NWX-HHS FDA

Moderator: Pat El-Hinnawy
August 30, 2010
2:00 pm CT

Coordinator: Welcome and thank you for standing by. All participants will be on listen-only until the question and answer session of today's conference. As a reminder the conference call is being recorded. If you have any objections please disconnect at this time.

I would now like to turn the call over to our first speaker Ms. Pat El-Hinnawy. Ma'am you may begin.

Pat El-Hinnawy: Thank you (Tonya). Good afternoon everyone this is Pat El-Hinnawy with the FDA Press Office.

I'd like to welcome you to another Joint FDA and CDC Media Briefing on the latest updates for the Salmonella Enteritidis Outbreak involving the recall of shell eggs from Wright County Egg and Hillandale Farms of Iowa.

Our speakers today are Mike Taylor, FDA's Deputy Commissioner for Food. Mr. David Elder, FDA's Director of the Office of Regional Operations.

Also joining us today is CDC's Dr. Chris Braden, Acting Director in their Division of Foodborne, Waterborne and Environmental Diseases.

Because of the level of interest in todays call and topic and the number of reporters we will for today limit each reporter to one question with no follow-up.

With that I will turn it over to Mike Taylor for an opening statement.

Mike Taylor: Good afternoon and thanks everybody for joining us this afternoon. We do want to provide you with updates on four topics. First, we'll ask Chris Braden from CDC to update on the cases - the case numbers. We'll also talk about FDA's plans going forward to prevent these problems in the future through enforcement of our new Egg Rule.

We'll also talk about the inspectional observations we've made in the facilities that are involved in the ongoing outbreak. And then talk about a recent new lab result. But so first we'll start with Chris Braden from CDC.

Chris Braden: Thank you Mike. Again my name is...

Woman: Hello?

Chris Braden: Yes, hello can you hear me?

Pat El-Hinnawy: Yes, go ahead Chris.

Chris Braden: Okay. Good afternoon my name is Chris Braden. I am the Acting Director of the Division of Foodborne, Waterborne and Environmental Diseases at CDC.

We have no new information to report compared to our last update on Friday the 27th of August. What I would like to do however is to make sure that people understand what the number of cases we're reporting actually represent.

On our CDC Web page that is www.cdc.gov/salmonella we have reported that between May 1st and August 25th approximately 1,470 reported illnesses were likely to be associated with this outbreak.

Now that number the 1,470 is derived from the total number of cases that are reported through our PulseNet Surveillance System. Now PulseNet is the National Subtyping Network made up of state and local public health laboratories and federal food laboratories that perform molecular surveillance of food borne infections.

These are the laboratories that conduct what are called DNA fingerprints of isolates that obtain - are obtained from patients.

Unfortunately the - the fingerprinting that is done for this particular pathogen - Salmonella Enteritidis is not very discerning. We would expect quite a lot of cases to be reported with this particular fingerprint through the PulseNet System.

That is why we explained that a total of 2,403 illnesses were reported during that timeframe. And we would expect given previous years experience 933 illnesses during this timeframe.

So the difference between those two numbers 2,403 and 933 is what we're calling the outbreak reported - or outbreak associated illnesses the 100 - 1, 470 number.

I just wanted to make that clear. And for additional information again you can consult the Web site at www.cdc.gov/salmonella. Thank you. Back to you Mike.

Mike Taylor: Okay thank you Chris. Before we walk you through the inspectional observations we've made in this case I want to just take a couple of minutes to talk about measures FDA has taken to prevent these sorts of cases from occurring in the future.

It is critical of course that we be able to respond to and contain outbreaks like this when they do occur. But the central thrust of FDA's Foods Program it is to prevent outbreaks like this.

And that of course is the reason why FDA put in place the Egg Safety Rule that - that actually went into effect in July. Too late to prevent this outbreak, but we think it is going to be a powerful tool for preventing outbreaks like this in the future.

This - the Egg Rule establishes very specific standards that egg producers must meet to prevent contamination of eggs with Salmonella and Enteritidis and it is their legal duty now to meet these standards to implement these preventive measures.

To support compliance with the Egg Rule and protect public health FDA is going to very thoroughly enforce this rule. We are planning to inspect in the coming 15 months all of the egg production facilities that are subject to the rule. About 600 of these facilities - these are the ones that produce anywhere from 50,000 laying hens - or, involve 50,000 laying hens or more and they account for 80% of egg production.

This is a strategy - an expected strategy that we have begun preparing prior to this outbreak as part of our responsibility to hold producers accountable for meeting the standards in this rule.

The inspection activity will though be informed by the experience that we've had with this recent outbreak linked to eggs.

