

Sherri McGarry: This is Sherri McGarry. We're, again, we're reviewing the information on the

sources of the ingredients of the feed. The feed mill is part of the structure

with Wright County Egg.

And again, I would like to emphasize that the feed was being distributed to, as

far as our information and records that we have reviewed, the feed is only

going to Hillandale Farms of Iowa and to Wright County Egg Farm in Iowa.

Hopefully that clarifies the question.

Molly Peterson: OK. Thank you.

Pat El-Hinnawy: Next question.

Coordinator: Next question comes from April Fulton with NPR. Your line is open.

April Fulton: Yes, hi. How - do you expect a much greater expansion of the illnesses as we

go forward or find other farms? Are you testing other farms for this as well?

Dr. Jeff Farrar: Hi. Jeff here and we'll turn it back to Chris at CDC as well. As far as the

illnesses, I think Chris addressed that partially in his earlier comments. But as

far as whether there'll be any additional recalls, we've consistently said from

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day one that it will not be unusual at all to see additional what we call sub-

recalls, additional brands of eggs being recalled over the next few days.

I think as early as, as recently as yesterday there was one or two more added

to the list. So that's part of the process of a large recall of a widely and

complex distribution. So it's very possible we'll see a couple of additional sub-

recalls over the next few days.

Chris, can you address the additional illnesses question?

Dr. Chris Braden: Sure. Again, this is Chris Braden at CDC. So we would expect additional

illnesses to be reported. Again, remind folks that it's a two to three week time

lag in our surveillance system for reports. So we do expect that.

The other component to that answer however is that we also are continuing to

monitor for additional clusters of cases to make sure that we're not missing

another source of illnesses. As I reported before, we have not identified

additional clusters of cases.

Also I think it's fair to say that the distribution, the potential distribution of

these eggs is such that it certainly could be responsible for the distribution of

cases that we're seeing in different states. And so we consider the current

identified sources potentially being responsible for all the cases that we're -

that we're seeing.

So those are sort of coming together to indicate that you know there - there

may not be additional sources of illnesses as we continue to monitor.

Dr. Jeff Farrar:

Hi. This is Jeff here. We're obviously getting a lot of interest around the feed issue as we've heard a lot of questions focusing on that. I want to try to add a little bit of perspective to that.

We obviously want to share the findings with you as soon as we have them. But I want to make really clear that we do not know at this point how, when, or where this feed may have been contaminated. That's part of our ongoing investigation and we'll work very hard to try and determine that.

But the finding of a positive in the feed essentially raises a lot of additional questions for us to answer at this point. We don't have answers to those questions. But we will be working hard to get those for you.

So it's a little bit confusing. We don't have all those answers but we're working hard.

Pat El-Hinnawy: All right. Next question please?

Coordinator: The next question comes from Janelle Alecia with MSNBC.com. Your line is open.

Janelle Alecia: Oh, thanks very much for taking my call. I'm wondering when you might be posting the Form 483 for us to see.

Dr. Jeff Farrar: Hi. Yes. This is Jeff here with FDA. Our folks are working very hard to finalize those Form 43s. And for those who don't know, our 43 is basically a report of our findings during our inspection.

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We have committed to post those 43s as soon as they are presented to the

company which we hope will be very soon, hopefully within the next few

days.

Pat El-Hinnawy: OK. Next question please?

Coordinator:

Next question comes from David Brown with The Washington Post. Your line

is open.

David Brown:

Hi. Sorry to be fixated on this feed but my understanding is that Quality Egg

produces feed and pullets for both Hillandale Farm and Wright County and I

believe other you know other farms and enterprises in the area, that part of

Iowa.

Is that your understanding? If it is, can you say something about the

investigation that's going on at Quality Egg if there is one? And a little

something about how if Quality Egg produces the feed, is there then further

production of it that goes on at Wright County before it is then sent to both

Hillandale and is used at Wright County?

