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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

Wednesday, June 15, 2005

Renaissance Waverly  
Atlanta, Georgia

[TRANSCRIPT PREPARED FROM TAPE RECORDINGS.]

OZN-0277

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## P R O C E E D I N G S

MS. FRASER: Whoever wants to go to the microphone, that would be helpful. And if you could, tell me your name and association as you come forward. It's more just to help us kind of figure out where, you know, the context of the questions and the applicability of them.

A while ago I passed 40 and glasses became a mandatory reading requirement. So bear with me. It took me at least two years to get out of denial.

All right. Our first question is are mail order businesses considered retail food establishments? It depends on who you are sending your product to. The fact that you are a hard--you know, a physical facility as a grocery store or doing something out of your home or doing something over the Internet, that isn't critical to us. The critical thing is does you meet the definition.

And so a retail facility was one that is selling food to consumers as its primary function. And if you meet that primary function test in terms of who your customers are, the fact that you are

mail order or a physical location is not going to be the derivative. If you are a mail order company and most of your customers are not consumers, then, no, you are not a retailer.

So it really is turning on do you meet the definition in the regulation. But assuming you do and your customers are mostly consumers or more than 50 percent are consumers, then yes, you would be considered a retail facility.

The next question is at a dairy manufacturing plant, we order our raw milk from a milk coop. The coop arranges for a truck to go to several dairy farms and then deliver the milk to our facility. For our immediate previous source records, is the immediate previous source information on the coop acceptable, or do we have to have information on each individual dairy farm?

The coop is acceptable. You are only responsible for who is the person delivering food to you, what's coming into your personhood, who are the recipients of the food that you release. You are only subject to those transactions to which you

are a party.

So what you see coming in is the coop delivering the food to you. It is the coop's responsibility as part of their records to identify all of the sources of the food that it receives from one, two, three, four different farms, and that would be the coop's immediate previous source.

The food released would be to you, and you would be the coop's immediate subsequent recipient. And when we do a traceback, we would end up--the way we usually end up with tracebacks, if it's not a tip somewhere in the line, is sick consumers, and we end up kind of figuring out the distribution trail. We would end up at some point to you, and you would tell us you received the milk from the coop. We would then end up with the coop to find out the source of the milk from them.

We manufacture key lime pie for restaurants, but we also sell our damaged pies to the public. What kind of records do we need to keep? Do we need the names and numbers of those who buy our damaged pies?

You are a manufacturer so you need the records for your immediate previous source, because you are more like a central kitchen or you are more like a manufacturer. So your immediate previous sources of all the ingredients coming in as a nontransporter, your immediate subsequent recipient, the immediate subsequent recipient, a restaurant is a business. The fact that the restaurant is exempt does not exempt you who are providing food to the restaurant.

So your immediate subsequent recipient to the restaurant would have to be captured. Damaged pies to the public, I'm assuming the public here is consumers, and there is an exemption for those who are providing food directly to consumers do not have to--this one.

So those who are distributing food directly to consumers do not have to establish and maintain records identifying consumers as their immediate subsequent recipients.

So that's it for paper copies, and you can either still write them down or pass them to the

aisle or come up to the microphone. And again if you would, even on the paper copies, if you would just list your name and affiliation or come up to the mike and do that, that would be great.

MR. : We would represent a company that by definition would be large, and by your explanation we would be a nontransporter. So we would be a large company as a nontransporter, and we are quite integrated, so we will ship from our own--we will manufacture, ship using our trucks to a distribution center, and then ship to retail outlets, some of which we own, or franchise, some of which are independent.

So throughout that chain, from what I understand, we would--and we are dietary supplements also, so we are tracking by lot number, and that information does request, so therefore we need to track by it.

Is there any point where tracking by lot number in what I have just described no longer is necessary? For example, if we are shipping from our distribution center to a store with less than

10 FTEs, do we need to track lot number to that store? Does the receiving store need to track receipt by lot number?

MS. FRASER: That's a good question, and there is a discussion on the vertically integrated company structure in the rule, but we did not address that issue, and that's one that we are looking at in the Q&As because--let me take the retail store first.

The retail store has no obligation to record lot number. The lot number only applies to those who manufacture, process, and pack, and so they don't have an obligation or not.

With respect to the ones that you own, you are not--you know, you are not releasing the food except to the consumer. So coming out of your personhood, you have lot numbers coming in. What goes out of your personhood is going out of the retail store that's I'm guessing going to a consumer, and then you would meet the same exclusion here of no duty to record information to consumers.

The question we haven't answered, and that we are looking at for guidance, is throughout your vertically integrated company, should we require you to record lot number down through the packing stage, which is what we would do if you weren't vertically integrated? Or do we not, because, you know, you have to do it through the manufacturing process.

So we are still considering that. We haven't quite--for equity and fairness, we are trying to make things both as parallel as possible but also consistent with how we have considered a person to say you don't have to track in truck corporate transfers, and it's a tough one to try and wrestle that one out.

MR. : This is a very big question for us because we have got 5,000 stores. So I'm not sure I quite got that.

My real question is our obligation to tracking shipments from our distribution centers to the stores, whether they are ours or not.

MS. FRASER: Right. That's the piece we



still need to answer, and at minimum it would not be to the retail store. So at least we would not have you track it to the retail stores because if you weren't vertically integrated, the distributor would not have to track it to the retail store.

