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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

FDA OUTREACH MEETING

"Ensuring Compliance with the new FDA Rule for Establishment and Maintenance of Records Implementing Section 306 of the Bioterrorism Act"

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Question and Answer Session

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P R O C E E D I N G S

MS. FRASER: Let me get started, if everyone can please take their seats, or at least their conversations outside. That would be helpful.

I'll ask that if you have a question, you go to a microphone so that'll assist us with making sure, one, everybody can hear it, and two, that we can record it for our transcript, and if you don't mind, I'm going to sit because my feet are a little tired.

Generally, questions that come in, if they're ones we've already consider in the rule or they're kind of straightforward applications of the rule, those are ones I can answer. We do get a number of questions, you know, notwithstanding all of the public comment and we thought we'd answered every nuance. There's obviously many other things that we did not think about or did not fully consider. Those are the ones that we do answer and will be answering in question-and-answer guidance documents.

The reason for that is if it's a question of interpretation of how the rule applies, which is a legal construct, it is something that is establishing and saying you either can do it this way or not, or you're in or you're not, we have to go through the same level of clearance that we had to go through for every other question we answered in the preamble.

It's not just what I think. It's what the lawyers think. It's what the commissioner's office thinks, and so forth, and so that is partly why it takes us so long to get documents out, partly because we've been spending a lot of time in outreach, and so the same staff, but a handful of us, and the same staff that are asked to go out and do these outreach meetings, and the staff that are working on the guidance document here are also working on developing other rules that need to be issued. So we're going as fast as we can, as much as we can, but recognize it's probably not as fast as you'd like us to but it is, you know, as I said, you had the best of us and that's about all we can

do.

If you don't want to come to a mike, and you want to write your question down, that's fine. And if you do come up, I'll ask that you just give your name and, you know, affiliation. It kind a helps me understand where the question is coming from in terms of the context, although it is generally applicable.

So I do have one here and it says that if there are three elevator lines, A, B, and C, and there are ten individual loads of grain in each, and if a person loads a rail car out of bin A, does the FDA just want the info from bin A?

Yes. Well, I'll answer that in two ways. As you receive each load of grain in each of those A, B and C elevator lines, you will need to keep records for the media preview source of that food. That is all food received. So as you're receiving the food, then you will need to keep track of all of that.

If the question is really related to as you're distributing it to a rail car, or as you are

using that elevator to make a product, what do we want connected to the information for each lot of finished product must be linked to incoming ingredient, then that is with specificity as to what you reasonably expect is in that finished product container, and if you're only pulling it from elevator A, then it should just be the ten lines for that data element that's going into what's in the finished container.

So it is with as much specificity as to what you reasonably expect. We do expect some diligence with that, not just give us the smorgasbord of it's A, B and C, and it could be up to thirty, when you know full well that rail car had no expectation of having anything in B and C, if you're only pulling from elevator A.

So that's the only question I have here, and whoever wants to be the first brave person--

[Laughter.]

QUESTION: I've got to be really short to make this work. I'm Dave Creechie [ph] and this is a really bad sound system, and I'm going to carry

on with the elevator question. I represent a trade association. In that case that you cited with one bin, its common, in a grain-handling operation, millions of bushels of storage, that if you're loading a train, all bulk commodity, that that could, over the period of a two-year recordkeeping period, constitute grain from every source you purchased grain from in the last two years, because it's not only a truck arriving and being put into a bin.

It's in-house transfers, cleaning operations, segregating, sorting, it might be a number of operations. Most systems, I can't say all because I don't know--but most systems don't keep track of grain beyond the original receipt.

You receive 5,000 bushels of grain. That grain goes into bin A, and then after that, it could be transferred, in-house, many times, over a period of time before it's loaded out and shipped to someone.

Is it then, under the sort of reasonable expectation, that you could, in loading a unit

train of grain, hundreds of thousands of bushels of grain, that the source, the previous source could be everybody you purchased grain from over a period of time?

MS. FRASER: It could be. I would think--you know, again, as I said, this rule does not require you to reconfigure your manufacturing operations. You may choose to think about is a there more efficient business practice than having to record thousands of grain, and if, again, you're looking at the perspective of the purpose of this regulation is to allow for an effective traceback by the FDA in a public health emergency, or whether you want to do an effective traceback, even if we're not in a public health emergency on your own, how effective is that going to be if you think your reasonable expectation is five grams that might be left or five pounds that might be left, and yes, this regulation may require recordkeeping practices that you currently are not doing.

But there is a requirement to link outgoing product with ingoing received product, and

when we say to the extent reasonably available, that is tied to how specific the information is. It is not saying you don't have to do it at all.

QUESTION: I think I understand. The question, it's still, I think for most businesses under what normally is there, they're not going to be able to link the, every bushel of grain in a train to every bushel that came in. You probably have to limit it over a window of time. But I'm sure everybody--there's going to be other questions along that line.

Another question I have, and I have three, is regarding the issue of if there's a reasonable suspicion that there might--you know, in terms of requiring access to records.

How would that apply in a case, or would it apply, or what would be FDA's expectation with two possible outcomes? And that's naturally-occurring toxins that might be detected in grain. An example. I'm at an export elevator in the Gulf of Mexico and I end up with a positive aflatoxin over the FDA food limit. Would that create a

traceback, all the way to some farm in Illinois?

And another one is unapproved genetically, GMO grains, biotech grains, such as Starlink or BT10, that might end up being detected in an export lotto, 500,000 metric tons in an export-import location, Japan. Would that create a traceback situation? Either of those.

MS. FRASER: Japan, just for example, of course.

QUESTION: Just for example.

MS. FRASER: Bioengineered foods also is in my office, so I have another--yeah. Going to the aflatoxin one, this is a, as I said, this is not just terrorist-derived. We have to meet a serious adverse health consequence, death to humans or animals. That could be intentionally occurring, it would be naturally occurring. It could be bad practices, agricultural practices, that leads to hepatitis in green onions.

It doesn't really matter, at the point of accessing records. It is do we have a reasonable belief that there is a serious adverse health

consequence? and yes, that could trigger a traceback and access to the records.

In the case that you reference in terms of BT10, Starlink corn, the standard would still be the same. It's do we have a serious adverse health consequence? The current example of BT10, our finding to date, we just received a submission from Sagenta [ph], we have not finished evaluating it, but based on all we know right now, the BT10 looks like BT11. We don't see that standard being met.

So, no, we would not be demanding, under this authority, access to records. Could these records be used to do an effective traceback is a different question. I think the recordkeeping here can be used by private entities. It might be something that you give voluntary access to FDA to assist in that, if there is a reason to do that.

But in terms of do we have a right to demand access and are you in legal violation for refusing access? that only occurs if we meet that public health standard. So that's the best I can answer it. The standard for accessing is a clear

public health emergency.

I'm going to ask you to limit your questions to one, just so I can get people and then we can take second rounds and third rounds.

QUESTION: That's fine. I'll come back later.

MS. FRASER: Okay; that's fine.

QUESTION: Hello. I'm Bob Luddke [ph] with Feed Management Systems. We provide software to the feed industry. I've got a question that goes to more the definition of a farm. There's a lot of medium and large integrators out there that manufacture the feed for the animals, some all the way to processing the animals themselves.

A lot of the integrators, they own the animals but the growers, or the people that are taking care of the animals actually own the facility. And I've heard a couple different interpretations of whether they qualify as a farm and are exempt or not, as to whether that same ownership that you had mentioned in the slide--does that go to the animals, or is it the same ownership

based on the facility?