Dr. Jeff Farrar:

Hi. This is Jeff here. I understand the confusion. We'll try to clarify this for

you. The feed mill is part of the Wright County Egg production facility. So it

operates as a part of that facility.

We don't know if the feed came to the - the feed ingredients came to the

facility contaminated, if the feed was contaminated at the facility. That's part

of our ongoing investigation.

Pat El-Hinnawy: Thank you.

Dr. Jeff Farrar: Does that answer your question?

David Brown: Well, sort of you know. Is there - does this feed go out to other farms once it's

worked over at the feed mill at Wright County you know other than the two

we know about? And are you checking them out?

Dr. Jeff Farrar: As Sherri McGarry mentioned, the feed from this feed mill goes to Wright

County and Hillandale as far as we know at this time. It is not distributed

elsewhere. Again, we are looking at all possibilities here of how

contamination could have gotten into the feed or onto the farm as evidenced

by the environmental samples that Sherri mentioned.

These contaminations can come in through numerous routes including

rodents, including shared equipment, including workers. So we're looking into

all those possibilities in our investigation.

David Brown: OK. Thanks.

Coordinator: Would you like to take the next question?

Pat El-Hinnawy: Yes. Thank you.

Coordinator: Janet Cho with The Plain Dealer. Your line is open.

Janet Cho: Hi. Thank you for taking my question. I had a question regarding the number

of illnesses reported. There - you said the updated number was 2400. Is that -

is that - that's all the cases, not just the ones directly associated with this strain

of Salmonella, correct?

Dr. Chris Braden: This is Chris Braden at CDC. So what the number of illnesses that I quoted,

that's 2403 between May 1st and August 25th, what that number represents is

the number of illnesses due to Salmonella enteritidis with this particular DNA

fingerprint pattern or PFGE pattern.

Janet Cho: OK. So these are all due to the tainted eggs?

Dr. Chris Braden: No. So the other piece of the information that's important to understand is that

we would normally expect during this same timeframe about 933 cases.

Janet Cho: OK.

Dr. Chris Braden: All right? So that's - so this is a fairly common PFGE pattern for Salmonella

enteritidis and there are a lot of cases out there. So the difference between

those two which is calculated about 1470 may be associated with the

outbreak, at least they are more than what we would expect given the history

of Salmonella enteritidis with this particular PFGE pattern.

Janet Cho: OK. And then when you - so when you post this on your Web site, is it going

to be later today? Is that going to be broken down by state?

Dr. Chris Braden: No. We really can't say by state how many of these illnesses are associated

with the outbreak pattern by state. So we're not giving information by state.

One of the reasons for that is a state may have even fewer than expected cases

or just the expected number of cases but still have cases related to the

outbreak. So that's a very hard thing to distinguish.

And so we would just rather just say that we would anticipate that any state

could be or could have cases that are associated with the outbreak.

Janet Cho: OK. Thank you.

Dr. Chris Braden: You're welcome.

Pat El-Hinnawy: Our next question please?

Coordinator: Your next question comes from Joan Murphy with Food Chemical News.

Your line is open.

Joan Murphy: Oh, yes. Thanks. Thanks for taking my call. I'm trying to figure out whose

responsibility it is to test the feed for Salmonella.

Dr. Daniel McChesney: This is Dr. McChesney from FDA Center for Veterinary Medicine.

The feed testing really should be - is the responsibility of the company to

ensure they're delivering a safe product to their - to their animals in this case.

The FDA does sample but it's really the firm's responsibility to ensure they're

providing a quality product to their birds.

Dr. Jeff Farrar: This is Dr. Farrar and I'll just add that obviously a finding of Salmonella

enteritidis in poultry feed would clearly mean that that feed was adulterated.

Joan Murphy: So it's up to the company to test. Do you know that the company was testing, I

guess, on the - at the feed mill?

Dr. Jeff Farrar: We - this is Dr. Farrar with the FDA. We don't have that information at our

fingertips. We'll have to get back to you on that.

Joan Murphy: OK.

Pat El-Hinnawy: Thank you.