The question is that we haven't answered is we do require tracking for part of your internal records, at least manufactured to your own distribution center, however that is.

MR. : And that's not a problem.

MS. FRASER: Right. And that piece we haven't answered in guidance. But there is no obligation for anyone to track from the distribution point to the retail store.

MR. : By lot number?

MS. FRASER: Right, by lot number.

MR. : Okay. Thank you.

MR. : With regard to --

MS. FRASER: And you are?

MR. : My name is Sid Camp. I'm with HC Grill Company.

MS. FRASER: I'm sorry, can you all hear

that in the back? Okay.

MR. : With regard to a food manufacturer that sells to a retailer, a very large retailer that has several distribution centers, would the lot tracking records require us to know which distribution centers receives which lot?

MS. FRASER: Yes. From the manufacturing standpoint, you would have to track by lot number the release of your product to the --

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MR. : --airline warehouses, for example. Also we may have an importer that might want to bring food into our facility, nonperishable products to be received there, and then picked up from there. So we would have to keep track of the--we have all the records to begin with since we're doing the customs entry, but on the other hand, we have to keep track of who brings that food to our facility and who we give it to?

MS. FRASER: I'm sorry, and you are a-- what's your operation?

MR. : We're custom brokers and

freight forwarders.

MS. FRASER: This would turn on--and are you--you are actually taking possession, custody and control of the food as opposed to just doing paper transactions?

MR. : Right, in this case we do because we have a bonded facility and the customer might have a problem with FDA that needs to be resolved, maybe labeling product, for example, or something like that, country of origin or whatever, and we may hold it in our facility as a bonded transfer to our facility and we may hold the food there until this matter is resolved, really to avoid the expensive storage charges it would be some place else.

MS. FRASER: Right.

MR. : And on the other hand, also we have a situation where we might have an importer that might want to bring in a nonperishable product to our facility on a container to be offloaded and then be picked up from there. So we just want to know what the--we

have all the records as far as records are concerned, don't worry about that. We just want to know what is our responsibility as far as keeping track of the one up and one down.

MS. FRASER: Right. You do have a responsibility to keep track of it. The question is going to be whether you are going to be considered a nontransporter or a transporter. What we have said, and probably not--if you look at the--I think it's the registration Q&A, we clarify holding, and so when we look at the definition of holding, we are really looking at warehouses and people that are storing food distinct from terminal facilities that may hold food for some, even if it's hours or days, but if it's part of a normal transportation process, we don't count that as holding food. We count that as part of transportation.

It sounds like you are doing a combination of the two, that there is some aspects that are really more of the typical flowthrough of a transportation process, and there are some aspects

that are--you know, whether you're storing it for some period of time as a warehouse. And so you are really going to have to look at those aspects of what you're doing. Are they transportation related, or are they warehouse type related.

In either event, you are going to be subject to the one up, one back. It's just whether you're going to fall under the nontransporter requirements or you're going to fall under the transporter requirements. But there is an obligation on both sides to do one up, one back.

MR. : Okay. Thank you.

Also our responsibility is strictly to note who brings us the food, who we turn the food to, who we--we have a transportation company if the customer is not picking up, the transportation company. We transfer the food to them. We noted that we had transferred to them with a bill of lading.

MS. FRASER: Well, if you are on the transportation side and you want to use the DOT bill of lading requirements, which are in the motor

carrier regulations, as long as you are complying with those DOT requirements, that would be sufficient.

It depends on, again, which option you decide you are following. If you are following option one, then there's a little more specificity. If you're following option two, which is the DOT bill of lading, again, yes, that would be sufficient. Assuming you are a transporter.

For your nontransporter activities, the bill of lading is not going to be sufficient to give you the same specificity that you need to comply with what the nontransporter has to have in their records, which is a lot more specificity than the bill of lading, which tends to be a little more generic in description of product and packages received, and it's not as detailed as we have for a nontransporter.

MR. : Thank you.

MS. FRASER: I need to go back to my dietary supplement guy, because your answer wasn't consistent with the answer I gave over there, and

that's part of the piece we need to figure out. Because to the extent you are a manufacturer releasing product versus just a distributor releasing product, that's the piece we still need to figure out. Does the fact that you're a manufacturer releasing it to your retail store mean you need to track the lot numbers because, as a vertically integrated company, should I treat you the same as the gentleman over there, who asked me that he's a manufacturer, sending it to a different retail store, where he does have to track lot number, or the fact that you are vertically integrated and you are coming into your same personhood, do I say you don't.

So I didn't give you the right answer. That's the piece we are wrestling with is how do we equitably treat a manufacturer who is sending to a retailer that is not part of their system, and a manufacturer who is vertically integrated down to the retail store and sending it, and do we require lot numbers for both, do we say no, you are vertically integrated, we don't. And we just are--

there are good arguments on both sides of that that we are still wrestling with.

MR. : [Off microphone.]

MS. FRASER: Yeah. You know, this is one that's--I'm hoping within the next month or two. It's on the top of the--because it is very critical to understand in the vertically integrated, that one is one that we are wrestling with and hope to get out.

Samples is another one where the nuances involving samples is another one we are hoping to get out in the first edition of the Q&A document.