If it's on the facility, since the actual farm that the animals are being raised on is owned by a different individual than the integrator, but the animals are owned by the integrator, would they still be subject to the regulation?

MS. FRASER: Well, the farm is defined as a facility, so the farm is not defined in terms of what's on the facility. The farm is defined in terms of it's a facility in a common location, grows crops, raises animals or does both.

So in terms of meeting the farm exemption, we're looking at is the facility itself exempt from the operation?

The recordkeeping rule applies to persons who are engaged in a variety of activities including manufacturing, processing, packing, holding transporting, distributing, receiving or importing food.

In that case, you know, it's--the person in your case, I guess is the integrator, it still, it comes back to the farm is the one that is

actually receiving the food, I guess, or is receiving the business. I think you're getting into, you know, what is the corporate--what is the personhood that's subject to the activity? But when we're looking at the farm, we're really looking at what is the ownership of the facility cause it's the facility we have exempted, is the covered activity of growing those, or raising those animals on the farm, and when we're talking, you know, heads of cattle or heads of livestock, we look at that as a business enterprise.

Those aren't the consumers as of, you know, the pet cow in the back yard kind of thing.

QUESTION: So in this case the contract grower or the farmer that owns the facility would be exempt, but the integrator that owns the animals that are being raised on that farm would not be exempt; is that correct?

MS. FRASER: The integrator, you know, I guess you have to look at what is the activity the integrator is doing that would subject them to the recordkeeping rule. They're not manufacturing,

they're not processing, they're not packing.

QUESTION: Well, they're manufacturing a feed. I guess that's the direction I'm coming from.

MS. FRASER: Okay. If they're manufacturing the feed, then they are subject because they are doing an activity that is not--you know, we allow the farm facility to be exempt for the activity that that legal entity is doing, of who owns that farm and the farm under the same ownership. The integrator is manufacturing feed. They don't necessarily--it gets to, you have to look at who's owning the farm there. So it's not one clean answer. It's going to depend on ownership of the farm, on one hand, and it's going to turn on manufacturing, processing activity, on the other hand, and where is the feed going.

Is the feed going to a farm owned by the same--you know--is the manufacturing, processing of that feed occurring on the farm owned by that, and fed to animals on that farm, or same farm under the same ownership?

QUESTION: No; typically not.

MS. FRASER: Yeah. So to the extent it's not, then the integrator is subject to the regulations because they are a manufacturing, processing activity. They are not under the farm exemption.

QUESTION: Okay; thank you.

QUESTION: Thank you. Anton Keattle [ph] from Tar [?] Corporation. I've got several questions but I'll limit to just one right now.

In regards to the first name and contact information of the media privy source and/or the transporter, do we need to be able to provide down to the regional type facility or is headquarters, corporate-based infrastructure sufficient?

MS. FRASER: We're really looking for the facility that you receive the food from. You know, when you look at what the records say, the records have to--somewhere in one of those slides it says, you know, the records have to be created at the time the activity occurs and the records must be kept at that facility or a reasonably

accessible location, which basically was intending you to send it off to public storage, if you were running out of room kind of thing.

You know, so giving us corporate headquarters for a company like Kraft, that might have hundreds of facilities, is not going to get us the--we're doing a traceback, trying to trace the direction of where the food went, either down or up from where it came. We're looking for the immediate previous source of that food, not it might be corporate headquarters because it did not come from corporate headquarters.

QUESTION: Okay. Thank you very much.

MR. ROBERTS: Mark Roberts representing a food manufacturer with a research facility. I believe there's an exemption in the rule regarding foods manufactured for the purposes of research and I just wanted to know where to draw the line on that, whether it's internal sensory evaluation or focus groups, mall intercepts, in-home testing, samples for customers, things like that. Where does that stop?

MS. FRASER: The exemption in this rule for recordkeeping is not with respect to facilities. It's with respect to samples that are used solely for testing but not for consumption.

And so if you are consuming the sample, whether it is, you know, in a mall, whether it's in a restaurant, then the recordkeeping provisions would apply. If you're sending it to the lab to run stability tests, color tests, you know, then it doesn't.

We have had outbreaks where people have been test marketing samples in restaurants now. Restaurants are exempt by statute here. But one of the reasons for us keeping samples, particularly when they are fed to consumers, is that it has been a public health issue in the past.

QUESTION: Internal sensory evaluation with company employees?

MS. FRASER: That is one of the ones we are still figuring out because it gets to--you know, again we're looking at what comes into your corporate entity. So if someone is sending you

samples--and it's not always--you know, maybe, do you want to purchase this for distribution? are you going to be a supplier? you know, can we establish a business relationship here?

And so that is a food product that has an immediate previous source. Now you're giving it to your employees. The thing we're wrestling with is are the employees more like consumers or are they more like businesses?

Because we have said consumers are not businesses and, you know, what is--and that's one of the ones that's in our Q&A, that we're still--there are good reasons for answering it on either side and so we're just trying to figure out what's the consistent logic there.

You know, to one extent you could say--and I'm not going to really answer your question, I guess I'll say right now, cause we're still figuring that one out.

But the things we're thinking about along those lines are, you know, if the point that we find out there's a problem or consumers are getting

sick, and you have a good way of saying, well, you know, all my poor employees got sick but, you know, we found that out, we can find out from you where that food product came in, is that any different than a retail store? That's on one hand.

If you're taking that same product and sending it to thirty of your stores across the country and, you know, are you more like a distributor or are you more like an intra-corporate transfer? Are they more like employees or are they more like businesses?

What makes for an effective traceback in terms of this distribution? And so those are the kinds of things we're wrestling with and hope to have answered within a month.

QUESTION: Thank you.

QUESTION: Good morning. My name is Nancy Husnick [ph]. I'm from Target Corporation. I wanted to focus on the farm exemption, see if I can have it go through the entire process here.

What we would like to do is we do donate some food to nonprofit organizations, but one of

the things that we would like to do, if anything, to save trash space, is if we have what I would call less-than-fresh produce in our stores, and we would like to donate it to like a pig farm or an animal farm in a community. We'd like to be able to do that and since farms are exempt at the head end, I'm hoping that the exemption label for farms carries through all the way to the tail-end as well as far as making donations.

MS. FRASER: The exemption for farms applies just to farms and what they do, so you can't piggyback on--

QUESTION: I'm trying to hard.

MS. FRASER: I know. The exemption that you can piggyback on is a nonprofit. Now most farms are not nonprofits. The reason we allow the nonprofit exemption is a competing public policy of do we impede donations to charitable entities when they serve a public good, for people who otherwise would not have food, on one hand, and a recognition that businesses are most likely keeping track of those donations because they're taking a tax write-

off, you are doing it out of the goodness of your heart but you're also doing most likely a tax deduction. So there are records, if we need the records, under the records access authority.

And so those two things led us to say we will create an exemption for nonprofits. Your donation to a farm is a donation to another business, or it's a transfer to another business now.

However you're capturing that as a business transaction, whether you're charging them or not charging them, it's still a transfer from one person to another person and there is no--that isn't a basis for us to say what's different about you transferring it to a farm who happens to be exempt by statute, and you transferring it to another business which isn't exempt by statute. That is a transfer outside your person, that we would require you to capture in the records.

QUESTION: So you would still want the itemization then as--

MS. FRASER: Yes.

QUESTION: I see. Thank you.

MS. FRASER: I'm sorry. The one piece on that that we got in a question is when you're doing those kind of donations to pig farms, animal farms, do you have to capture that specificity of, you know, ten bushels of corn, or can you just say, if it all went into a hopper, you know, one hopper worth of food products, and that's one of the questions we have to answer in guidance because it's one of those nuances we did not--what's the specificity in incoming product to outgoing? Can it just be half a car full of foodstuffs comprised of--add a list of cornbread, milk, whatever.

