

NWX-HHS FDA

**Moderator: Pat El-Hinnawy
August 23, 2010
2:22 pm CT**

Woman: I don't want to disconnect us.

Coordinator: Welcome and thank you all for standing by. Participants will be in a listen-only mode until the question and answer session. At that time if you'd like to ask a question please press star then 1.

Today's call is being recorded. If there are any objections you may disconnect at this time. I'd now like to turn the call over to Ms. Pat El-Hinnawy. Ma'am you may begin.

Pat El-Hinnawy: Thank you (Lexie) and good afternoon to all. This is Pat El-Hinnawy with the FDA Press Office. I'd like to welcome you to this joint FDA CDC media briefing on the Salmonella Enteritidis outbreak involving the recall of shell eggs from the Wright County Egg and Hillandale Farms of Iowa.

Today our speakers are Dr. Margaret Hamburg, Commissioner of Food and Drug. She will make a short opening statement.

Joining her are Dr. Jeff Farrar, FDA's Associate Commissioner for Food Protection, Sherri McGarry, FDA's Food Emergency Coordinator.

And also joining us is our CDC colleague Dr. Chris Braden, Acting Director of the Division of Foodborne, Waterborne and Environmental Diseases.

Dr. Hamburg if you would like to make your statement now.

Margaret Hamburg: Sure. Thank you very much. Well I do want to make just a few opening comments with regard to the ongoing investigation, the new egg rule, potential registration, and our message to consumers and then turn it over to Dr. Farrar and the others to provide specific updates and respond to questions.

I'm actually supposedly on vacation now, but this is very important and I did want to join at least briefly.

I should also mention that we will try to do updates of this kind as media interest continues. So hopefully this will be the first in a series over the next day, possibly weeks.

First let me say a word about the investigation. As I think you all appreciate this is a very complicated and intensive investigation that has resulted in a massive recall of more than 500 million eggs distributed nationwide.

And FDA is continuing to work very closely with CDC and our state colleagues which is essential to a successful outcome.

FDA's investigation includes more than 20 investigators on the ground in Iowa. And as part our investigation FDA is evaluating potential causes of contamination at the farms associated with the outbreak.

In general the likely sources of salmonella outbreaks on egg farms include rodents, shipments of contaminated chicks or hens, lack of bio security controls, and tainted feed. And so we're obviously checking out all of those possibilities and other conditions and practices.

We want the public to know that we don't have any evidence that other farms are involved in this outbreak. However this is a continuing investigation and we will obviously follow the evidence wherever it takes us.

And in addition FDA is working to ensure that eggs are not sold to consumers from these farms until we know that they can be shipped and consumed safely.

And I think that you all probably are aware of foodsafety.gov which is a good source of information about the recall.

And, you know, we do appreciate it if you let your readers or listeners know about foodsafety.gov because it's the best way for them to get the information that they need.

I wanted to say something about the new egg safety rule. It's something of an unfortunate irony of this outbreak that it - that just a few weeks ago on July 9 FDA implemented new egg safety rules that for the first time put specific food safety standards in place so that we can hold companies accountable for taking the right preventive measures to reduce the risk of salmonella and other foodborne illnesses.

These new rules went into effect for large farms last month. And over the next 12 months we're going to be conducting hundreds of inspections to ensure that they're being followed.

So we believe that had these rules been in place at an earlier time it would have very likely enabled us to identify the problems on this farm before this kind of outbreak occurred.

And on a related note I've been receiving a lot of questions about the food safety legislation that's currently pending in Congress and whether FDA needs new authorities.

Certainly it comes as a great surprise to the public to learn that FDA cannot compel recalls but that recalls to this day remain voluntary. And this has been a long-standing gap in FDA's authority.

The legislation that Congress is currently considering would give us that authority and other critical tools such as enhanced authorities to trace back products to the source, to require firms to implement preventive controls, and to provide FDA access to important records.

It would also strengthen our abilities to ensure the safety of foods being imported into the United States. So we do hope to see that legislation passed in a timely way.

And in closing I wanted just reinforce the important messages to consumers. First that it's always the case that consumers need to handle eggs safely.

This means that they need to keep them refrigerated. They need to wash their hands before and after handling eggs and to wash cooking utensils and food

preparation surfaces with soap and water and that eggs should always be cooked thoroughly.