MR. : Good morning. My name is Bill Rudasill, and I am with Bruce Salads/V&H Foods in Charlotte, North Carolina. We would be considered a small business. We manufacture pimiento cheese, chicken salad, so forth. We don't put lot numbers on it. We do have a date that we can track when the product was manufactured. Do we need to add a lot number or can we use the date as we are doing now?

MS. FRASER: You don't need to add a lot



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number. You can use the date. The question that's also teed up for the Q&A is when we were thinking lot number or other identifier, part of what we were thinking was manufacturing codes. A number of these other public meetings, people have said we use the sell-by date as our substitute lot number, and is that what you are requiring in that provision? And it's one of those things we have to go back and think about. Should lot number of an identifier be considered a requirement or permissible that you can choose to do or not do under the--to the extent it exists, information?

So, yes, you can do it, whether you are required to do it is a question we need to answer.

MR. : Okay. Also some of our raw materials, we--as far as I can tell, we would be considered a nontransporter because we manufacture the product, our employees deliver it to the grocery stores/restaurants. So I guess what I need to ask is some of our raw materials has lot numbers, some of it does not, and we record and we keep records of everything that comes in, but we

might get a trailerload of cheese in and it doesn't have a lot number. We know when it came in and we know within a reasonable timeframe when we used that cheese. Are we going to have to have lot numbers added to the raw materials?

MS. FRASER: The lot number requirement does not require you to create lot numbers if they don't exist.

MR. : Okay.

MS. FRASER: If they do exist and you are a manufacturer, processor, packer, then you do have to record them. But there is not an obligation to create one where there is none.

MR. : Okay. One other question. When we load this product on--we've got 50 route trucks. When we load this product on the trucks, we record the date so that we can know exactly when the product was put on the trucks when it was made. Right now we don't have a way of recording exactly what stores--we know within 10 stores each day where that route person works. But we are going to have to come up with a way to record that date as

to what was put into each store that we work; is that correct?

MS. FRASER: Correct. Because that's the date you're releasing the product for however much product you are releasing there.

MR. : Okay. Thank you.

MR. : Hello. Chris Albanese, pet products. I was wondering how this rule affects products such as bird seed or rawhide dog bones.

MS. FRASER: It does apply. Those are all considered animal feed products, much like chewing gum and feed for humans. So it does apply.

MR. : Okay. Thank you.

MS. : I have a couple of questions. I think you have touched on all of them. I just want to make sure I'm clear on the answers.

MS. FRASER: Okay. If you could get a little closer to the mike.

MS. : So the first question would be I am the manufacturer for the

nontransporter. I contact with transportation company A, they subcontract with transportation company B. I am responsible for knowing transportation company A's information?

MS. FRASER: Correct.

MS. : Second question, very similar. I again am the manufacturer, the nontransporter. My customer decides to come pick up from my location and today what I have is customer pickup.

MS. FRASER: And that's fine, because the transporter that took the product from you and your immediate subsequent recipient are one and the same.

MS. : Okay. Perfect. That's what I was hoping you would say. And then the third question is I ship the product to a warehouse that I contract with, so I manufacture it here, I ship to warehouse company A, and it is still in my custody, basically, and then they ship it for me to customer X. We, I think, are okay to have the documentation on site at warehouse company A,

right? We don't necessarily need it at our manufacturing site.

MS. FRASER: Well, there's two pieces of that. The warehouse is a different personhood even if because--and they would independently meet the nontransporter definition because they--if you look at the definition of a nontransporter, immediate previous source, it's one who owns or has custody, possession or control of the food. They actually have possession of the food or custody of the food or control. They have one of those. You may own it, they may have custody, possession or control.

The place where the activity occurs for you is where you release the food. You release the food at your manufacturing facility, that's your records.

MS. : Okay.

MS. FRASER: They have an independent obligation for whatever they are receiving or releasing into that warehouse because they have custody, ownership or control--it's not ownership, custody, possession or control.

Whether you two work out some arrangement between you that, you know, we don't need--we'll keep--I mean it's--the requirement is to keep the records on site or a reasonably accessible location.

MS. : Okay.

MS. FRASER: And so you can meet that obligation. Just recognize that when we are doing a traceback, we are going to come to you, if that's what we have in the records of the chain, and we are going to expect access to those records as soon as possible, not to exceed 24 hours. So if the records are over at the warehouse, you are going to need to make sure you can produce them within that timeframe to be compliant.

MS. : We had had some previous discussion that said since it didn't actually leave our custody, it was an intercompany transfer. So that maybe warehouse A wasn't necessarily required to --

MS. FRASER: But they are not--that would be an intracompany transfer if it were your

warehouse.

MS. : Okay.

MS. FRASER: But if it's not your warehouse, it has left your personhood. It has gone to some other person status, and the vertically integrated means that each step of that movement of the food is within the same--it's sort of like the farm definition, it's in the same ownership, the same control. Subsidiaries tend not to be, even if the subsidiary--those are different personhoods. You have legally constructed them as different personhoods. That's a different custody and control.

So vertically integrated needs to be everybody is exactly the same in that movement of the food.

MS. : Okay. So our legal responsibility would be able to say it was manufactured here, transported here, and then warehouse A --

MS. FRASER: Is your immediate subsequent recipient.

MS. : Okay. Great. Thank you.

MS. : My name is Christy Scott, and I work for ESAY America, a Blair Company, and we ship multiple lots to customers. Do we need to keep records that give us quantity of those multiple lots, like 20 cases of lot No. 058, or whatever it is?