QUESTION: I'm Beth from Fresh Cut Industry. I was curious on, we've got a lot of, we do a lot with distributors and we do a lot with individual restaurants on selling them five-pound bags of fresh cut types of produce.

Now do we have to specify what lot they got, if they got one bag of this and one bag of that? Cause we load out over 200,000 pieces a night on 45 trucks. Do we need to identify each

piece and where it's going and to who?

MS. FRASER: And you're a distributor?

QUESTION: We are a distributor and a processor.

MS. FRASER: Because you are a processor, yes. IF you were just the distributor, no.

QUESTION: Okay.

MS. FRASER: But to the extent there is a lot number. But if there is a lot number, because that lot number requirement applies to manufacturer, processor and packers, then. yes, you would have to record the lot number.

QUESTION: Okay; thank you.

QUESTION: Hi. Brian Amtrout [ph] with Flaktoss [ph] American Group. Does a co-packer count as part of the corporate entity? Or that would be IPS?

MS. FRASER: It depends on legal constructs. So sometimes yes; sometimes no. I mean, if you draw, people really say draw a bubble around your legal identity and however your legal identity is, if you have different activities

within that bubble, we're only looking at what food you receive into that bubble, what food you release out of that bubble. If you're repacking activity is within the same legal construct, and you're manufacturing, then repacking, then releasing, we don't need to see those in immediate steps.

If you're manufacturing and you're sending it to a repacker that you partially own or it's a subsidiary but it has a different legal construct, you are releasing to a different person, so you would have to capture that activity.

There's not a generic answer. The answer is going to turn on when you're looking at the applicability of the rule, you need to look at what's your personhood and what's the activity you're performing within that, and then answer the question of what's coming in and what's leaving that.

QUESTION: All right. Thank you.

QUESTION: Good morning. Mike Plumb from 3M Company, a test material and system supplier. The question I have is we talk a lot about the "as

soon as possible" requirement, no less than 24 hours, and with the 4:00 p.m. scenarios, is there a best embodiment that the government is going to recommend or propose?

I think we kind a crossed the bridge between electronic systems and paper systems, and maybe a 4:00 p.m. request on a Friday makes it highly unlikely, and maybe a paper system would be able to comply with that ASAP rule.

MS. FRASER: The obligation is 24 hours. You know, ASAP is what we prefer but 24 hours is the legal obligation. So I need to stick with what's your legal obligation.

When we looked at developing this rule, we had an option of saying electronic records, the cost would have tremendously gone up for particularly the small and very small, the "mom and pops." Many of them may be exempt under the retail, ten or fewer FTEs, but 80 percent, a little more than 80 percent of the entities subject to this rule fall within the small or very small category.

So we did not require electronic records. What instead we said was you can choose how you want to keep your records but you have to meet the 24 hour limitation at the outside.

And so if you choose to comply with that by electronic records, yes, that's much more beneficial for a lot of reasons. You can search it, you can do a number of things. But if you choose to have an excellent filing system or an excellent shoebox system with your paper records, then that's sufficient as well. We're not going to dictate that you can't do that.

QUESTION: Thanks.

QUESTION: Hi. Teresa Herd [ph], L-Today [ph] Cooperative. My question is really related to on a routine, normal surveillance, FDA surveillance on an annual basis. They come in, just normally. Typically, we are going to see a record request? Because it does, if it's just a routine surveillance, what are we going to anticipate?

MS. FRASER: I get this question a lot and this is really on the enforcement side. I'll

answer that in a couple a ways. I do think that when inspectors come in, they ask for access to a number of things,and there is a difference between can we demand access, are you in violation of precluding access? versus can you voluntary turn over the records?

I think a number of requests, and there are inspectors who may say, Are you in compliance with the recordkeeping provisions? Can you show me the records?

That is within your prerogative to say yes, no, whatever. They cannot invoke the bioterrorism act as demanding authority to access those records unless they have gone through what we have in our guidance and have shown a public health emergency, and if you find that happening, then we need to hear about it because we have been engaged in extensive training to make sure people are not inappropriately demanding access to records.

One of the things we are looking at at headquarters is should we have a systematic kind of approach where we say, okay--because, you know,

right now, the way we find whether somebody's in compliance or not, as a demand provision, is to say, okay, we have a public health emergency. That's the last time I want to find out that I have huge holes in my chain.

And can we say that inherent in the authority to require these records is an ability to pick a food product, randomly off your supply chain, and say, Show me the records that are associated with this, for example.

Or let me pick this date window and let's see the records associated with that. And we're exploring that, and if we do come out that way, it would be through another draft guidance.

You would get a "heads up" about it. It's not, you know, we wouldn't just be spot check, doing it, but it is something under discussion as to, now that we have the regulation out there, compliance dates are approaching, how do we demonstrate for the benefit of all that we have a system that works, if we do have a terrorist threat on the food supply?

QUESTION: Is it also typical of the field inspectors to indicate, due to biosecurity reasons, you can't copy their credentials? I mean, I don't know.

MS. FRASER: Charles, the question was can inspectors say that you can't copy their credentials because of concerns of counterfeiting or replicating the credentials, or anything like that. That's part of his side of the house.

MR. BECOAT: Just for your information, we do have a number of staff here from the district office. We have compliance officers and investigators here who can answer your questions outside of this question-and-answer session.

But I'm going to let one of our compliance officers answer that question about the legalities of the question asked.

MS. : Hi. When it comes to the credentials, it's not anything to do with the actual bioterrorism act that regulates whether or not you can actually make photocopies of the credentials. I'm not going to swear to it but I

believe it's actually a Title 18 prohibition. So it's something that the bioterrorism act has no impact on at all. It's something that just, it cannot be permitted.

MR. SLOCUM: My name's Bob Slocum. I'm with Kemp's local dairy products, a manufacturer. My question is one I get internally a lot. The question goes like this.

We record lot numbers and suppliers of various components or finished products, packaging, and various ingredients, and the question gets to be to what extent do we need to record those internal--when we get these products delivered, we'll record lots, quantities and dates and source.

Do we need then to record those numbers in our manufacturing records as we produce lots of finished ingredients? Or is it satisfactory, under the regulation, to simply record a lot's numbers and dates at receipt? Is that clear?

MS. FRASER: You're a manufacturer?

MR. SLOCUM: We're a manufacturer.

MS. FRASER: What your obligation for us,

in terms of the requirements is, you have to record the lot number on the food products received and since you're putting the finished product in the packaging, then the lot numbers on the packaging material would also have to be recorded as it's received.

On the outgoing side, as you're releasing product, and I don't know, like is milk one of your products, or--

MR. SLOCUM: Milk's one of our products.

MS. FRASER: Okay. So milk, in its bottles or containers, then those release products should also record the incoming ingredients, if that's coming in in lot, or the packaging as it's going out. How you choose--that needs to be for us in your immediate, subsequent recipient records.

So who received those products with the lot numbers for both the ingredients and the finished packaging material. How you choose to do that, whether you choose to do it in your manufacturing records, whether you choose to do it in some other way, we leave it to you to figure out

how you want to link those two.

We just specify what the incoming records have to contain and what the outgoing records have to contain. But there is that requirement to link incoming ingredient with outgoing product.

QUESTION: Okay; thank you.