Dr. Daniel McChesney: This is Dr. McChesney. I think the point here is that the firm

should have, if they - they should probably be testing but they also need to

have preventive controls in place to assure that the product they are

developing, if they're not testing, doesn't contain Salmonella enteritidis in this

case.

Joan Murphy: And does it - one last question. Does the FDA rule address this? The

new egg rule? Or is this just already in place and the FDA rule doesn't really

touch on it?

Man: I don't think so.

Howard Levine: This is Howard Levine in FDA's Office of Chief Counsel. The egg rule does

not explicitly mandate that feed be tested for SE. It does reflect a concern about SE- it addressed bio-security measures in ways that - in things like

controlling for animals to make sure that feed does not become contaminated

in layer houses.

Joan Murphy: Yes.

Howard Levine: And the rule has other testing but not explicitly for the feed.

Pat El-Hinnawy: Thank you. Our next question, please?

Coordinator: Next question comes from (Phil Gaft) with CNN. Your line is open.

(Phil Gaft):

Thank you. This is a question that may involve a couple of you all starting with Ms. McGarry. I just wanted to make sure I understand this. What you all are saying to summarize a little bit but I've been a little confused is, you all are tracing this salmonella. You said it's indistinguishable from the outbreak streak to feed. That was distributed to both farms, both Hillandale and Wright County? It was produced at Wright County. Questions whether it was contaminated there or before it got there but I want to make sure I understand the, the - we're kind of going back - the swab samples you found at, at barns, at Wright County Egg. Are those related - were those barns related to the mill?

Sherri McGarry: This is Sherri McGarry, thank you for the question and I'm trying to clarify the results. The first thing that I mentioned when I discussed the findings, the first thing I mentioned was the salmonella confirmation with the indistinguishable TOGE pattern or DNA fingerprint going back to Wright County Egg layering farms. So we're able to identify that in the - at the layering hen farms from environmental samples collected at some of the farms.

(Phil Gaft):

Those are both Wright County Farms (unintelligible) I'm sorry I had a bad connection here.

Sherri McGarry: That's correct.

(Phil Gaft):

Okay, but you believe that the contaminated seed was consumed by, by hens at both Wright County and Hillandale correct?

Sherri McGarry: The feed was - yes, the feed was provided to Wright County Egg Farms and also to the - some - to the Hillandale Pullet Facility and also the pullets that went to Wright County Egg as well.

(Phil Gaft): Okay, but no...

Pat El-Hinnawy: Thank you, sorry.

(Phil Gaft): That's OK. Thank you.

Pat El-Hinnawy: Next question, please.

Coordinator: Your next question comes from T.J. Houghstetter with Los Angeles Times.

Your line is open.

T.J. Houghstetter: Hi, guys, just one, I swear one very small follow up question with regards to

the seed. When you guys are doing the examination on the seed are you guys

actually already starting to trace back to whoever was supplying the

ingredients to the mill or was, was the company itself actually doing its own

farming for the ingredients?

Dr. Jeff Farrar: This is Jeff Farrar with the FDA, we are asking those questions right now on

the farm. Most poultry operations they do get at least some ingredients from

outside the farm that would be normal procedure so we are going to follow

that trail back where it, it leads.

T.J. Houghstetter: And if so is there any way to be able - can you tell us at least what some of

those ingredients are? I mean, obviously, is it corn, soybeans, are these you

know suppliers that would be also coming from Iowa or from all across the

Midwest?

Dr. Jeff Farrar: It, it - this is Jeff Farrar again. It's simply impossible to saw at this time. I'm

not a poultry scientist by any stretch but corn and things such as meat are -

meat and bone meal would be fairly routine ingredients in, in poultry feed.

Sherri McGarry: Thank you, our next question please.

Coordinator: The next question comes from Melinda Hemmelgarn with Standard Democrat.

Your line is open.

Melinda Hemmelgarn: Hi, are all of the chickens who consumed the contaminated feed

been suspect for laying contaminated eggs and what about the litter from those

chickens that consumes the feed. Can we assume that that's contaminated as

well?