They should know that eggs tainted with salmonella look, smell, and taste normal. So if consumers have any questions as to whether the eggs in their refrigerators are among those that have been recalled they should either discard them or take them back to the store.

And of course as I mentioned before consulting foodsafety.gov is probably the easiest way to identify whether eggs that people have in their homes are part of the recall.

So we really do hope that you will direct consumers to foodsafety.gov to check about important and related safety information.

So with that I will turn this over to our experts who will be happy to give you any additional information and updates and answer questions you may have.
Thank you.

Jeff Farrar: Thank you Commissioner this is Dr. Jeff Farrar, Associate Commissioner for Food Protection with the US Food & Drug Administration.

The way we've done these in the past it seems to work fairly well in that initially we'll start by asking our CDC colleagues to give a little bit of an update on the epidemiological aspects of this investigation.

And we'll follow that with a bit of our FDA update and then open it up for a few questions. So Dr. Braden if you could please.

Chris Braden: Yes thank you Jeff. Again my name is Chris Braden. I'm the Acting Director of the Division of Foodborne, Waterborne and Environmental Diseases that CDC.

As I have stated before there is a lag in reporting. In other words it can be between two to three weeks between when a person is exposed and becomes ill to the time that we learn about them through our reporting systems.

And because of that we would expect additional cases to be reported. And that is true since our last update from the 19th of August. We've have had more cases reported to us.

It's about 40 cases in that timeframe so far although we would expect that maybe more cases will be reported the early part of this week after the weekend.

We also continue to monitor for clusters of illness as part of the ongoing investigation. And we do this through coordination and communication with our state and local public health investigators.

I can say that we have not identified additional clusters of illness that would help us indicate that their - help us determine that there's any other sources of eggs that are - would be responsible for illness to date. So that's all I have as an update right now from CDC.

Jeff Farrar: Thank you Dr. Braden. Again this is Dr. Farrar at the FDA just to give a couple bullets on our update on the FDA investigation.

The investigation at Wright County Egg Farms and Hillandale Farms continues. Our teams are still in the field at least through the end of this week possibly into next week.

A little bit of specifics there, the team has completed their initial assessment at Wright County Farms and are now turning their attention to the pullet rearing facility at that Wright County Farms area.

In addition the team is completing their environmental assessment at Hillandale Farms.

Since our last update we've also had a chance to touch base with the US Department of Agriculture regarding the hatchery operation in Minnesota from which the chicks for both of these farms came from.

We have been provided information by USDA that says that particular operation has been SE certified free since 1989.

We're also finalizing our investigation of the feed source at Quality Egg which is the parent company of Wright County Egg Farms, finalizing our collection of samples and submission of those samples.

Obviously in our last call we talked about the fact that we had collected quite a few samples earlier last week. We expect those test results to be finalized early this week.

We can also tell you that we plan to provide further details regarding our findings at the farm later this week when we hope to issue what we call our FDA Form 483 which is basically a list of our inspectional observations at that location.

As soon as that report is finalized we will post it on FDA's Web site. Again we hope that that will be available this week.

So with that that's kind of a broad update. I think I'll turn it back to Pat for any questions.

Pat El-Hinnawy: Thank you Dr. Farrar. I think we'll now open the call to questions from the media. (Lexie)?

Coordinator: Thank you. If anyone would like to ask a question please press star then 1. Please un-mute your phone and record your name when prompted. To withdraw a request once in queue you may press star 2.

Once again it's star then 1 to ask a question at this time.

Your first question comes from (Philip Brasher). Your line is open.

(Philip Brasher): Yes it's a question I guess for Jeff. Could you - you all have identified or said and Commissioner Hamburg said that they were not up to responsible standards.

What's specific, what kinds of concerns have you all found in part of your investigation? And are they focused more at the farms or the pullet operation?

Jeff Farrar: Thanks for your question. The specific findings of the observations there on the farm are being assembled and placed into the 43.

Obviously we've kept our commissioner up to date. But as soon as the 43 is finalized that is shared with the facility and then we'll post that online. It's just

simply a little premature for us to get into the specifics of the findings at the farms.

(Philip Brasher): Do you have any test results back yet at either of these operations either on the hens or the environment?