QUESTION: Hi. I'm Mark with CHS and my question relates to bulk grain, once again. I'd like to pose a scenario where we have a facility that has multiple bins, each bin contains grain from 25 farmers, and we load out either a train or a ship or a barge, and we draw grain from ten bins to meet that order.

My question is will FDA be satisfied with a list of 250 names, 25 each from the ten bins in question, as a reasonably available response to your question?

MS. FRASER: If that's how you're loading and that's, you know, that's the specificity you have, then I think the answer is yes, that's what's reasonably available to you. If--you know, I'll put it the other way. If you know that bin B,

which might have however many, 25, 50 lots in it, has run dry at some period of time and so now you're really only drawing on bins A and C, then we don't expect to see the same listing complete because what's reasonably available to you is to know that you ran dry on whoever those 25 suppliers that went into bin B. But we're not asking you to say it's only these 25, if there's--I mean, you're really like that cookie manufacturer with the flour and three silos.

It's just that your three silos happen to be ten and they happen to have twenty-five sources in each as opposed to three. That was a simplistic example, but the example still is, applies across the board. But we do require you to keep some specificity and that's part of why we look at the date received, and we do expect some due diligence as to what actually is occurring on a day to day basis or in a lot to lot, as a ship basis, as to what actually is there for your reasonably available records.

QUESTION: The simple scenario that I

posed also gets further complicated with house transfers as we transfer from bin A to bin C to bin D, and then collectively ship out, and the math of 250, for example, could become 350, 400 in short order.

MS. FRASER: Yeah, and I think, as I said, you know, that's typical practice. Then those are transfers we require you to keep track of, you know, to be able to do the incoming/outgoing, however you want to do that. You may want to think about does that make the most sense from a standpoint of keeping track of that linkage, on one hand, and on the other hand, you know, if there is a problem with one of those lots, one of those suppliers, one of those sources, how much of your product is subject to administrative detention because it's the same public health standard.

How much of your product may be subject to recall or may be--you know--how much of that is on a business side, do you think that implicates or not, but, you know, that's a business decision on your part. For purposes of our records, which is

what you're asking, however that intermingling, commingling happens, is part of what your reasonably available requirement would cover.

QUESTION: Thank you very much.

QUESTION: Hi. I'm John Litke with General Mills. I was just curious. On the joint facilities that are both FDA and USDA, I guess I just wanted clarification. To what extent, if there are ingredients that are shared between both a USDA line and an FDA line, to what extent are the records subject to this, to the maintenance provisions as well as--I guess I'm just curious.

With our USDA products, are those formulas and everything exempt, or would the ingredients that are also in FDA products still be subject to the one up provisions of all of this.

MS. FRASER: to the extent it is exclusively USDA's, then you're not subject to these requirements. To the extent that it is FDA's, in whole or in part, then you are subject to these requirements. So, you know, products that we essentially consider as a USDA exclusive line,

where FDA is not really managing oversight on that, you can segregate off those products that are being sent over to that and not worry about establishment and maintenance but if it's, you know, for the lines that are ours, you're going to have to keep track of those records.

What we will see from your supplier is that they sent you, you know, 200 pounds of product X. You may have had 50 pounds go to the USDA line and 150 pounds go to our line. We will see, if we're doing that traceback, the 150 pounds come down and, you know, we'll do a traceback and at some point we may say--and that's part of the reason why people say, well, why do you require both the supplier and the receiver to keep track of quantity. It's for those very reasons of figuring out checks and balances.

We may say, well, what happened to the other 50 pounds. But it's not one where you're required to do something that's USDA exclusive.

QUESTION: Okay. And the fact that the 50 pounds went to the USDA line, I guess, and you're

going to come back with the question, because we didn't provide the records for those 50 pounds within 24 hours, that's not going to be a problem?

MS. FRASER: Well, you're going to have--my guess is we will have X--if it's on the USDA side, that's not a problem because we don't have authority to access that side. But my guess is what you will have in terms of records access is you're going to show a receipt--and I don't know, I don't know how you receive it, it's a pure guess.

My guess is you're receiving 200 pounds of that product and you're showing that in your records and how you manage that internally is one thing, and the incoming product, outgoing, incoming ingredient to outgoing product is what we're going to see.

But my guess is when you show that, when you turn over those records within 24 hours of request, my guess is I'm going to see the 200 pounds.

MS. FRASER: Well, right, and I guess what I'm saying is you're gonna see 200 coming in,

you're gonna see 150 going out, and the question if what happened to those 50, and since we didn't provide any records on those 50, is that gonna be an issue?

MS. FRASER: I mean, the fact that you're a co-regulated facility or there's a USDA line, I think that's a verbal conversation. We cannot hold you liable for something you're not subject to turn over.

QUESTION: Okay.

MS. FRASER: But I'd focus on are you exclusively USDA on that side as opposed to co-regulated on that side, because you're only exempt for exclusive USDA jurisdiction, not joint USDA-FDA jurisdiction.

QUESTION: Okay.

QUESTION: Our depositor releases a truckload of goods to Super Value as a will call. They're going to pick it up at our facility. Is it our requirement to get the trucker's name, address, phone number? Or is it Super Value's requirement to take care a that?

MS. FRASER: You know, this is sort of like the registration rule. You need to look at the definition of a nontransporter which is one who owns or has possession, custody or control of a product as the immediate previous source.

So if you are a warehouse, while you may not own the product, the question may be do you have possession, custody or control of that product? That's a fact-specific question. In some cases it might be yes; in some cases it might be no.

But if you meet on the possession custody or control, and you are manufacturing, processing, packing, yada, yada, you have an obligation to comply with this regulation.

How you choose to discharge that between you is a private matter, saying okay, Super Value, you keep it or we'll keep it or we'll both keep it because we don't trust--whatever you do, you have an independent obligation if you meet the requirement.

It's the same as the registration rule.

You know, in the registration rules for warehouses, we said we recognize that warehouses were sublet often but the same thing--the duty to register was on the owner or the operator of the warehouse.

We didn't need two registrations. If one person registered, they met the obligation for both sides. If nobody registered, both were in trouble.

So it's the same kind of thing. You may be subject to the rule because you do a covered activity, the manufacturing process, et cetera, and you meet the definition of owned, or has possession, custody or control. So we can't tell you that just because they do it or keep the records, you don't have a responsibility.

The responsibility turns on whether you meet the definition of who is subject to this rule.

QUESTION: I'm not sure if I follow. Again, Super Value sends a trucker in to pick the product up. Again, we have custody and possession but technically not control. That's our customer.

MS. FRASER: But it's an or, not an and.

QUESTION: Okay.

MS. FRASER: So because you meet the possession, custody or control, then you are subject as a nontransporter and you are holding the food, which is the covered activity, so you are separately subject to the rule. Whether you choose to establish a contractual obligation or part of your lessee/lessor agreement, whatever it is you want to do, doesn't relieve you of legal liability for being responsible for the activities that you do which are possession, custody, and holding.

QUESTION: Okay; thank you.

QUESTION: Hi. I have a question I really want to sort of expound upon, a question that I believe the gentleman I believe from General Mills had asked, and it's just a question as to at what point our authority comes into play, which yes, I am FDA, so that's where the our part comes into.

When you have a product, when we're talking about exclusive USDA versus FDA regulation, I'm thinking in terms of like a hot pocket or maybe a corn dog which is USDA. A portion of that ingredient is FDA in terms of the corn meal or the

flour or the vegetables that are used in the hot pocket. So at what point does it become, considered to be an exclusive USDA product, where if they receive in a 100 pounds of flour, 50 pounds goes to an exclusive FDA-regulated product, 50 pounds goes to a USDA-regulated product. At what point does that exclusivity nature come into play?