MS. FRASER: You a manufacturer, processor, or packer?

MS. : Uh-huh.

MS. FRASER: Yes.

MS. : Stacy Kinsley. We are primarily a distributor, so I assume we would fall into the transporter category.

MS. FRASER: If you are a distributor, you are a nontransporter.

MS. : Okay. Nontransporter. Okay. Even if we have our own trucks that transport to a warehouse?

MS. FRASER: Right. A transporter is really--the sole purpose for them having the food is to transport it.



MS. : Okay.

MS. FRASER: You are in the--if you look at that definition of who is subject--persons who manufacture, process, pack, transport, distribute--transport and distribute are two different areas of coverage. So you really are in the distributor category. You happen to be transporting as part of your distribution, but you are a nontransporter as a distributor.

MS. : Okay. So I guess--I'm not sure if that's going to shake out in the Q&A side, but we would have to have records of that distribution as well as the records to the warehouse? I mean I guess that's where it--you know, you said you can't do both, but it seems like we would be doing both.

MS. FRASER: No, I'm saying you don't have to follow the requirements for a nontransporter and the requirements for transporter. You are either following the requirements for nontransporter, which is also going to pick up your transportation piece, or you are following the requirements for

transporter, but you don't have to comply--you don't have to do both sides of the requirement.

MS. : And we are also considering a little more integration. We have outsourcing for people who do kitting, so it may have pieces of cheese cut, already packaged with pieces of meat cut, already packaged, and people are assembling them into a tray for further sale. If we were to actually do that on site, would we be--any extra precautions in terms of, you know, lot numbers, et cetera, or even if we didn't do the (inaudible)?

MS. FRASER: You are basically repacking the product, so you would be--which is a part of packing. It's in the packing definition. So from the standpoint of your putting the product--you would have the lot number requirement as a manufacturer, processor, and packer, to the extent there is a lot number.

With respect to the packaging material, if the cheese is already prepackaged and the meat is already prepackaged, that is the--whoever did that

has the obligation of tracking that material as part of the finished container that's contacting the food. So they would have to keep records of who was the immediate previous source of the packaging material, and you are their immediate subsequent recipient if the cheese is packaged in the little prepackaged things.

You are dealing with packaging materials now. You are not dealing with the finished container that contacts the food because it's already in a liner, basically. It's like the cereal box.

MS. : Right.

MS. FRASER: So you don't have any obligation to keep track of your packaging material. You would just have the records access provisions for any records you might have on that, but not an independent duty to record that, because it's not touching the food.

MS. : Okay. And then the women before me who were discussing the warehouse being the legally responsible party for the next step of

the packing, okay, I understand legally responsible, but in terms of our reputation, in terms of are you recommending that the manufacturer keep--has access to that record, inspects the warehouses, even though they theoretically--I mean they are by the law? However, we could suffer many consequences if they are not doing it correctly.

MS. FRASER: We don't give the recommendations on how you want to discharge your legal obligations in your business. So as a matter of business practice, you may want to contract, establish processes, procedures, legal obligations between you and the warehouse.

MS. : Okay.

MS. FRASER: But that does not change from our perspective what your legal obligation is and what their legal obligation is. So if, as a matter of contract, unlike the transporter who gets to get out altogether, between you as independent parties, either you keep the records for the warehouse, the warehouse keeps the records for you, you both keep the records, that's between you all. It's not

legally from our perspective--you are a nontransporter subject to the regulation, and they are a nontransporter subject to the regulation, and you both have independent legal responsibilities to comply.

MS. : And lastly you said that handling samples will be teed up for the Q&A. Is there anything that you can share on that now, or just wait till the --

MS. FRASER: There is some discussion in the rule, in the preamble, and that's a nice one to search on samples, because it doesn't pop up too many times. What we say with respect to samples now is that if you are handling samples and it's just for lab tests, no records are required. So they are not part of the recordkeeping regulation. So if you are doing it in the lab, stability, and color and all of that, samples aren't required.

If you are handling the samples for consumption, then recordkeeping is required, and we have had outbreaks in restaurants, for example, where people are test marketing products and it

wasn't made well, people have gotten sick. So there is a reason for not just saying a sample is a sample.

If you are looking at a trade show, then you do have right now the obligation of recording the immediate previous source of that product, because it is coming in like a retailer. But you probably fall to the extent that the people at your trade show are consumers, then you fall under the exemption that distribution directly to consumers does not need to be recorded, and so you don't have to keep track of, you know, all of the 80 of you in the room or the consumers coming through.

The piece we still haven't--that we have had two questions, at least two questions--we have had a lot of them come up on samples--where do buyers fall. So if I'm a buyer for another company where we have said businesses are not consumers, should I treat the buyer as a consumer or should I treat the buyer as a business, and if the buyer is taking 80 samples of your cheese packages back to their facility and they are using their employees

as the test market, are the employees businesses or are the employees consumers? That's one question we're wrestling with.

Another question that came in was, well, what if we--you said consumption--we have to keep records for consumption except for consumers. What if I have lab animals. I have the lab rats and I am feeding them the product, do they count as consumption, do they count as consumers? Who are those lab animals? And we just didn't think about lab animals in that context.