Jeff Farrar: Again, good question. We do not have any confirmed positive test results at this time. There are a lot of test results in the queue. Those will be coming into us on kind of a flow basis over the next several days.

Pat El-Hinnawy: This is Pat El Hinnawy. Operator if I could ask you to have the callers identify themselves and their media outlet before they start their question that would be very helpful to us? Thank you.

Coordinator: Next question is from Elizabeth Weise with USA Today.

Elizabeth Weise: Hi. Thanks for taking my question. So I had a question about the chicks versus the pullets. So these chicks are coming from a - an SE certified free plant. But you're also testing the pullets.

Can you talk a bit about the ways in which Salmonella Enteritidis might be introduced into the pullets and what - how might that affect the farm?

Jeff Farrar: Sure this is Jeff Farrar again with FDA. The way that pullets could be infected are very similar to the way the laying hens could be infected, either through cross-contamination from equipment moving from say contaminated laying houses into the pullet rearing facility.

It could come in through rodents or pests. It could come in through contaminated feed and similar sources. So those are the general areas we'll be looking at.

Elizabeth Weise: And so you know they weren't in the chicks coming in but we don't yet know if they were, if it was in the pullet house?

Jeff Farrar: Correct.

Coordinator: Your next question is from Malcolm Spicer with Elsevier.

Malcolm Spicer: Yes thank you. This is Malcolm Spicer, Elsevier Business Intelligence. Gentleman is there some concern or is there any concern about these contaminated eggs affecting products that use the - use egg as ingredient as opposed to simply whole eggs reaching consumers?

Jeff Farrar: This is Jeff Farrar with the FDA. I'll take a shot at that. The eggs that are used in those types of products, keg mixes and so forth are by and large pasteurized products.

Firms are well aware of the risk that use of raw eggs can pose. So those processed products will utilize pasteurized eggs.

If we find that that is not the case, that a firm may be using inadequately treated eggs we will certainly bring that to everyone's attention. We have no indication of this time that that's the case though.

Malcolm Spicer: No indication that these contaminated eggs are distributed to companies that would use them for in mixes for instance?

Jeff Farrar: The eggs have been diverted to pasteurization on all locations from both farms as of late last week or middle of last week.

Malcolm Spicer: Okay. And if I could follow that up please. Dr. Hamburg was clear about, you know, the new egg safety rules perhaps had they been in place earlier prevented this and the mandatory recall authority as part of the food safety reform legislation would also help.

In addition to those, what would you say FDA and I guess CDC and perhaps USDA too could use in way of additional authority to further tighten safety along the food chain?

Jeff Farrar: Well this is Jeff Farrar again at FDA. Just to reinforce the commissioner's message, the pending legislation is absolutely critical to FDA.

There are just numerous important measures in that bill that will give us new authorities and resources to do our jobs. So we really look forward to seeing that legislation passed in the very near future.

Malcolm Spicer: Thank you sir.

Coordinator: Your next question is from Gardiner Harris with New York Times.

Gardiner Harris: Hi. Thanks for taking my call. So I guess I have a couple of questions. One is - there's obviously a debate in the country about caged and not caged hens. Is there any evidence that one is safer than the other and that if these hens had not been caged they might not have been infected?

Two I don't - so because these chicks come from a certified SE free place does that mean that we know for certain that the chicks were not infected?

And then finally if you could be a little more specific about how this legislation might have prevented this.

I mean clearly I would think this facility was gearing up to comply with the egg rule I mean other than some provisions that provide you with the authority to sort of declare a recall when a company doesn't have it.

I mean the Senate version of this legislation doesn't particularly give you much new money to do inspections. Inspections would be once every five years.

I mean help me understand what is it about this legislation that would have prevented this outbreak from occurring?

Jeff Farrar: Yes Jeff here, good question. To get into a little bit of the specifics of the legislation, boy, it's hard to figure out where to start.

Areas such as mandatory preventive controls for all food processors is a huge step forward in itself or would be a huge step forward. Some of those...

Gardiner Harris: And that's not in the egg rule?

Jeff Farrar: Sorry?

Gardiner Harris: That's not in the egg rule at present?

Jeff Farrar: Well the egg rule fortunately does have specific standards in place for egg farms to comply and requires them to have a prevention plan.