Dr. Jeff Farrar: As to the litter from the chickens that, that is part of our investigation. We're

obviously looking at that. I don't have the answer for where that chicken

manure may have gone from these farms yet but that's part of our

investigation. That, that - the cycle that can happen on chicken farms is, is

very interesting biologically in that however chickens get contaminated either

through rodents or contaminated feed or through cross contaminated

equipment.

The chickens can then shed the organism, it can become encapsulated in the

egg or on the egg. It can be passed in their feces, again and for instance using

the rodent example. Rodents can come through, come in contact with that

feces from the infected chicken and, and spread the infection you know to

other birds or other barns on the facility. So once it's established in a poultry

farm that cycle can be difficult to break.

Melinda Hemmelgarn: So will those chickens that ate the contaminated feed then be destroyed?

Dr. Jeff Farrar:

This is Jeff Farrar again. The decision on what to do with the chickens rests with the farm. We are engaged in discussions with both farms and have been assured clearly that these farms will not sell shell eggs to the public until FDA gives its approval. So those - we've been provided those assurances by the firm.

Melinda Hemmelgarn: Thank you.

Coordinator: The next question comes from Rosemary Parker with the "Kalamazoo

Gazette". Your line is open.

Rosemary Parker: Thank you. Do you anticipate a recall of feed or feed components? And if that does happen if that extends to other farms even smaller farms that might have used this feed? How will you follow up on that?

Dr. Joshua Sharfstein: Hi, this is a new speaker. This is Josh Sharfstein. I'm the Principal Deputy Commissioner of the FDA. I haven't been in the room but I, I've been listening to some of the call and I just think on these questions about feed that we should back up a little bit.

> I just want to make sure that people hear and are able to communicate the issue because when I first heard about the feed issue I thought well the feed is before the chickens therefore if they're finding it in the feed it must be a feed problem.

But in fact and I'll turn to the experts to talk about this a little more, the feed facility is at the location of all these problems and their multiple ways when

you, when you find it in the feed it could actually just be part of the general contamination of these farms.

So Dr. Farrar I heard mention that you could get it through rodents, you could get it through environmental contamination, get it through birds, in fact in certain situations it may be that there ingredients of the feed that are provided by the farm.

So the sense that the investigators have is that there's evidence of contamination at the farms. While they have found it in the feed they are not concluding any kind of cause and effect relationships.

To be thorough FDA is going to be looking at the ingredients that came to the feed facility and finding if there's a problem but - and I will turn to a couple of people here. I don't think that that is even the leading hypothesis at this point.

I think that people are, you know, more focused on getting all of the data and then thinking about what the cause is but I don't want anybody to think that there's like an off-site feed manufacturer that has it therefore there is a cause and effect.

They made it. That was the cause of the contamination. I just want to clarify that because its there and because they're multiple potential roots of contamination that it may just be part of the overall contamination problem and I'm going to ask a veterinary expert from the Center for Veterinary Medicine Dan McChesney to see if he'd elaborate on that a little bit.

Dr. Daniel McChesney: Sure, I'd be happy to. I think one of the important things to realize and follow along like Dr. Sharfstein said is that the feed for these animals

goes through heat treatment before and so - which is sufficient to kill salmonella.

So it really suggests that if there is a problem that's being given to the birds through the feed is that it's a recontamination of that feed after some processing sampling which would go to the cycle Dr. Sharfstein was talking about on the farm. So I think that's you know something we surely need to investigate and I think I'll stop there unless.

Dr. Joshua Sharfstein: I want to be sure that maybe we give people a chance to ask additional follow up questions on that because I don't want people to think that - because a typical outbreak investigation you'd think well we're just working backwards in the chain and so you might hear the feed and think well that must have been the cause but in this case because it's there - because of the scientific points that Dr. McChesney raised and because we know of general contamination at this location and we cannot make that assumption.