And, you know, I know the animal rights activists will have one answer and so those are kind of the nuances with respect to samples. But there is some discussion on samples right now that draws the line between consumption and not consumption.

MS. : Okay, just like for my company, we would ship most likely to a sales representative or--which would be external, like a broker, for presentation for new items. So if I were, in my mind, thinking about it, I would have

the lot information and then the carrier, like the UPS, however you ship it. And that's all I need.

MS. FRASER: Right.

MS. : Okay.

MS. FRASER: They would just be an immediate subsequent recipient, just like a retail store. It just would be in that case, it would be the buyer or the company that you shipped it to.

MS. : Thank you.

MR. : Hi. My name is Atkinson. I'm with a company here in Atlanta called Grain Service Corporation. We are consultants to merchants and warehousemen (off microphone).

Let me give you a hypothetical question. I am a grain merchant, operate a facility that receives bulk food, let's say wheat, and ships out bulk food, wheat. Within that facility I commingle and blend. Let's suppose you have a problem that you can trace back to one of my shipments and you come to me. With the records I have now, about all I can tell you is it's been five years since the last time I cleaned out my facility. During that



five years I have received wheat from literally hundreds of personhoods and thousands of shipments.

As far as I know, wheat in the shipment that caused the problem may have included wheat from any or all of those shipments I have received. Do we have a problem?

MS. FRASER: Yeah.

MR. : And what do I do about it?

MS. FRASER: But whether we have a legal problem versus whether we have a public health problem, for sure--let me see. There's probably a couple of ways of answering that question.

Your obligation, which is probably what you are really interested in, under the --

MR. : Selfishly, yes.

MS. FRASER: That's okay.

Under the rule, your obligation to record lot numbers is as of your compliance date, whatever date that may happen to be. This December, next June, next December. And so we are only capturing food received or released after that date.

To the extent that--and, you know, the

grain industry probably creates--has some of the more complicated or massive listing of either lot numbers, if they have lot numbers, or if they don't have lot numbers, just suppliers, and their commingling example--you know, my very simplistic cookie company has dramatically increased in this common silo where you are commingling not three flour sources, but you are commingling hundreds of flour sources, and linking incoming ingredients to outgoing product. Your listing of lot numbers and suppliers might not be just companies A, B, and C, it might be 1 through 10,000, 1 through 500, whatever.

I think that is the realistic expectation. We are not--you know, we say we aren't requiring you to reconfigure your facility, and we are not. I think from the standpoint of to the extent you can think about what might make for a more effective traceback realistically, not just for our purposes, but so that we are not implicating each and every shipment and every shipment that you may have had and commingled, both of us are better

served.

To the extent that there is a problem, I think realistically while you may have commingled five years' worth of grain--I'll leave Gary to talk about whether you should have cleaned that in the last five years or not; I don't know, but I think realistically if there is a problem with an outbreak with a grain supplier, my sense would be and my instinct would be it's probably more likely it's with one of your more recent shipments, and we are tracking it by date received than it is something that you had four years ago.

MR. : But you could never be sure.

MS. FRASER: Right. Because those people should have been sick a while ago. So unless it just happened to be something--so I think we still would--my sense would be again as an initial matter of investigating, even if you gave us a listing with 200 sources, we probably would focus in the first instance on the first 20, 30, 50, whatever you received in the last month, two, three.

But, you know, we do recognize the grain industry is commingling a lot of products, and to the extent you can think about what's realistic, not only so you don't have to keep track of this massive batch commingling, commingling, commingling, commingling, so that your lot number listing keeps growing exponentially, you are better served and we are better served.

MR. : Good morning. My name is Alan Wollensky, and I am a distributor with National Distributing Company here in Atlanta. We import wine and spirits, and I have a couple questions on this, when I direct import from overseas suppliers that may have numerous vineyards--I know that all these vineyards have to register with the Food & Drug--is it the recordkeeping from the importer that I am responsible for when we import wine and spirits into our warehouse? Is it from--we may have an importer that collects all these wines or spirits from various suppliers.

MS. FRASER: Well, first of all, wineries-

-the vineyard typically is exempt because it's a farm. The winery would be required to register as a manufacturing facility. So, you know, whether it's the vineyard or the winery, really what we have in our database is just the winery itself.

MR. : Right.

MS. FRASER: And most of them are on the same vineyard, so we would only have the winery piece.

You are responsible only for your records. Your records as the distributor is who is your immediate previous source.

MR. : Which would be the importer?

MS. FRASER: And then that would be who your immediate previous--assuming it's not just a customs broker who is doing the paper shifting, but if it's an actual importer, all you have in your records is it's the importer.

The importer's records now must identify the immediate previous sources of all the wine and spirits that that person brought in from however

many vineyards abroad or wineries abroad that he or she received it from.

MR. : And normally in a packet, there's--that we receive, there are invoices from the various different wineries that the product was picked up, which would be part of our record. Would that be sufficient?

MS. FRASER: We don't answer what is sufficient. We just tell you what your records must contain. So you have to match up what we have in the regulation as your nontransporter requirements, and make sure that your invoices and everything else you are getting have all of the information we have listed, and to the extent it does, then, yes, they are sufficient. To the extent they don't, then you need to supplement to make sure you have captured everything that you do have to the extent you want to use invoices as part of your records.