So for eggs that's great but it doesn't address all the other processors and commodities we deal with.

So in addition to that there are things like importer accountability, you know, holding importers accountable for the safety of foods, mandatory recall the commissioner mentioned.

Gardiner Harris: Right. I know all those things. I guess I'm wondering how specifically it might've helped. I mean in other words you have a recall here. How might like having the egg rule in place earlier or having this legislation have prevented this?

Jeff Farrar: Well I think it's also important to note the egg rule in itself is not going to prevent the illnesses. It's the implementation, the consistent implementation on all the farms on every day that's going to prevent these illnesses.

So the egg rule gives us the standards and tells the farms what they have to comply with. But then, you know, there actually has to be followed through.

So we are confident that overall if egg farms embrace this egg rule and implement it on every farm every day we will see a significant reduction overall in SE illnesses.

Gardiner Harris: Okay.

Pat El-Hinnawy: Thank you Gardiner. This is Pat El...

Gardiner Harris: The cage issue - I'm sorry. Can we just do the caged one? That's sort of an important thing.

Jeff Farrar: Yes, he had a couple of follow-ups.

Pat El-Hinnawy: All right.

Jeff Farrar: The caged bird Gardiner, I'm going to have to plead a little bit of ignorance on. I have seen research in the past that showed higher levels of salmonella in free range chickens versus caged chickens, but I'm not the poultry expert. So I'll have to defer that and we'll have to get back to you.

Gardiner Harris: Okay thanks so much. I'm sorry to pester you with so many.

Pat El-Hinnawy: This is Pat El-Hinnawy again. Because there's so many reporters on the call we'll ask that you each limit yourself to a question and a follow-up. Thanks.

Coordinator: The next question is from Paula Reid with CBS News.

Paula Reid: Hi. Paula Reid with the CBS Evening News. I know last week you all named 17 states where these eggs had been sent and then distributed all over the country.

Have there been any additions to that list of 17 states or is there a better way to communicate, you know, which states are definitely impacted by this outbreak?

Jeff Farrar: Hi. This is Jeff Farrar with FDA. I don't have the exact number on the states handy. I think we may be up to 22 states involved in the recall but I'll need to confirm that.

Paula Reid: Okay. Would there be any way for me to get that updated information?

Jeff Farrar: Yes, we'll have our press folks give you a call back.

Woman: (Unintelligible).

Jeff Farrar: Oh actually I'm being told we'll post - make sure that information is posted on our Web update.

Paula Reid: Great. Thanks so much.

Coordinator: The next question's from Tom Costello with NBC News.

Tom Costello: Hi. Thanks, two quick questions for you. On the - Dr. Braden, did I hear you correctly to say that you had - you cut out a little bit.

Did you say that there were 48 new cases but no known clusters? And so does that mean then that we're looking at a total still with just several hundred confirmed?

Chris Braden: Hi. This is Chris Braden at CDC. So I've stated that we have received about 40 additional reports since the last update on the 19th. But again, we're still receiving reports on an ongoing basis. So please look to our Web updates for the finalized numbers at any one time.

In addition I said that we had not identified additional clusters of illness. And we are looking for those clusters in order to make sure that we're not missing a - an additional source of eggs or another product that could be responsible for illness.

So as far as the question of confirmed, we don't have a set definition of what would be confirmed. In a number of circumstances people may say that those

people that they have links to eggs through these types of clusters and so forth might be considered in that category. And there are quite a number of those but I don't have the - a specific for you.

Each state is using a little bit different approach to reporting their numbers. I know that a few states are reporting several hundred illnesses each in their - from their particular jurisdictions.

Tom Costello: Okay. And now could I address a question to the FDA? I think a lot of us are struggling to understand exactly what is the distinctive role that FDA has versus USDA in checking the hen houses for salmonella.

As I understand it, you claim, the FDA claims you did not have authority to go into these hen houses and do any testing until July and yet the USDA was only responsible for the chicken. Is that correct?

Jeff Farrar: This is Jeff Farrar. Let me see if I can add to that a little bit.

FDA has very broad authority under the Federal Food, Drug and Cosmetic Act that allows us to go on to farms and conduct investigations or inspections. And in fact we have done that in the past.

However, most of those inspections at farms have been limited to those situations of where there were outbreaks or recalls involving the farm.