The inspections will start in September this coming month. We'll be prioritizing the inspections based on our system of the risk posed by specific facilities. So it's the facilities that we think have been potentially at greatest risk of problems will be inspected first as we go through this inspection plan.

We'll be working closely with our state regulatory partners during this process that they will be supporting this effort to achieve compliance with the rule.

I'm also going to be informing the public about the progress that we made during these inspections and we will be following up with you as the - as the process unfolds.

Again, the - the important thing to emphasize is prevention of these outbreaks and then the ability to enforce a rule that ensures prevention of the problem that led to the outbreak in this - in this case.

We think that the industry's compliance with this rule will significantly reduce the risk of SE infections and outbreaks in the future. And it's our job through our inspection program to again see that happens.

We also think that it's important that the - the legislation that is pending in congress now be passed to physically strengthen our ability to enforce these standards through additional records access authority, additional resources to

conduct inspections and other oversight activities. Stronger enforcement tools including mandatory recall authority and other remedies to deal with compliance in these sorts of cases.

So with that emphasizing prevention in the future let me turn it over to Dave Elder who will walk you through the inspectional observations the so called 483 Form which is the form - number that the - identifies the form that we use to report our observations to the regulated firms. And these forms that of course are now available on our Web site for your inspection - Dave.

Dave Elder: Thank you Mr. Taylor. Good afternoon everybody. Over the last few weeks a team of more than a dozen FDA investigators has been inspecting the two firms at the center of the egg recall, Hillandale and Wright County - also known as Quality Egg.

Today we are announcing that the FDA has issued inspectional observational reports through these companies. That means the current inspections are concluded and these documents are mandated by law to issue at the conclusion of the inspection and they list significant objectionable conditions observed by FDA's investigators.

Before we turn to the specifics of the report as background I'd like to answer some of the common questions about what a 483 is all about. First, when is a 483 issued?

A 483 is issued when investigators observe any significant objectionable conditions. Our investigators are trained to ensure that each observation noted on the 483 is clear, specific and significant.

The observations are cited when in an investigators judgment these conditions or practices observed indicate that an FDA regulated product is in violation of FDA's requirements.

Such as when a food is being produced, prepared, packed or held under conditions whereby it may become contaminated with filth or maybe rendered injurious to health.

What is the purpose of a 483? The 483 notifies the firm of objectionable conditions and is presented and discussed with the firm's senior management with the goal of seeing changes made quickly.

Firms are encouraged to respond in writing with their corrective action plan and then implement that correction - corrective action plan expeditiously.

Third, is the 483 intended to be an all inclusive list of every possible deviation from law and regulation? No, it's not. It's a report - this report doesn't include observations of questionable or unknown significance at the time of inspection.

There may be other observations that exist. But our investigators note what they saw during the course of the inspection and rely on the firm to take full corrective action of any deviations that these 483 observations may represent.

Third how is the - fourth, how is the 483 shared with the firm? Well these two 483's have been discussed with the firm's management. And a discussion ensued today at Wright County Egg and last week when the Hillandale 483 was issued to discuss the - each observation so that they have a full understanding of what the observations are and what they mean.

The firms have informed FDA that they will not ship shell eggs to consumers until FDA is confident the eggs are safe for consumption.

Fifth and finally, what are the implications of the 483 for agency enforcement and what happens next?

Well the 483 does not constitute a final agency determination of whether any condition is in violation of the FD&C Act or any of our relevant regulations.

The 483 is considered along with what is known as an Establishment Inspection Report or EIR which will be prepared by our investigational teams. And this EIR includes inspectional evidence that will be considered in totality of the overall situation.

The agency will consider all of this information and then determine what further action if any is appropriate. All options are under consideration but I really can't be more specific at this time.

As you know FDA does not comment on enforcement actions in advance of taking them. And so we will not be able to comment on any enforcement decisions during this phone call.

Now I'm going to turn to some of the observations noted at Wright County Egg and then a little bit later Hillandale Farms.

And again, these inspections and these 483's do represent the first that were conducted FDA's new egg rule.

And you can now view the redacted versions of both of these reports on FDA's Web site.

Starting with Wright County also known as Quality Egg this inspection was conducted between August 12th and August 30th of this year. The inspectional observations listed pertain to Quality Egg Plants 1 through 4 and 6 and the Quality Egg feed mill.

Now just to explain a little bit more, Quality Egg LLC is the legal name of the business in Iowa, which includes a number of layer farms, pullet farms and a feed mill.