MR. : Another question as far as transport companies. When I import wine and spirits and I go through a freight forwarder, they will

contract with a steamship line. The steamship line will bring it into the port and then I will have a drayage company bring it up to our facility. Is it just the drayage company that--that's the last trucker or transport company that handles the product before it gets to our warehouse.

MS. FRASER: Well, only the transportation within the U.S. is captured by this regulation. So most of the--you know, if it's coming from abroad by steamship line, that's not going to be captured in your records. It may be captured in the importer's records that the transporter that brought the food to them was the steamship line.

MR. : Even though I'm paying the freight for that?

MS. FRASER: Again, we are only looking at--we are looking at who is the transporter that brought the food to you, and so the person that brought the food to you--it's not the steamship line, it's the trucking company that went from the importer to you.

The importer has an obligation to say the

transporter into that person was the steamship line, the transporter that took the food from him was the trucking company that went between the two of you.

How you are paying for it is a little separate from--we are tracking the pathway of the food. We are not exactly tracking who is paying for what.

MR. : I don't have to track the trucker that picks it up say in France and takes it to the port?

MS. FRASER: It's literally one step up, one step back. So who brought it to you directly.

MR. : And just one final question. On the prior notice, I know that notice has to be given to FDA before the container arrives into port. What are going to be the penalties --

MS. FRASER: If food doesn't move?

MR. : Well, let's just say a container comes into port January 1, 2006, and there is no documentation on the container. It's not my fault, it's maybe the steamship line didn't



present the bill of lading, the supplier didn't supply all of the documentation.

MS. FRASER: Actually prior notice is in effect now, took effect December 12, so it isn't even 2006. The container can show up today without prior notice. It does not move to you until we get it.

MR. : Right. I understand. Do you know what the penalty --

MS. FRASER: That's the biggest penalty. I mean Customs can also impose fines.

MR. : Right.

MS. FRASER: Which they have done in some egregious cases.

MR. : Right.

MS. FRASER: But people care less about the fines than about where their food is and why it's still sitting on the dock.

MR. : Right.

MS. FRASER: So the biggest penalty really is you don't get release of your product until we get prior notice.

MR. : Because I'm on the receiving end, I'm really at the mercy of the steamship lines getting the bill of lading to a customs broker. I'm also on the receiving end --

MS. FRASER: But that's a private business matter. That's not our legal obligation. Our legal obligation is we get prior notice, else you don't get your food product.

MR. : I understand. Thank you very much. I appreciate it.

MS. FRASER: I have one here, and then I'll come back. Stay there. But I have one here.

This is an agribusiness technology company. Are there any plans to perform certifications or mock inquiries to ensure that persons are complying in or capturing the needed information for FDA traceback before a public health emergency occurs?

This is one of my top questions that I would like to do. It is a legal question as to whether we can do it, and so I have teed it up with my general counsel's office as to can we do that,

because I don't want to find out and Gary doesn't want to find out we are in a public health emergency and we want a traceback and then we find out that 20 percent--none of you here, of course--but 20 percent of the folks out there who we need their records just said, ah, they'll never find me so I don't have to do it, and I'll play the odds of not complying and wait and expect that the odds of a public health emergency involving my product are slim to none.

I think, sitting where I sit, that there should be some aspect of demonstrating compliance before you actually get into that situation.

That being said, that is a legal question, so we are exploring that, and to the extent that we do end up that we are going to do mock audits or things of that nature, you would see it in a guidance document before we actually implemented it. So it would be advance notice.

As of where we sit right now, we don't have plans of a mock audit. You may see investigators as they come through just asking, are

you prepared, are you in compliance, are you ready to be in compliance, do you have the mechanisms in place for being able to--if I picked up this product here and this was involved in a traceback investigation, could you get me the records associated with it within 24 hours.

You may see those questions, but that is more a part of their consultation, helping you comply with the requirements as they are coming through.

And again, that is different than demanding access to records under the authority of the act, which we can't do until we have--at least right now--until we have a public health emergency and met the standard.

Yes.

MS. : My question is actually quite linked to the gentleman here.

MS. FRASER: And you are?

MS. : My name is Kristen Herman. I'm working with an international trading consulting company. In other words, we deal with

compliance-related issues for customers, manufacturers, predominantly.

I understand that Customs, U.S. Customs is in the process of actually--well, it is available now for importers and customs brokers to utilize software to do electronic filing, and I understand also by the year 2010, 26 U.S. government agencies will have or have already direct access to the software. I understand that private entities as well as the customs brokers are encouraged to utilize this software to file their documents because obviously prior filing is required, as was stated, 48 hours before the shipment arrives to be approved by U.S. Customs, the agency I understand who enforces your regulations, FDA regulations, as well.

So from your perspective, how much cooperation will there be with the U.S. Customs authorities to develop the software? And of course we have five to six years until this software is fully implemented. But from my perspective, having had exposure to workshops to learn how the software

works, I mean this one up, one down is very traceable or would be traceable if everybody buys into the system.

And from your perspective, what is the input? And also from the FDA's perspective, I mean technically speaking, Customs enforces, but nowadays because we have only hard copies, it requires a very educated Customs official to understand what documents are sometimes required for certain shipments.

So therefore--and also they only do spot-checking. But, of course, if you have everything electronically available and are encouraged to do it, then the supplemental documents are included.

MS. FRASER: I'll answer that, and then I'm going to ask that we limit this in the first instance to recordkeeping questions, and then we will come back to the others.