MS. FRASER: That's a great question and it's one that we're trying to clarify in the Q&A for that very reason. Should the exclusivity back up to receipt of the ingredients, even though there are ingredients, or should the exclusivity just be at the line and it's one that we--I'm not sure it'll make it to the first one because it's one we have to iron out with USDA as well but it might be in the second edition of the Q&A.

We're trying to have a whole USDA section on what does exclusive jurisdiction mean for those kinds of situations--the corn dogs, the everything pizza--those kind of weird commodities that kind a cross over in different places.

QUESTION: Hi. I want to ask another

question in regards to like a broker. Brokers typically, in the dairy industry, may or may not tell you where the ship to destination is. Ship to--they are taking not physical ownership to the transport--I mean, it goes from the transporter and let's just say it's going to P.O. Box so and so in New Jersey. What is the obligation to the nontransporter in knowing where that product's going?

MS. FRASER: You know, this is one of those that the business practice and the requirements are, may not be quite in sync yet, and you have an obligation to get them in sync.

Commoners [?] wrote in and maybe particularly the customers brokers, and said we shouldn't be subject to the rule because we're just the middle man and we just do paper transactions. We facilitate trades. We're not the immediate previous source. We're not the immediate subsequent recipient. So we shouldn't be subject to the rule. And the final rule, we agreed with that. There's a discussion in the preamble, if you

search on broker. One of the things, if you pull up the rule online, on the FDA Web site, it's hyperlinked, so you can like scroll down to definition of farm and it'll jump into that part of the rule.

Or you could pull it up and just search on farm and you'll get farm everywhere it pops up, which is too many places. But if you search on broker it'll jump to the discussion on broker.

So brokers we did not count as a media previous source and the media subsequent recipient. Your obligation as a nontransporter is to capture not the broker's name but the immediate--now we also hear that brokers want to protect their sources cause they don't want you cutting them out, and so they don't want you making your own arrangements.

And that's where, on the business side of the house, not from our standpoint, your obligation is clear. We want the immediate previous source. You may choose to discharge that by saying okay, broker, I have an obligation to turn over these

records in 24 hours at most, you know, maximum of 24 hours. I will record you in my record but you need to have in your provision an ability to turn over that same information to help me discharge my obligation. But the obligation from our perspective is yours.

How you choose to discharge that between you and your broker does not involve us but that might be one of the ways that you choose to do that, that makes both sides as happy as possible.

Or you may choose to say, well, until you can give us that information we--I mean, you know, that's the side of the house we don't get involved in. But those are the--the responsibility is still yours.

QUESTION: I'm George Shimber [ph] with Horizon Milling and the question is related to the dates of the start-up as the grain industry's unloading our new crop across the summer and fall, and we start in December, and most of us have probably lost the identity of the grain that's in some of the elevators at least.

On December 9th, as we start to keep track, are we keeping track of all lots that go into that finished product, and what's the standard for lots that may have been lost in, you know, massive bins and flatware houses, et cetera?

MS. FRASER: Yeah, it is, and it's not just--this applies to all manufacturers and anyone else who has the incoming ingredient, outgoing product linkage. You know, for some period of time, which might be weeks to months, to a year or more, depending on your activity, there will be gaps in the records, and we recognize that because you don't have an obligation to record the lot number or keep track of it until your compliance date hits.

So for the large folks, December 9th, you'll be releasing product that won't have that linkage because you had no duty to record lot number before December 9th. At some point as you're receiving more product, it may be okay--the outgoing product on that rail car or whatever has, you know, these 200, we know, and X amount we don't

know because we received it before December 9th, and that's acceptable, and at some point, you know, you'll reasonably expect that you've cleared the bins and moved forward.

QUESTION: Can you tell us anything else about how the requests will come in to, say, like a distribution facility? Is there any commonality in the type of formatting that we might see?

And what I'm getting at is: Can we expect that the request will be this item, I need all information based on when you received it over the last two years from this, you know, from whatever manufacturers and from whatever carriers brought that product into your facility?

Or will those requests possibly come in as a, hey, you know, I want to know as much information as possible about any product that you receive from this vendor and/or this carrier?

MS. FRASER: The only standardized that I can tell you, it'll be a Form 482. Other than that it's going to be case-specific. It's going to be based on how much or how little information we

know, and, you know, the reasonable belief an article of food is adulterated and presents a threat of serious adverse health consequences or death.

To the extent that we've had sick--you know, on one hand, let's say we have a number of people in the hospital and we figured out they all ate green onions or they all ate--you know, that might not be specific enough that the request may be we need records on all the green onions you received over the last X days, X weeks.

To the extent we find out they all ate the same kind of cereal, then it might be very specific to a particular brand or a particular type. To the extent that we have a threat from the FBI, the CIA, that says, you know, we've received word from a facility that they think their product line was tampered with or we think a shipment or a truck may have been tampered with--it might be everything that was on that truck and all products that could have been.

So it's really going to be as specific as

possible, and I can't answer it beyond that because it's going to depend on the nature of the threat and the type of information we have. But when you look at our guidance, one of the things we have to work out with the Office of Enforcement and the General Counsel's office is the scope of the request to make it as specific as possible, tying it back to our reasonable belief an article of food is adulterated.

What is the article of food is what that ties on and that's going to be as specific as we can get it.

QUESTION: Good morning. Doug Ludders [ph] with Minnesota Department of Ag. But my question relates back to my previous life which was in the grain industry, and it come about because of my review of this bioterrorism act and enforcement guides, and our FDA contracts, blah, blah, blah, blah, where we are to ask about BT registration when we do BSE compliance inspections.

So it gets to be a twisted life I have here for the question. But in review of the

guidance document sent out earlier about definition of a farm, the question comes up, is that post-harvest activities generally cause a product to, or entities to fall out of the farm classification into the BT registration classification.

So it's not uncommon for, in Minnesota, to have farm storage systems that will contain a year and a half's worth of production of crop, and in that length of time, certain lots may need to be treated for insect infestations.

So this would be a post-harvest treatment. So now does that farm become BT registerable, and then, since I was in a retail establishment, is there an obligation on the part of a retailer that would be selling the fumigant or the treatment that goes on that grain, to make a connection?

So, first of all, does the farm become BT registrable because they're treated for insect infestations?

MS. FRASER: We're going back and looking at the registration guidance. We did say that in the registration guidance. When we got to the

recordkeeping rule, we had a number of farms kind of come back in and say, you know, the very scenario you describe, this doesn't make any sense, we do this, and you're causing us to lose our exemption.

So in the recordkeeping rule, we clearly said in the preamble, you can apply pesticide and you won't be subject to the recordkeeping rule.

And it is not consistent with what we said in the registration guidance. And so now we're going back and revisiting the registration guidance. My sense is we'll probably come back out the same place that says--which is where recordkeeping came in, that you could do post-harvest application but that is one we have to complete.

So currently, you're right--under the registration guidance as we've interpreted it, that would require you to register. Yes, it is not consistent with recordkeeping and yes, we're revisiting that guidance and hope to clarify that there.

QUESTION: Right. It was kind of a stretch to get from strawberries to grain there, because I think strawberries were used in your example.

MS. FRASER: Somebody sent us--you know, we bless the hands, and unfortunately, very few of us were farmers in our previous life. On the question on the retail, though, you asked about does the retail have to keep track of the fumigant.

No. That is not a--in terms of whether that's a--I think that's more on the regulated, on the EPA side. We do have in the registration rule an exemption for pesticides regulated by EPA.