We are going to be thorough and investigating all possibilities but it wouldn't be accurate for us to say or be reported that we're sort of working backwards or finding the feed and that's the focus of our investigation. You know to the exclusion of the other things.

So I hope that helps to clarify this but I do want to make sure we have a chance to answer any questions on that point.

Coordinator: And the next question comes from Steve Osunsami with ABC News. Your line is open.

Steve Osunsami: Yes, two questions, Chris, for you, the 2403 number. Is this the same - I mean the last number that I remember we were talking about was about 1200

illnesses? Is it - is the new number of illnesses related to this outbreak 2403 or 1470?

And then for Sherri, when we first talked I thought you said that there were four positive samples. If you could go over that again if there were four matches, it sounded like two at the feed site and two somewhere else, can you tell me I have that correct?

Dr. Chris Braden: Hi, this is Chris Braden. Thanks for the question. So you know previously what we had reported for a narrower time frame was a total of 1953 with 700 as a background and that gave us that 1200 that we thought that may be related to the outbreak. Currently now what we're saying is that there's 2403 with about 930 as a background. So, now we would equate that to about 1470 as potentially related. Does that answer that question?

Man:

That does. That does. I just wanted to make sure we all got that correct because I think the number that everyone was hearing was 2400. Sherri?

Sherri McGarry: Yes, sorry for that. To clarify we have four samples now with indistinguishable DNA pattern to the operating strain. Those four samples were collected from Wright County Eggs farms, two of the farms. In addition we have two feed or feed ingredient samples, a total of two, again with an indistinguishable pattern to the outbreak strain.

Man:

OK.

Sherri McGarry: Our next question please.

Coordinator:

Our next question comes from (Elena Saliuck) with Thomson Reuters. Your

line is open.

(Elena Saliuck):

Hi, thanks for taking my call. Actually a lot of questions have been already asked. What I wanted to clarify is the chicken feed again - beating around the bush, beating around feed. The chicken feed came from the Wright County Farm and that's correct and I think that's been clarified. So what's your next step? Was that feed you're breaking down into the ingredients and tracing them back or what exactly are the steps that you're taking with that feed.

Dr. Joshua Sharfstein: This is Dr. Sharfstein again and I'll turn to the other experts to add anything. I think that it's part of the overall investigation of the facility. So there are multiple other samples at different parts. It could help us understand the cause of the contamination. So there, there - it's important to understand that we're in the middle of an ongoing investigation where there are lots of things that are being looked at.

> In terms of the feeds, there will be a look to see if there are components of the feed that might have come in with salmonella, but as you heard Dr. McChesney say, she thinks that that is an unlikely cause because the way that the feed is treated. It's more likely to recontamination issues or focus even though we're going to be thorough in looking through feed.

> Our focus is really not on the feed but the overall contamination of the facility and I don't know, Jeff or Sherri, is there anything you want to add to that?

Dr. Jeff Farrar:

I think that answers it very well.

(Elena Saliuck): OK, and just to clarify. Have there been any deaths connected with this?

Dr. Chris Braden: Hi, this is Chris Braden, CDC. I believe the question was about any reports of deaths, is that right?

(Elena Saliuck): Yes.

Dr. Chris Braden: Yes. No reports of death...

(Elena Saliuck): OK.

Dr. Chris Braden: ...associated...

(Elena Saliuck): Thanks.

Dr. Chris Braden: ...yet.

(Elena Saliuck): Thank you.

Coordinator: The next question comes from Lyndsey Layton with the "Washington Post".

Your line is open.

Lyndsey Layton: Hi, thanks very much for taking the call. I just - I'm thinking as we're talking

there are millions of eggs that are coming out of these hens at these two big operations and someone said, oh Jeff, I think he said that the companies have agreed not to sell them to the public. Are they being sold for pasteurization or

what's happening with those eggs and have the companies - have they not

been selling them since your investigation began?