MS. : Right.

MS. FRASER: So that we don't dovetail in the things that may not apply to everything.

You are really talking about probably

three different things going on.

MS. : Oh, yes, multiple. It's very complex.

MS. FRASER: Customs is developing a new system, their A system, the automated commercial environment. It is intended to be the one-stop-shopping for all advance notice requirements for all agencies, and so whatever notifications are required by USDA, FDA, and anybody else, TTB, would come in through this one electronic filing.

All of the agencies are participating with Customs in developing the requirements, the technical requirements for that system. FDA is heavily engaged in that, and Gary reports in through the Office of Regulatory Affairs, so that's the side of the house that deals with imports. They are the ones heavily engaged in that. That is a ways down the road.

Customs does--the prior notice and the registration rules were coissued with Customs and FDA, so they are joint rules. They actually were issued by HHS, which is where we report, Health and

Human Services, and the Department of Homeland Security, which is where Customs reports, or is a subset of.

So they enforce prior notice. They are not parties to the recordkeeping rule. That is just ours. They are not subject to--the requirements do not come in through Customs. They will not come in through ACE.

There are other technologies that are under development, our FID and others, that if anyone were using that and we ended up with let's say the distributor, the distributor might have everything up the chain for us so that we wouldn't have to do this walk up the staircase one step at a time. That would be wonderful for us. It is not a requirement of the regulation, but it is something that technology may get us, all of the information at one stop.

The more that we see that, I think, again, the better off all of us are, but that is how you comply versus what is--whether it's through technology that can get you more than the one step



and what you are required to do to comply are two different things. And right now all you are required to do, because that's how the statute was written, was you are only required to just do immediate one step back and immediate one step down.

MS. : Thank you very much.

MR. : Jeff Stevens from McKee Foods. We are a manufacturer. My question is about food contact packaging, and I understand that it applies only to the packaging that the consumer receives. In some cases we make an ingredient ourselves by combining several things and then store it in a bag or a box for a few days or up to a week, and then it becomes added to something else, it becomes our final product.

So do these intermediate packagings have to be recorded?

MS. FRASER: No. We only require you to record the package that the consumer is going to receive the product in. If you are the person putting that product into that package, then you

have to identify for us the immediate previous source of that packaging material. If you are a manufacturer, processor, packer, the lot number of that packaging material, the date you received it, everything else. All those other intermediary containers are not subject to that because that's not what the consumer is going to receive it in.

You would be subject to records access requests for any of that other material. And if you are a manufacturer of that material, you are not subject of any of these requirements except for the records access provision.

So for people with packaging material through contact substances, just recognize that while you don't have to establish and maintain records, that are tracing that information, you are subject to the records access provisions, and you do need to be able to turn over within 24 hours the information related to that product, assuming we met the standard for the serious health--adverse health consequences.

MR. : Thank you.

MR. : Good morning, Leslye. My name is John Smith. I represent a large retail vertically integrated company. We do manufacturing. We have our own distribution, transportation, and retail. And I have a long list of questions. Some of it is just confirming things you have already said, but regarding lot numbers from our manufacturer, we realize we have to keep that for those items that we manufacture. But when it goes to our warehouse, does our warehouse management system need to also capture that lot number?

MS. FRASER: That's the piece we are still figuring out. That's the dietary supplement gentleman's question, too, is how far, if at all, do you have to discharge your obligation down in your distribution chain.

MR. : Because if we were to receive from a manufacturer that's not within our company, we wouldn't have to capture that lot number; is that correct?

MS. FRASER: If you were to receive--as a distributor?

MR. : No, no. We are receiving our warehouse product from a supplier that we purchase it from.

MS. FRASER: Right. If you received it in your warehouse, you would not for that activity.

MR. : So aren't these two the same activity basically?

MS. FRASER: It is, but it's --

MR. : Okay, the answer is to come; right?

MS. FRASER: Right. It's to come because if--you know, do we stop it at packing stage and not the--you know, it's where do we stop it, if at all, or do we say you're not subject to it because ultimately your person you are distributing to is a consumer and there's no lot number requirement. That's sort of the trade-off.

MR. : Right. And did you say earlier that subsidiaries are considered, to use the vernacular, separate bubbles?

MS. FRASER: Most likely. I won't say generally across the board, but most likely a

subsidiary is a separate legal person under the law, in which case it is a separate bubble.

MR. : Okay. Next question has to do with what we are calling edible waste, either from the manufacturing process or from--in our retail stores, we call them pig barrels. They go to farmers, they go to--in other words, farms and ranchers and so forth, and they consist of a lot of things. Is there any recordkeeping requirement regarding the transfer of that edible waste to those farms?

MS. FRASER: Yes, because it's food, for us, even if it were inedible waste, it is still food. There's case law that says garbage is food. You know, things that have spoiled are food. The question that we are--we need to answer is, again, looking at you, since you are a manufacturer, do we require lot numbers of all of that stuff that went into that barrel, or can we just say this is a barrel of edible waste that might have bread, milk, eggs, breakage, a bunch of stuff, and so it's just food. Or how much specificity do we need?

But it is part of your transfer of food released.