The (layer) farms operate as Quality Egg LLC, Wright County Egg Division. The polit farms operate under Quality Egg LLC, (DeCosta) Farms or (DeCosta) Feed Mill are DBA's - Does Business as Quality Egg LLC's for the Quality LLC Feed Mill which supplies feed for Wright County Egg Division and also to Hillandale Farms.

Generally speaking the names are often used interchangeably among Quality Egg, Gregg County Egg and (DeCosta) Farms.

Among the observations noted by our investigators at Wright County were the following; the firm failed to fully implement and follow procedures in its Salmonella Enteritidis Prevention Plan.

Some examples of that are that the firm failed to prevent stray poultry, wild birds, cats and other animals from entering poultry houses. Outside access doors to manure pits were pushed out by the weight of manure which was piled in some cases four to eight feet high thereby providing openings into the poultry houses for wildlife or other animals.

Further, animals including rodents were able to enter the poultry houses due to structural damage that included things like missing siding and air vents or gaps at the bottoms of doors.

The firm failed to eliminate birds from laying houses and to control rodents or flies. Our investigators observed bird nests and birds in one poultry house, live rodents in at least one poultry house at several plants, and live and dead flies that were too numerous to count in many poultry houses at certain plants.

The live flies were observed on and around egg belts, feed shell eggs and walkways to different sections of the egg laying areas.

There were live flies, crushed under foot when employees walked in the aisles at work and there were live and dead maggots observed in the manure pit at one plant.

In addition our investigators observed the failure to implement practices that protect against the introduction or transfer of Salmonella Enteritidis between and among poultry houses.

Specifically our investigators observed that the firm lacked separate entrances to each poultry house those requiring the use of shared corridors between certain houses.

We observed employees failing to change protective clothing when moving from one house to another. And failing to clean and sanitize equipment prior to moving between poultry houses at one plant.

We are going to turn now to Hillandale. The 483 for Hillandale covers observations made at two separate firms, two separate plants each consisting

of multiple houses. And this inspection was conducted between August 19th and August 26th.

Among the observations noted by our investigators is that we did observe that the firm failed to fully implement and follow procedures in its Salmonella Enteritidis Prevention Plan.

Examples of that are that are investigators observed the failure to eliminate entry ways for rodents and other pests into the egg production facilities. To bait and seal rodent borough holes in the egg production facilities and to eliminate the potential rodent or pest harborage places near the - near the structures.

They also failed to eliminate standing water adjacent to the manure pits or to eliminate liquid manure.

Our investigators also observed that the firm failed to maintain documentation that 19 week old pullet's were Salmonella Enteritidis monitored, or raised under SE monitored conditions.

They also observed that the firm failed to take steps to make sure that SE isn't transferred into or among poultry houses. Our investigators observed uncaged hens tracking manure from the manure pits to the cage tend house areas.

And before wrapping up let me mention that these inspections were initiated and follow up to several clusters of SE illnesses that did trace back to these firms. The inspections were conducted in part to determine compliance with the new Egg Rule, samples were collected during the inspection to verify whether or not preventive controls are effective.

And second as part of our environmental assessment and root cause analysis and follow-up to the clusters of SE illnesses.

Again you can access the 483's on FDA's Web site. And I thank you for your attention and welcome questions when the time is right - Mr. Taylor.

Mike Taylor: Okay thank you Dave. Before we take questions let us talk to Jeff Farrar to report briefly on a new analytical result.

Jeff Farrar: Thank you. This is Jeff Farrar Associate Commissioner for Food Detection at the FDA.

As previously reported in the last conference call we want to keep you up to date on our latest test results as they become available.

We have one new test result to report to you today. We have confirmed salmonella with an indistinguishable DNA fingerprint in a water sample collected at one of the plants from Hillandale. This water sample is from what is called Spent Egg Wash Water.

That is water that is used to wash the exterior of the eggs as the eggs are coming down a conveyor line from the laying house into the packing facility.

So again, just to summarize matching DNA fingerprint isolate from spent egg wash water from Hillandale Farms. Back to you Mike.

Mike Taylor: All right thank you Jeff, this is Mike Taylor, and I think we're ready to open it up for questions.

Pat El-Hinnawy: Yes. (Tonya).

Coordinator: Thank you. At this time we are ready for the question and answer session, if you would like to ask a question please press star 1. To withdraw your question please press star 2.

Once again, to ask a question please press star 1. One moment.

Our first question comes from Elizabeth Weise, with USA Today. Your line is open.

Elizabeth Weise: Thanks so much for taking my call. I really want to find out if these - it sounds as if eggs from especially the Wright County production facility are still going to a breaker plant.