What's been missing from FDA's point of view is the specific standards on the egg farms, you know, to which we can hold egg farms accountable to.

With the passage of the egg rule we now have those standards and we will be beginning routine inspections of egg farms throughout the United States. Does that help?

Tom Costello: Yes I think it does. But so was the USDA doing anything at these - was it doing any inspections at all prior to you getting those new egg rules?

Jeff Farrar: USDA has a couple areas of authority here. USDA has specific authority for what we call breaker plants where the eggs go to - you know, the broken eggs go for pasteurization.

They also have under their animal and plant health inspection service authority for diseases of chickens like foreign animal diseases of poultry. So that's more or less a broad explanation.

But safety of shell eggs, food safety of shell eggs falls under FDA.

Tom Costello: Okay, thank you.

Coordinator: The next question's from (Alayna Elliott) with Reuters.

(Alayna Elliott): Hi. Thanks for taking my call. I was wondering, I know that this is one of the largest outbreaks and largest recalls in the recent history. Is there a way to find out when was the last time that, you know, close to half a billion of eggs were recalled?

Jeff Farrar: I'm looking around the room here to see who's been around FDA longer than I have which wouldn't be hard. I'm fairly new to the agency.

But we have looked at our records and we don't have ready information to suggest that there were larger recalls in say that last eight to ten years.

Okay and my other question was I understand that no other farms have been linked to this outbreak. However I also have kind of seen the signals that more recalls may be coming, maybe sub recalls.

Do we expect any more eggs to be recalled or is this kind of it?

Jeff Farrar: What we're - we've said in the past couple of days that additional sub recalls would not be unusual at all. And we're basing that on our experience with other large recalls that a few large manufacturers have sent product to wholesalers and distributors who repackage that product and sell it under other brand names. So we fully anticipate that there may be additional sub recalls in the next few days.

(Alayna Elliott): But as far as the total number, this should have accounted for - the 550 million should have accounted for all these eggs already or not?

Jeff Farrar: We don't anticipate any additional recalls of shell eggs from Wright County or Hillandale. Those have been included in the initial recalls.

(Alayna Elliott): So I guess my question is - I was confused - what is the definition of a sub recall?

Jeff Farrar: Yes, good question. So for instance in this case Wright County as an example as an egg producer would sell large volumes of eggs to their clients, their customers, some of whom would package these eggs under several different brand names and may in some cases just sell bulk eggs to their customers who may repackage under different brand names.

So the recalls of the specific brands beyond, you know, Wright County and Hillandale Farms brands would be what we call sub recalls.

(Alayna Elliott): Okay. Just again to clarify -- sorry I keep asking -- but to clarify the total number of 550, we're not expecting to change that?

Jeff Farrar: We have no information at this time to suggest that number will change.

(Alayna Elliott): Thank you.

Jeff Farrar: However, just to qualify that, the investigations are still ongoing. As Dr. Braden mentioned, we are still working with CDC and state health departments actively investigating reports of illness and will investigate any clusters that come to our attention. And we'll take our investigation wherever that goes.

(Alayna Elliott): Thank you.

Coordinator: Next question from Daniel DeNoon with WebMD.

Daniel DeNoon: Thanks for taking my question. Now this is a question for Dr. Braden. So we have a certain number of illnesses. I wonder if you could repeat the number of illnesses suspected to be due to this outbreak?

And then could you talk about the multiplier that CDC uses to sort of guesstimate the actual number of people who might actually have fallen ill during the outbreak?

I think I remember seeing the number 38 as a multiplier in the egg rule.

Chris Braden: Yes, this is Dr. Braden at CDC. So the number of cases that we have identified - and let me just explain this number a little bit.

These are the number of illness isolates. In other words, the actual bacterial that are obtained from testing of patients that have become ill with salmonella are forwarded to public health laboratories. And they undergo what we call some molecular analysis or DNA fingerprinting.

Those results are submitted to the CDC. And in many instances those results can be fairly discerning about how might be connected of the cases involved and who are not.

But in this particular circumstance as we stated before, the technology doesn't do a good well - a good job at discerning these cases.

So in our last update we had 1953 illnesses in general reported through this system that have this one type of DNA fingerprint of their isolates.

However we would expect about 700 illnesses again with this same particular DNA fingerprint of their isolates in this same time period.