QUESTION: My name is Mark Welkin [ph]. I'm with a--we're a private-label manufacturer of, you know, pasta dinners, things like that--relates to food contact surfaces. Some of the items we pack into a pouch material; some of them we pack into a carton.

We know where we get those from. We have records on that. Does that have to be tied to the specific lot of the outgoing food product? Right

now, it's kind of handled on a, you know, first in, first out basis. We know when we're receiving these and when they're moving through our facility.

But whereas all food raw materials are being tracked, you know, to our finished lots, do we also have to do that with food contact surfaces?

MS. FRASER: You do, because you're the person that's putting the product in contact with the container, the finished container that contacts the food. Then you would treat that container, for all practical purposes, as if it were a food ingredient in terms of tracking immediate pervious source and linking incoming product with outgoing--outgoing product with incoming ingredients or incoming food contact substance materials of finished container. So you would have to keep track of that.

So your lot number going out the door would be both the food and the container lot number, if that was something that existed when you received it.

QUESTION: Okay; thank you.

QUESTION: Bob Luddke again. This goes to more the definition of reasonably available. If a manufacturer has separate storage capabilities to be able to separate one lot number from another, to keep grains or other bulk commodities from being commingled, but because of the current business processes that they've got, or business practices, they choose not to use that capability that their facility has, reasonably available--does that mean they need to change their business practice to make sure of that capability of keeping lot numbers separate or will they be able to continue on like they're doing today?

MS. FRASER: I think that's reasonably available. I think what we said is we didn't require you to reconfigure. We didn't require you to build new silos. We didn't require you to, you know, build designated bins. But just because, right now, you may dump, you know, let's say flavoring comes in in gallon containers and you just dump it in without recording lot numbers but you easily could, because they come in and you're

adding it one at a time, that is reasonably available.

If you're configured to do it, it's reasonably available. We're just not requiring expenditure of funds but we do recognize some business practices may need to be modified.

QUESTION: So if the capability is there, there will be a requirement to--

MS. FRASER: We will say that's reasonable available.

QUESTION: Okay; thank you.

MS. FRASER: The gentleman in the back who I didn't let ask your third question. You had a third question.

QUESTION: [inaudible].

MS. FRASER: Okay.

QUESTION: My question is if you have a bin with, say, 25 lots in it, and what is that bin never goes empty, and you're running ingredients out of it, and as the inventory goes down, you got in ten more lots, and than as that goes down you had ten more lots.

At what point can you successfully say that those first 25 lots are out of there?

MS. FRASER: I'll ask you that. I mean, I think--I can't answer that question. I think that, you know, again, looking at the purpose of the recordkeeping regulation, where we're trying to do an effective traceback, if that's the only bin you have and that's how you can, you know, you just store, and, you, you know, at some point, you know, there's plenty of engineers--in my former life I was an engineer--they can calculate percentages and, you know, what's your expectation on what you think is in there.

But I can't answer that specificity of, you know, how much is good enough. I think that's something you're more expert at your operations than we ever will be.

QUESTION: So you don't think it'd be reasonable to say if it takes two years before we actually empty it, say, well, these are the past lots over the two years, you don't think it'd be reasonable to give them that list?

MS. FRASER: It may very well be and it may be that you want to segregate it and say it's most likely these, because this is the--you know, maybe you want to have it in date order, that these are the lots we received on this date, and so the likelihood of it being--while there may be one percentage left in there from two years ago, there probably is some residue of that in there, we probably would have seen somebody very sick, if that was the cause of it.

So I think yes, it has to be on your listing if you think there's still some percentage. But as we're doing a trackback investigation, my guess is we're going to focus on what's much more likely to be percentage-wise in that bin or that silo in terms of volume because the other stuff we should have seen an impact on public health, if that was the cause.

So what's in your records may have two years worth but what we're focusing on from a public health standpoint, my guess would be, is the more recent addition to your bin.

QUESTION: Again, we're in a public warehouse environment. Because we do not pack, progress or manufacture food, we do not have a requirement to show the lot numbers, where they were shipped to when it leaves our facility?

MS. FRASER: Correct.

QUESTION: Okay.

MS. FRASER: Have I made one person happy?

QUESTION: Well, it seems like you lose continuity, you know, in that whole process.

MS. FRASER: Well, we do, we do lose continuity. The proposed rule did have a lot number requirement all the way down to the retailer and for those of you who are subject to the prior notice rule, to the extent that noon the day before was the red flag before the bull, lot number was the red flag before the bull on that proposed recordkeeping rule to go all the way down to the retailer.

The commoner said we have a, we can more readily do it without a tremendous cost, under existing technology RFIB is not there yet, and

other technologies aren't in widespread use yet. We can more readily do it from the manufacturer/processor into the warehouse standpoint than we can out of the warehouse, given the way pallets are combined, reconfigured, just in time, and all the other things.

And so we made a tradeoff between what we would prefer as the best recordkeeping system, which would be lot number all the way down to the retailer, with the cost impact, and so we balanced it and came out with just manufacturer, process, packer in the final rule.

QUESTION: I may go 0 for 3 here but I'm gonna ask anyhow. In regards to the corporate entity that you talked about earlier this morning, I'll give you a quick example, and just your answer, if you could.

Distribution facility, we own the product, it goes on to our trailer, we own the trailer, and then it goes to our stores. However, we use a third party to actually haul the trailer to the store.

As far as the transporter side of things, are we then subject to be able to provide the transporter that hauled the product, although it's on our trailer going to our store from our facility? Or is that all considered our corporate entity and we're not subject to that?

MS. FRASER: You own the product, you own the trailer; but who's transporting it?

QUESTION: Third party.

MS. FRASER: Then you have released it to another person, so--I'm sorry.

QUESTION: That's a swing and a miss.

MS. FRASER: But at least you knew.

QUESTION: [inaudible].

MS. FRASER: Well, no, the agreement is one--the question was as long as he has an agreement with the transporter to maintain the liability, he doesn't have to worry about it. You know, that's an interesting question because what that gets into is you could, as the immediate previous source for the transporter, agreed to maintain the records for the transporter, and be

the person, and does that change whether you're the nontransporter or immediate previous source or not?

I guess if you kind a worked out what it would end up doing, is you would transfer--the records would say you've transferred it to the transporter but you've assumed the obligation, so you've taken it back, so maybe it is one record.

But in doing that, you're responsible for everything the transporter would be responsible, which is not just identification of the immediate pervious source. You now need the transportation route and all of their--you know, whether it's the DOT obligation they're doing, because we need to know the route of movement on the transporter side and even if you are complying with the DOT motor carrier transport, that's buried in their regulations as route of movement as well.

So yes and no. I mean, yes, it's not as simple as we retained it within our personhood because the obligations the transporter have are not identical to the obligations he had as a nontransporter.

QUESTION: I want to get back to this gentleman's question here about reasonable, available. In here, we're talking about records; okay. He was talking about structure. So now we're getting to interpretation. Okay.

So what I'm talking about, if I have 70 bins, and I could keep each farmer separate, am I required to?

MS. FRASER: You are not required to. He was getting to--and I understood it a little differently. Do we require you to keep it separately--no--

QUESTION: Actually the question I was asking was more towards him but it kind of applies equally to a food manufacturer or feed manufacturer, in his case a grain [inaudible].

MS. FRASER: The requirement--and "reasonable available" shows up in two places--but the requirement for lot number is, to the extent it exists, the requirement for linking incoming ingredient to outgoing product is to the extent the information is reasonably available, and that goes-

-it's not to say you don't have to link it. It says that you have to give us the degree of specificity to the degree it's reasonably available.