But I've got to ask can you comment on whether or not these are anywhere within industry common standards?

Mike Taylor: Well this is Mike Taylor. We have - we have no reason to believe that this is indicative of practices throughout the industry. This is a set of practices that were previously associated with a very significant and unusually large outbreak of illness.

The reason we're going to inspect every facility subject to the rule though is to verify and be sure that we do have broad compliance with these rules.

Pat El-Hinnawy: Our next question.

Coordinator: Our next question comes from Mary Clare Jalonick with Associated Press. Your line is open.

Mary Clare Jalonick: Hi. You guys said that they - that both of these companies failed to implement and follow procedures. I guess I'm just a little confused on which rules are they not following?

We're you all - you said you were testing compliance with the Egg Rule but were they also not following their own procedures and - or their own - what they set out that they were supposed to do.

And also I know you can't comment on specific enforcement actions but could you give an example of what an enforcement action might look like if they were found to not be following the Egg Rule.

Mike Taylor: Well let me comment briefly. Again, we really can't foreshadow the actions that are available. You know our - the tools that exist in our law essentially consist of the ability to seize products that is in commerce. That is not applicable here because you know, we have stopped shipment of products to consumers from this facility. And the firm has committed to us that they will not ship products to consumers until we are satisfied that this problem has been solved and that we can - eggs shipped from this facility will be safe.

Now the other potential remedies under our statue are injunctions and criminal prosecutions. But again we are in the process of analyzing this evidence and considering what enforcement action would be appropriate.

I'll ask Dave to answer your question about the compliance.

Dave Elder: Yes thank you. You asked whether or not the observations represent deviations from the rule, or deviations from operating procedures that are intended to implement the rule and the answer is both.

Pat El-Hinnawy: All right next question please.

Coordinator: Our next question Malcolm Spicer with Elsevier. You're line is open.

Malcolm Spicer: Yes thank you. My question deals with further of the Food Ingredient Supply Chain. I've talked with several nutritional product companies who are understandably concerned about their supply of egg - egg ingredient for their products.

What would your advice be to firms that are further up the supply chain as far as the safety of their - of the egg products I guess.

Mike Taylor: Again I - firms - any firm should pay attention to the source of supply of their product and they should understand how it needs to be handled to produce a safe product for consumers.

So, if there are sourcing eggs and incorporating them in process food products they absolutely should be sure that their processed to a degree that kills salmonella.

Pat El-Hinnawy: Next question please.

Coordinator: Our next question, (Phil Brassier) with Des Moines Registry. Your line is open.

(Phil Brassier): Yes I wanted to question to clarify the mice that you - the live mice that you observed. I thought I understood you to say there was one farm but looking at Page 4 of the Wright County Report it looks like there were four sites with numerous houses where live mice observed.

And one of the questions - I mean, this company has said it's now in compliance with FDA, the Egg Rule and was previously following the United Egg Producers Program.

They were not following either, were they?

Mike Taylor: Again the observations sort of speak for themselves. And clearly these - the presence of rodents is something that is objectionable. And I can't speak to the UEP Program but we've made these observations because they are significant observations and deviations from what should be happening.

Pat El-Hinnawy: Next question please.

Coordinator: Our next question Daniel DeNoon with Web MD. Your line is open.

Daniel DeNoon: Thanks for taking my question. I'd like to follow up on the idea of what is normal in a very large chicken processing facility. Can you give us some idea of what a normal place looks like?

For example, you've got the observation here at Wright County where there is four to eight feet of manure underneath the egg laying operation. What would be a normal distance? Can you give us some sense of what a normal chicken operation looks and - because I don't have any way to gage really have deviant these operations are.

Mike Taylor: Well again we - well it's really premature for us to try to make comparisons. But clearly the observations here reflect significant deviations from what is expected.

It's expected to manage the waste from animals in a way that does not create a risk of contamination.

And again, we'll be going from facility to facility being sure that is being done systematically under the new rule.

Pat El-Hinnawy: Thank you. Our next question.

Coordinator: Our next question (Kala Pelerman) with CNN. Your line is open.

(Kala Pelerman): Hi, thank you for taking the question. Just a clarification that Hillandale talking about the spent water that was washing the eggs, you're talking about like that would be like the water that you collect in the pool beneath it. You're not suggesting that they were washing the eggs in contaminated water - correct?

Mike Taylor: This is Mike Taylor. Jeff Farrar can answer that.

Jeff Farrar: Yes hi, Jeff Farrar. That is part of the information we're accessing. This is kind of important to put the finding in context though. It's really important at this stage to ensure that we don't draw any conclusions as to the cause or the source of contamination on either of these farms.