Dr. Jeff Farrar: Hi, Jeff Farrar, FDA. Correct, these farms have not been selling shell eggs to

consumers since the recall at each of these facilities. The eggs are being sold

to pasteurized egg firms and they are going through a treatment, a validated

treatment to inactivate salmonella. So it's important to reassure consumers

that pasteurized egg products are perfectly safe.

Lyndsey Layton: Thanks.

Coordinator: The next question comes from Alicia Mundy with Wall Street Journal. Your

line is open.

Alicia Mundy: Hi, thank you for taking my question. This may go a little bit to - some of the

others ask about the contamination, but you had mentioned early on

environmental that the samples you had also found, I believe environmental

samples and if I've got that correct could you just expand on that a little bit?

In other words were there samples besides the feed?

You had mentioned environmental samples and I was trying to get an idea of

what that meant.

Sherri McGarry: Yes, this is, Sherri McGarry, again (unintelligible) and the environmental

samples that are speaking to that were collected at Wright County Egg Farms

that are positive or swab samples and we collect those in general form

environmental - those are environmental samples such as manure and traffic

areas such as walkways and other environmental surfaces.

Alicia Mundy: Are you able to be any more specific on where you found these samples or

that about does it?

Sherri McGarry: The information we have for the specifics are - one of them I've collected

from manure and another - basically characterized it as surfaces are walkways

in the barn and the other also had to do with manure.

Alicia Mundy: Thank you.

Coordinator: The next question comes from William Neumann with the "New York

Times". Your line is open.

William Neumann: Yes, hi again. You said that the rule - the new egg rule does not require

feed testing. So is that a loophole in the rule and are you going to have to

consider adding that requirement for feed testing? And also can you just

characterize the overall contamination level that you're finding here as it

compares to other egg facilities that you guys deal with?

Dr. Jeff Farrar: Can you repeat the second part of the question?

William Neumann: Sure. The first one's just about the rule needs to be changed to add feed

testing and the second is you talked about looking at the overall contamination

levels here. So I want you to characterize what those overall levels are, the

overall sort of conditions and standards that you're finding at these farms as it

would compare to other farms, that you know other egg production facilities.

(Josh Hudkin): All right, this is (Josh Hudkin). I need to take the first part. It's kind of -

salmonella contamination in feed would make the feed adulterated. So it's

illegal. So we have - there's a whole other separate area of law in dealing with

the safety of feed that would apply here. I would definitely say it's premature

to make any conclusions about the egg rule until we really understand what's

going on in this situation.

I don't think that, you know - partly because what I was discussing before,

this may be well just be the you know bird got in and you know contaminated

them or just contamination in the facility overall.

So we'll obviously be taking a look at everything as all the pieces of the

puzzle come together but because there's strong law on this plane and because

the investigation is ongoing it would be premature to say anything specific about the egg rule.

As far as the levels of contamination I will maybe turn that back to Jeff to get a sense of that.

Dr. Jeff Farrar:

Yes, this is Jeff here with FDA. It's really important to note that this is the very first results that we're beginning to get in here. There's many more results in the queue that will be coming in within the next few days that may well give us a clear picture of the extent of contamination on this farm or clues as to the possible source so it's really too early to begin to evaluate the extent of contamination on this farm.

William Neumann: Thanks.

Coordinator: (Mary Claire Joloneque) with the Associated Press.

(Mary Claire Joloneque): I'm sorry. Can you hear me? My microphone was on mute. You all just said that you all found the salmonella in manure and in other places on the farm. Would that be normal in other egg farms as well? Is that something that you would normally find in manure or just sort of around a barn?

Sherri McGarry: This is Sherri McGarry and I'll ask Dr. McChesney to add to this

(unintelligible) but it is not what we would expect to find having salmonella

with a matching PFG pattern to the outbreak strain when salmonella enters it.

We would not expect to find that.

(Mary Claire Joloneque): And are there any other details you can give about what you guys called the widespread contamination problems? What might that - without giving us specific results because you're not able to do that - what might that

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look like? What might this widespread contamination problem look like? Is it

rodents? You know, is it - what could it be?