And what I understood his question to say is we can give you that linkage, you know, we have the capability of doing it, we would just have to make some adjustments to provide that information, and I do think, in the scenario he gave me that--and even in yours, where you say, okay, we have 70 bins and 70 shipments, can't we put one in each shipment? You know, this is one we could think about some more in putting guidance, you know, so don't take this as the answer, but off the top of my head, it seems to me linking incoming product to outgoing, incoming ingredient to outgoing product, if you have 70 sources and 70 bins, that looks pretty reasonably available to me off the top of my head.

Now, you know, people say, well, define "reasonably available" and we have tried our hardest not to because there is no one-size-fits-

all to what is reasonably available.

You know, can you do that if it's just bins sitting on the, you know, against the wall and you're opening them up? is one thing. If it requires reconfiguration and replumbing, it's another thing.

I mean, so there is not a clean answer. I would again put it back on you as to--on two fronts. What makes for--you know, if we're in a public health emergency, you don't want to be the one that's the, you know, legally or not legal--you don't want to be the one that's delaying the traceback. Take the worst case. It's a terrorist attack, they're contaminating a product you're handling, you want to be, for your name, reputation, for your business position, for your product position, separate and apart. Impact on public health.

You want to be in a place to get to the best answer. What helps you do that? And can you make those adjustments without causing massive drainage on your resources, is sort of--so we did

not define "reasonably available."

QUESTION: No; it wouldn't be cost-effective at all.

MS. FRASER: Yeah, and so, you know, I think that's sort of--we're not going to mandate and say yes, you have to do it this way.

QUESTION: Okay.

MS. FRASER: But we're looking at specific linkage to ingredients to products, to the extent it's appropriate. The other side is it's going to broaden our investigation and may implicate more of your product.

QUESTION: Thank you.

QUESTION: Dave Einberg [ph] for Izamill [?]. I've got two quick questions. The first one is on, in our business we do transfers from our manufacturing plant, load product on to rail cars, transfer them into trucks, and then deliver them to a final customer.

So my assumption is that we would have to identify the final customer receiving the product, and we'd have to identify the rail car that was

loaded, but not necessarily the carrier that went into the customer; is that correct?

MS. FRASER: Is the carrier you or carrier somebody else?

QUESTION: It's an independent carrier.

MS. FRASER: Then you've transferred outside of your personhood, even though it went back into your personhood afterwards,there was a break in the custody. It went from you to an independent person, back to you. Your immediate subsequent recipient as a--the transporter immediate subsequent--the transporter who took the product from you is that independent person--

QUESTION: Right. They transferred--that product then would have transferred to a carrier, a different carrier who then delivered it to--not in house but delivered it to--

MS. FRASER: Right but you only have to give who you released it from, on your side--well, let me see. So this is all transfer within your corporate structure, or not?

QUESTION: No; no. So the flour--the

product is loaded into a rail car, so we'd give you the information relative to the railroad and the car, et cetera. That cars moves to a final destination. Then a carrier that we've hired takes the product off the vehicle, or the carrier, and then delivers it to our final customer.

So, in other words, you have two carriers involved in that transfer to flour from when you released it to your final destination.

MS. FRASER: Okay. Then the duty that you have is to the rail car, is on your side. The customer has a duty to tell us that it's the carrier that brought the product to them, on their side, and also that they received the product from you.

QUESTION: So we would not necessarily, in our records, have to say where that finished product ended up. We'd just say it went to this mode of transportation and we ought to give you the--

MS. FRASER: You do have to say it ended up with the customer cause that's your

nontransporter immediate subsequent recipient. You will definitely have that. In terms of the transporter that took the product from you, the only reason I'm hesitating is you're arranging the whole thing and so you're actually not as clean as the nice example where it went from the truck to the plane to the truck.

You're actually kind of mixed up in that whole transportation activity. So I need to think about that aspect of it. But other than that wrinkle, if I take that piece of it out, your records would just say the rail car is what took the product from you and then we would--that rail car would have an obligation to tell us they delivered the product to the truck, and the store or your customer would have the obligation to say we received the product from the truck, and our nontransporter, immediate previous source was you.

QUESTION: One other clarification on ingredients and items that touch the product. So we use city water in part of our manufacturing process. Do we have to identify--obviously you

can't identify lots of water coming in. But is that part of the records as well, that water has touched--the water has touched the product and here's a source of that water?

MS. FRASER: You know, so the water is either a food additive or a food contact substance? Yeah; it's one of your ingredients to your--it's part of your ingredients or your additives to your processing. It's going to be food received in the form you received it, doesn't have a lot number, but the immediate previous source might be the city water supply.

QUESTION: That'd be part of the record--

MS. FRASER: Incoming record; right.

[Start tape 3.]

MS. FRASER: [in progress] and so forth. There's a discussion in the preamble that talks about whether we count that as food, in terms of thing that are--you know, there, I think you're more like a food context substance, where you don't have any obligation to establish and maintain records. You have a duty to have access to

existing records. So it's really tied to are you a food contact substance as we define that in the statute, or are you a food additive or food ingredient as we define that in the statute?

And you need to figure out which of those two halves you fall under, cause if you're a food ingredient or food additive, then you are subject to the establishment and maintenance.

If you're a food contact substance, unless you're putting, you know, the container in contact with the food, you're only subject to the access provisions.

MS. JOHNSON: Amy Johnson with FDA. I was wondering if you could--do you have insight about what USDA might be coming down the pike with as far as their type of regulations? Are they going to be requiring any type of similar records?

And the reason I ask this is it sounds like you are coordinating with USDA to clarify portions of this rule, and for the audience here that are dealing with co-regulated products, and things like that, as a public affairs specialist I

get a lot of questions where people seem a little anxious as far as, you know, complying with FDA regulations, and would they be expected to then do similar things for another regulatory agency?

MS. FRASER: I am not authorized to speak for USDA at all. I have not heard that they are doing anything new, which only means I haven't heard; it doesn't mean they're not.

I can say that when we got the bioterrorism act, one of the--and it was limited to FDA-regulated products, not USDA-regulated products, in part, the explanation was that this was to give us authorities that would be more in line with what USDA already had, and so that there was a feeling that between existing authority and I don't know what recordkeeping USDA has or not, but also with the inspectors in the plants, that USDA had more oversight, more control than FDA had, and this was something given to us.

So I haven't heard that there's anything, and at least when the BT act came out, there wasn't a sense in the federal community that USDA was

lacking in any way, that that needed new authority. So I haven't heard that. But the better place to start is probably USDA.

QUESTION: Hi. Joe Samaco [ph] with Cargill. As a processor, what about incidental food additives, like sanitizer and cleaners and chlorine tablets that you may add to your processing water? Must we keep track of all those ingredients?

MS. FRASER: Again, it's going to turn on whether, you know, under the definition, and look in the, you know, in the preamble--but it's going to turn on whether you're a food contact substance as we regulate that and define that, or a food additive, food ingredient, as we define that.

If you're a food additive and food ingredient, and some of it turns on technical effect in the food, and so forth, then you are subject to these establishment and maintenance.

If you're a food contact substance, then you're not. You're subject to the records access provisions. And just remember, even if you're not

subject to keeping records that we specified here for nontransporters and transporters, part of the records access provisions is to make sure you have procedures in place to turn over any existing records you may keep as a matter of business practice within the 24 hours.

So you may have that obligation to work on your business practices, even if you don't have an obligation to keep new records for this.

QUESTION: Thank you.