So we - the - you know, you can do the math, but that - we don't know which of those cases are actually the background cases or due to an outbreak.

As I stated earlier, we're getting additional reports as time goes on. We've had about 40 more. But, you know, please check with our Web postings and so forth for the numbers to be able to quote as far as that's concerned.

Daniel DeNoon: Now but doesn't the CDC have - oh well these are just reported cases which are kind of the tip of the iceberg. So how many illnesses based on the number of confirmed cases do you have...

Chris Braden: Yes.

Daniel DeNoon: ...would you estimate are out there that may be associated with the outbreak?

Chris Braden: Right. So you may have read in the egg rule and there's been some publications that would put the number of illnesses out there for every illness reported at about 38 to 1.

We've suggested it might be a little bit less than that in some previous interviews around 30. But it's certainly many more than are reported.

Daniel DeNoon: Thank you very much.

Chris Braden: You're welcome.

Pat El-Hinnawy: Operator, this is Pat El-Hinnawy. We just have time for two more calls.

Coordinator: All right.

Pat El-Hinnawy: So if you could - thank you.

Coordinator: You're welcome. The next question's from Jennifer Keiper with Fox News Radio.

Jennifer Keiper: Thanks for taking my questions. Question number one, speed, the speed of the process. I know Dr. Braden you'd mentioned that there's a lag time here between - in the reporting process.

Are you satisfied with the reporting system or would you like to see that sped up in some way?

Chris Braden: Yes hi, Chris Braden speaking. So there are parts of that lag time that we have no control over. It takes a certain amount of time between when a person is exposed to an illness and they actually come down with their illness. And that can be several days or a week.

And also we have very little control over how much time people wait before they would actually see a doctor and the time that it takes then for a - in a clinic or a hospital for the specimen to actually be taken and assessed in a clinical laboratory.

What we do have some control over is how much time it takes from a specimen that's actually identified as salmonella isolate in the clinical laboratory to get it to the public health laboratory where these other specialized tests are done and then of course the speed of those tests in public health laboratories.

And certainly we would like to increase that speed to make sure that our reporting is as rapid as possible.

I would say also that at the other end of the epidemiologic spectrum, you know, we have investigators going out to interview patients. And that information is terribly important to be able to determine these if there are - if

they're related and by having eaten at the same restaurants or event what other types of exposures that they have.

And that scenario where I think there's a - room for improvement to be able to interview patients when they're being reported in a rapid manner. And that just takes more in the way of resources.

Jennifer Keiper: And have you been able to determine whether the illnesses have come from those who've eaten at restaurants or more of them have come from consumers who have purchased eggs and had them at home?

Chris Braden: Well a minority of cases have been identified as - associated with restaurants or events. I would say a small minority.

So the source of illnesses for others could be a restaurant and we didn't pick it up, could also be another way that they've been exposed even if it is eggs either in the home or, you know, eating with others. But some of these could have sources of illness other than eggs. And that's why I go back to this issue about being able to determine whose part of the outbreak and who's not. That can be difficult.

Jennifer Keiper: Thank you for your time.

Chris Braden: You're welcome.

Coordinator: The last question's from William Neuman with New York Times.

Man: Hello?

William Neuman: Hi. I wondered Jeff, if you could tell us a little bit more about the pullet rearing operation, where is it? Is there just one of them? How big is it in terms of how many birds go through there?

Jeff Farrar: Yes, thank you for your question. The pullet rearing facilities are actually a bit spread out. There - it looks like there's at least eight different sites with multiple barns on each site. They are located within, you know, five to ten miles of the Wright County corporate office.

William Neuman: Okay. And all the birds in question here came from those? And also did they have a vaccination program in place?

Jeff Farrar: Our information to date says that the birds yes, did come from birds for Wright County egg farms and for Hillandale Farms did come from this pullet - these pullet rearing facilities. As to whether they employed vaccination, I don't know the answer to that but we will make sure we give you a call back.

William Neuman: Okay.

Pat El-Hinnawy: All right, that will have to be the last question for today's call. As a final reminder, a transcript of the call will be available shortly for those who were unable to take part today.

I'd like to thank you again for joining us in this call today.

Coordinator: This (concludes) today's call. You may disconnect at this time.

END