Dr. Joshua Sharfstein: This is Dr. Sharfstein. I think that if I use that term I would say in that that

could be one of the explanations for the findings of widespread contamination.

But I don't think we're seeing right now that we're finding widespread

contamination.

That's just sort of a, you know, the investigation is ongoing and there are lots

of potential things that could be going on. When the investigation is complete

and the 483 is posted I think you'll get a good sense of the various conditions

to address that question in a lot of detail.

(Mary Claire Joloneque):

Thanks.

Coordinator:

David Brown with the "Washington Post".

David Brown:

Thanks again. My understanding is that both Hillandale and Wright County Egg participated in egg quality assurance programs that were industry based

because Iowa does not have a state egg quality assurance program.

So I guess my first question is, is that you're understanding too? And second

many of these programs require regular environmental testing, swabbing and

looking for actual bacteria. And I'm wondering if the egg quality assurance

programs that they participated in required that and what they found.

Has salmonella been found in the past? Has it never been found? Has it never

actually been looked for by environmental swabs?

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Sherri McGarry: This is Sherri McGarry, based on what we know at this point the state does

not have an egg quality assurance program. So I think that addresses the first

question.

And as far as those voluntary programs it's probably best to check with the

industry associations. But I want to emphasize that the implementation of the

egg safety rules certainly has many preventive measures that we see will be

reducing thousands of illnesses in the future and is a program again for

prevention.

Dr. Joshua Sharfstein: And this is Dr. Sharfstein I would just add to that point that Sherri has just

made, you know, that it's interesting to go back to the egg rule docket and see

what people were saying.

But, you know, some people thought that these different types of programs

might be adequate and that they might even replace FDA oversight. And FDA

did not reach that conclusion.

And, you know, that's why we moved forward with the egg rule. And I think

that the situation here demonstrates that there is a need for strong federal

oversight of egg (unintelligible).

David Brown:

Okay thanks.

Coordinator:

Dave Brown with Fox News Channel.

Dave Brown:

Hello thank you for the opportunity both Hillandale and Wright County have

both declined to name the egg breakers that they are using to sell or unload the

eggs that they have that may have this issue with salmonella which raises a

question at least in the mind of Congress Bart Stupak of Energy and

Commerce Committee in regards to whether or not the public should know what foods ultimately these once recalled eggs are in.

And a quote he supplied to us in a statement says, "Consumers need to be fully informed on specifically what foods are being made with contaminated eggs that have been pasteurized. It has also important that the FDA work closely with these companies to ensure that all products made with the pasteurized eggs are tested and proven safe for public consumption."

This is just out this afternoon so it might be a bit of an early response that we're asking for from you all. But what efforts are being made to let the public know where these pasteurized eggs are ending up, in what food products. And what efforts are being made to test them to make sure that they are proven safe for public consumption.

Dr. Jeff Farrar:

We - this is Jeff Farrar with FDA we are in the process of reviewing that letter and we certainly will be responsive to that letter in a timely manner. For the time being our statement stands that eggs from these facilities are going to inspected approved USDA approved pasteurization facilities that we have in place validated treatments to essentially eliminate salmonella.

Dave Brown:

But pardon me but the question goes to consumer awareness and what it is that consumers should or should not know and the congressman has come down pretty clearly on the side of perhaps those that are overly cautious and don't wish to consume any food that's made out of what was once recalled eggs.

So the question again is what's being done to make sure that the public knows where these recalled eggs - what foods these recalled eggs end up in. And

what efforts are being made by the FDA to make sure that the foods made from these recalled eggs are tested and proven safe for public consumption?

Dr. Joshua Sharfstein: This is Dr. Sharfstein I think that Dr. Farrar answered the question. We will be looking at his letter and we will respond to it. And it's based on what we know scientifically about eliminating the risk that gives us confidence in the safety of the food.

Dave Brown: No I don't believe it's in regards to risk at all sir. I believe it's in regards to whether or not consumers know if foods that they are consuming have been made with recalled egg. That's the specific point raised by the congressman.