MS. FRASER: We have time for a couple more questions and then we'll call it a day so I can get to Atlanta, do this tomorrow.

MR. SMITH: Jeff Smith from DSF. We're a feed manufacturer. And under current GMP, we have to keep track of the medication side, and we have a pretty good lot tracking as far as some of the major ingredients, and then some of the smaller includes we haven't really kept track on every single small inclusion that goes into a formula.

So I'm wondering, on the recordkeeping side of things, is it sufficient, based on date

received, and the timeframe that you use this ingredient, that that's sufficient? Or is it gonna be an actual lot number? Say we received a lot where we've got, you know, like, say, 20 pallets of this ingredient and it takes us two months to go through that.

Can we just use the bill of lading and the receipt that we have, that has the lot number on that, and be able to say that this amount a feed had this ingredient in it? Or do we actually have to link that lot number to every single product that we go out the door with?

MS. FRASER: That's combining probably two different provisions. On one hand, as a manufacturer, processor, packer, you have an obligation to record lot number of incoming ingredient as you receive it, and outgoing product as you release it.

To the extent there is a lot number or the identifier, the question of how you link the incoming ingredient with the outgoing product is a reasonably available question which is pretty much

the same question that the grain folks were asking in terms of bins and how reasonably available is it to record that.

To me there is a difference between we have not been doing it and it is not reasonably available for us to do it, and you need to think about that for--I can't answer that question for you.

You need to look at your operations and say is it reasonably available to capture it with the specificity of lot number versus we just haven't been doing it to date.

QUESTION: So records, just for clarification, can be receiving papers that have identification from the supplier?

MS. FRASER: We don't say how you keep the records or what records you use. We tell you what information you have to have. So whether you want to use--you can use bill of lading. You can use whatever you want to use as long as whatever you piece together in your puzzle has all of the requisite information and you can meet the access

timeframes at the end of the day. So your system of compiling it and coordinating it gets you there but you can use whatever--they all don't have to be in one record. You can have--like the bill of lading might have 90 percent of what you need but you've got to add something else in a supplemental record.

QUESTION: And then one thing you said in your presentation--there was eight things that are required--

MS. FRASER: Oh, I just made up--I'm sorry. I shouldn't have said that.

QUESTION: Okay. I just wanted to make sure cause I was looking in there for eight things, so--

MS. FRASER: No, no, no. I should have counted. I'm sorry.

QUESTION: I'm Jeri Kasmerik [ph] and I represent a food manufacturer. We service primarily the convenience store industry and my question is we release our product to a third-party transporter that then takes it to drop sites,

frozen drop sites that we own, and then there are route trucks that pick up from those drop sites, that go to convenience stores. So do we need to keep track all the way to the convenience store? Or since we release it to the transporter, it goes to our drop sites, does it end there?

MS. FRASER: Well, the nontransporter you're releasing it to outside of your personhood is the--

QUESTION: ISR.

MS. FRASER: Yeah, the retail store. Cause you said you own the drop sites. So it's not really coming outside of your--but you're releasing it to a third party nontransporter?

QUESTION: Right. It goes from our facility by a third party transporter to drop sites that we own.

MS. FRASER: Yeah. That's one I think we need to answer in guidance because the competing things are we're looking at identifying the non--you know, on one hand we're saying for a vertically-integrated company, which is really what

you're talking about, as long as everything's within your control we don't need the internal records. But you're releasing it to a transporter who is not within your control, and so in that case I think we are looking for that as being something that has left your personhood, even if it's returned back in, because they may have gone through a different route of movement that we otherwise would not see and is not captured in your records.

So we would tend to look at it as it's not any longer--it's not with a vertically-integrated intracorporate transfer only because you have left--it's left your ownership custody or control in parts of that. So it would kind of be your immediate previous source and your immediate subsequent recipient in that case if yourself for that first transfer.

The second transfer is your immediate subsequent recipient is the retail store. So I think you actually have two sets of records in terms of your first transfer because it's left your

control, and then your second transfer, even though you're on either end of--you know, it left us and it came back to us. But I think that's kind of our thinking, is that in a traceback, the only way we would know--cause your records aren't going--part of this is, you know, we're only looking person to person to person.

If we get to you and we find a contaminated product, there isn't really an ability to know what the transportation company did per se. So I need to think about that one because--

QUESTION: If we do have that information, even though they're a third-party transporter, they have offices on our site, so that information would be available?

MS. FRASER: I don't know--send me that one in writing, cause I really want to think about that one some more, because, you know, they also are a transporter so they're under an obligation to keep their own transportation records, and if we get to you and you say, well, it went from here to here and this is the transporter we use--so I'm

trying to figure out the competing policy interest there and it's another one I could see coming out on either side. So I just need to think about that one some more.

QUESTION: [inaudible] with Kraft. That previous question might be able to be answered through DSD questions that came in with the original rule. Anyways, a couple easy ones for you. First of all, when the--

MS. FRASER: Been none easy.

QUESTION: Yeah, well, it wasn't easy but we worked it out. When a rule came out for record maintenance, you also asked for comments around access. When will those comments be coming out or that feedback coming out on record access?

MS. FRASER: That one the work group--that's a different work group. That one is run out of the Office of Regulatory Affairs, the implementation and enforcement side. They are working through the comments and looking at whether the draft guidance needs to be revised, and so my guess is probably within the next month or two,

that'll be finalized. And again, that's only for the first round of comments. We had a comment date in there just so we can issue it in final--and guidance always has final on it, but it's in quotes, unlike rules which are in final and usually we don't expect to return to them in the near future.

But that one should be coming out. But if you still have comments on the guidance, you always can send that in, as opposed to comments on the rule which we're not reopening the rule.

QUESTION: Would the same hold true for the Q&As coming out in a rule, then, in about a month or so? First round.

MS. FRASER: I think it's a month or two as well. It's more a matter of both are headed to the general counsel's office and the same attorney will look at both the Q&As, the access, and he's also working on our shell egg rule. So it's more a matter of just how much that one person can, you know, get done, and the order gets it done, and so-

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QUESTION: Thank you.

QUESTION: Leslye, I don't have a question for you.

MS. FRASER: Oh, thank you.

QUESTION: But I know you say you do have to get to Atlanta, so we want to get you out of here.

But if you have additional questions, in the pamphlet, in the handout, there's a place for you to send those questions. Unless Les, do you want to take one more? Is there one more question? We have two minutes. Last question?

MS. FRASER: I have a question. Can I ask a question? How many of you are large, have to be in compliance this December?

[Show of hands.]

MS. FRASER: Okay. Now how many are small, 11 to 499 employees?

[Show of hands.]

MS. FRASER: And how many are the very small?

[Show of hands.]

MS. FRASER: And how many are exempt?

[Show of hands.]

MS. FRASER: Okay; thank you.

And I do thank all of you for coming because I think this is helping us, and, you know, whatever we can encourage you to do to help your fellow persons get into compliance, we'd appreciate as well.

MR. : I also want to extend our thanks to Leslye, also for coming, for Rockville. I also want to make another plug. We will have another meeting with the BT regulations, a public health emergency. We know we all want to prevent that, so there will be another public meeting on food security, July the 12th.

The location has not been identified as of yet here in Minneapolis. It will be in the Minneapolis area, but that's July the 12th, on full security, and we will also have personnel from Rockville to give presentations then. So we look forward to seeing you all at that point as well.

Again, special thanks to Leslye, special

thanks to all of you for coming, and please read the material, send in those questions. Thank you.

MS. FRASER: Thank you.

[END OF RECORDED SEGMENT.]