This is a balance that we strive to find between giving you timely information and looking back when we do have complete information to try and interpret our findings.

So I just caution not to draw any conclusions yet regarding this particular result.

(Kala Pelerman): Just a quick follow-up. In other words you...

Pat El-Hinnawy: Our next question please.

Coordinator: Our next question Melinda Hemmelgarn with the Standard Democrat Missouri. Your line is open.

Melinda Hemmelgarn: Yes I was wondering with so many offenses that this operation has been accused of, what will it take to close them down?

Mike Taylor: Well this is Mike Taylor, they are closed down with respect to shipping eggs that is sold to consumers. The only way that they can move eggs out of there is if they go to a facility that has a validated process that destroys the salmonella.

So they are shut down for purposes of protecting consumers.

Pat El-Hinnawy: Thank you. Our next question.

Coordinator: Our next question Matt Hosford of ABC News. Your line is open.

Matt Hosford: Hi thanks actually my question was answered. Thank you very much.

Pat El-Hinnawy: Thank you.

Coordinator: Our next question Alicia Mundy with Wall Street Journal. Your line is open.

Alicia Mundy: Thank you for taking my question. I feel like I'm also asking just for a little bit of clarification or early comments you've been talking about what is normal or what is to be expected.

I've been trying to see if there were any other 483's that were posted on Egg Farms. And I'm not easily finding one. And I'm trying to just figure out when we're talking about what is normal, have you - have you had lengthy 483's such as this before with another egg farm.

Mike Taylor: Again these are the first inspections we've conducted under the egg rules. So there are no comparative EIR's as we - again, as we conduct further inspections they'll be further information you know, we'll make available as we go along.

Pat El-Hinnawy: Next question.

Coordinator: Our next question, David Shaffer with Minnesota StarTribune. Your line is open.

David Shaffer: Hello thank you. With regard to the rodents and the rodent holes does the FDA have a zero tolerance for rodents and rodent holes? Or, if not what is the level of tolerance?

Mike Taylor: Howard? This is Mike Taylor I'd asked - Howard - excuse me, Howard Levine from our counselor's office to answer that question.

Howard Levine: Thank you Mike. You have to look sort of you know, at the particular circumstances. And I would say that zero tolerance you know, lacks nuance. It's not that, it's looking at what would create cross-contamination you know, what would spread salmonella.

There is - keep in mind for example there is a significant difference between finding live rodents, you know, which means that they are not under control and finding you know, some amount of dead rodents.

And FDA has provided guidance you know, that is available publicly that gives firms more information on sort of what they should be doing. You know, and what is sort of considered normal and reasonable for rodents.

And you know, these things as reflected in the observations obviously did not meet that.

Pat El-Hinnawy: Thank you. Operator with that - we'll its going to take one more call.

Coordinator: Our last question comes from William Neuman with the New York Times. Your line is open.

William Neuman: Hi. I just want to get a sense of context here within each of these farms. When one reads the Wright County 482 for example it appears there is a description of a filthy operations with rodents and live birds and all sorts of problems.

But these are vast operations with numerous barns what is lacking here is the sense of is this - can I take this and apply it to the overall operation and conclude that this operation was riddled with problems, or are these reports simply highlighting a few isolated - well few is the wrong word, but a couple dozen isolated cases within an overall operation that might be clean if I was to walk around it or appear much more clean than I would realize from these.

So to put it in context in other words, describe how this applies to the overall cleanliness of each of these operations.

Mike Taylor: I'll ask Dave Elder to comment on that.

Dave Elder: Hi, hello again. You know, it's hard to draw exactly the conclusion you're trying to draw here, I can tell you what is on the 483 represents our investigators observations in the context of this inspection.

So when they identified observations relating to rodent activities or rodent entry ways or other violations of the Egg Rule, it is what they observed as objectionable conditions during this inspection conducted for the purpose of investigating this outbreak and accessing compliance with the Egg Rule.

It is hard to draw any other conclusions from it or make any other connections. This investigation stands on its own, it is the first that we've conducted under the Egg Rule. And these observations represent you know, real time on the ground look at how this firm complied - did not comply with the provisions of the Egg Rule. I can't really take it any further than that.

Pat El-Hinnawy: Thank you. Before we close I'd like to remind everyone that a replay of the briefing will be available approximately one hour after our call today. You'll find information on how to access that replay on your media alert that you received earlier this afternoon. I'd like to thank you again for your time and goodbye.

Coordinator: That concludes today's conference call. All lines may disconnect. Once again, that concludes today's conference call. All lines may disconnect.

END