Dr. Joshua Sharfstein: Right and I'm saying for that specific point I haven't even seen that particular letter. We will review the letter and we will get back to him.

Dave Brown: Thank you.

Coordinator: Susan Daniels with the American Society for Quality.

Susan Daniels: Thank you I have a couple of questions did I understand correctly that one of you said you don't know whether the new egg rule that took effect in July would have made a difference in this situation?

And then my second question is I've been reading that this egg farm Hillandale has a lot of fines, a lot of rule violations and so forth and kind of this there is an assumption that this is viewed as a cost of doing business. And can this new egg rule do anything to prevent that situation?

Dr. Jeff Farrar: Hi this is Jeff Farrar with the FDA. You had kind of a two part question that kind of tied together in my mind. And that is if the egg rule had been in place

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at the time these eggs were shipped would it have prevented the illnesses and

the outbreak?

It's very difficult to say definitively whether this outbreak could have been

prevented until we get to the end of the investigation and have a more

definitive understanding of what the causes and potential risk factors are.

What we have said consistently and will reinforce again is that we believe

very strongly that if this egg rule is implemented consistently on all egg farms

everyday that we will see a very significant reduction in SE illnesses and even

deaths from SE attributable to eggs in the U.S.

Susan Daniels:

And then the second part.

Dr. Jeff Farrar:

Can you repeat the second part?

Susan Daniels:

With the...

Dr. Jeff Farrar:

The violations sorry.

Susan Daniels:

Yes.

Dr. Jeff Farrar:

Yes we have read of violations that associated with DeCoster in the paper as

many of you have. Violations ranging from occupational safety and health, to

sexual harassment, to other non food safety related violations.

Our focus at the FDA is obviously on the authority that we have for food

safety. So that's clearly our focus.

Susan Daniels:

But can you force him to do - to follow your rules other than through fines?

Dr. Jeff Farrar: Well, FDA has numerous enforcement options available that can be employed

not only at this facility but any other facility that's found not to be in

compliance.

And in this situation as in any other if significant violations are found we will

deal with those through, you know, our tool box of civil and or criminal

options there.

Susan Daniels: Okay.

Pat El-Hinnawy: Thank you, are there more questions?

Coordinator: The next question comes from Molly Peterson with "Bloomberg News".

Molly Peterson: Yes hi I just wanted to clarify something about any testing that's gone on at

the Hillandale Farms facility.

Have any - it sounds like you're saying that all of the positive samples of

swabs taken came from Wright County Eggs facilities and not Hillandale.

Does that mean that Hillandale all the tests at Hillandale were negative? Or

are you still awaiting results from Hillandale?

Sherri McGarry: This is Sherri McGarry and as we mentioned earlier we have a significant

number of samples still in process. So it's...

Molly Peterson: Okay.

Sherri McGarry: ...really a little too early for that but I will just mention again that the feed that

we have a positive on that feed is from the chicken pullets feed. And the

pullets do go to Hillandale Farms of Iowa as well as Wright County Egg Farms.

Molly Peterson: Okay, thank you.

Pat El-Hinnawy: Are there more questions? I'm sorry we have reached the absolute limit of our time that's available for this. We want to thank you all for coming today and

thank you for staying though this long session Jeff, Sherri and Chris.

I'd like to remind you all that a replay of the briefing will be available approximately one hour after this. And it will be available until September the 15th at midnight.

You'll find information on how to access the replay on your invitation to this call. We've now reached the end of today's briefing and I'd like to thank you all again for your time. I'm sorry, no, no.

Dr. Jeff Farrar: This is Jeff Farrar let me just jump in and say thank you again for your time.

We understand the confusion surrounding the feed samples. We'll do our best

to try and add some clarity to that in our subsequent Q&As that we'll post on

our Web site. And we'll work very hard to keep you informed as new information comes in. So thank you very much for your time and your

questions.

Pat El-Hinnawy: Thank you and good bye.

Coordinator: This concludes today's conference call. Thank you for attending. You may