MR. : Well, in this case, though, we have two situations. One from manufacturing where lot codes is part of their business, and then at retail, which it isn't. It could be, you know, the unused part of --

MS. FRASER: Right. But then it would be transferred to a nonconsumer, and then that would be a transaction they would have to record to the extent it is reasonably available, and it seems to me that transfer to a pig farm is a business that's reasonably available to capture.

MR. : Even though the farm is an exempt entity?

MS. FRASER: The farm's exemption is their exemption, not yours.

MR. : Okay. Because our likely reaction is that we will stop the practice because there is no way to capture that kind of record. Tomatoes and carrots and whatever, and where do we get those from, and trace those back.

MS. FRASER: Well, part of the question, though--you know, that may tie to our answer of can you just say five gallons of general food, food product went to this distributor or this farm, versus, you know, I think--if we said, well, yes, you need the lot number, that probably drives you one way. If we said you can just capture the five gallons or the trailer that went over, that might drive you to another answer.

But we need to think about what does the law require in terms of tracing immediate previous source and immediate subsequent recipient. You are still sending it somewhere.

MR. : And I would also ask you to think about it in terms of the manufacturing entity doing that as opposed to multiple retail entities in one company. You know, we have hundreds of daily records or weekly records, whatever.

My next question has to do with we use brokers, transportation brokers on occasion. We have our own transport as well. If I recall, you

said that we would need to know who the broker is, and we do, but if they show up with a subcontractor transportation company, that's not our obligation to know who that is. We need to know who the broker is --

TAPE CHANGE

MR. : --so if our product is on their trailer, but it has our seal, this has to do with a sealed container and control, is it still considered outside the bubble?

MS. FRASER: It is outside the bubble in the sense that you have transferred it, but it's-- and this is another one of those--the vertically integrated presents its own set of challenges because it probably--and maybe we should have thought of that a little more. You know, in hindsight, it's like, duh, why didn't you think of that.

But, you know, our model was more looking at person to person to person, and the vertically integrated, that does multiple things, sometimes with their own trucks, which is part of what we did



consider. That came in on comments. Not with their own trucks was something we didn't really distinguish between.

Whether that should still be counted as vertically integrated because it's the nontransporters are the same, even though you are transporting it with a contract carrier, or should that be counted as transferring out of the bubble when the transfer out of the bubble is a transporter, not a nontransporter is part of the thing we just need to think about, what are the implications for one answer or the other, and we kind of tend to approach these questions two ways, three ways:

What does the statute say, what is consistent with our regulation, and what are the implications of one answer or the other on an effective traceback system. And do we create holes with one answer that we wouldn't get with a different answer.

MR. : So that will be part of the Q&A?

MS. FRASER: Yeah.

MR. : Okay. In transfers to charities or other exempted entities, you know, we have sales, for instance, in our retail stores that we give to food banks or whatever. Do our retail stores have to keep records of that that they give to --

MS. FRASER: If they are transferring it to a charitable entity as opposed to another exempt entity like a restaurant, if they are sending it to a charitable entity, they do not have to keep records of that because we count the charitable entity as a consumer for purposes of that transaction.

MR. : Okay, they stand in the place of the consumer literally?

MS. FRASER: Right. But if they transfer it to a farm, which is exempt, or a restaurant, which is exempt, they do have to capture that because we don't count them as standing in the place of a consumer.

MR. : Okay. And the next

question, if we purchase a product, so technically we owned it, but we ask that it get shipped to a third party warehouse, and then it comes from that warehouse into our company, the recordkeeping requirement starts when we receive it, not when we purchase it; is that correct? We don't need to know that path that it took to get to us except the immediate previous source.

MS. FRASER: Well, this ties on the definition of a nontransporter immediate previous recipient, immediate previous source is one who owns or has possession, custody and control of the food. We really are looking at what is coming into your bubble and where did you get it from.

MR. : Right.

MS. FRASER: You could be caught under either one. It came into your bubble when you owned it. You fit on the first half of the nontransporter definition.

It also came into your bubble when you took possession, custody or control of it, so it's--I can't--it's not just when it physically enters

your bubble, because the definition isn't either/or, it's when you take ownership and it's-- when you took ownership, it's entering your bubble as well.

MR. : But in that case you have then two transporters potentially involved because it went from the supplier to the warehouse on some transportation, and then from the warehouse to us on another transportation. So are we required to keep --

MS. FRASER: But if you look at--if either of those legs were where a terrorist attacks at a truck stop, let's say, are we going to have that record that says--now we may get it from who you purchased it from, we may get it from the distributor. It's an interesting question, but from a legal perspective I can't say that the way the regulation is written--now as a practical matter, that would be a nice one to send me because as a practical matter, you know, in that instance do we want to trace custody versus--you know, do we want to trace custody, possession, versus

ownership, or do we want to capture both.

Right now the way the regulation is written, we could capture both, or legally both are covered.

MR. : You could expand to multiple where you have multiple legs that are created before it gets to us.

MS. FRASER: Right.

MR. : And then that just expands the recordkeeping requirement.

MS. FRASER: No, I understand. It's just that that's--there's a legal answer and then there's a what should we interpret it to mean, which is what the guidance ends up doing.

MR. : I think this is my last question. Regarding food contact substances, in our bakeries in our stores, in-store bakeries, we create a wedding cake. We put nice little things on top of it. A lot of those are a little bit on the expensive side, so they are not sold with the cake, they are, quote, rented. So those things are--they contact food, they go out the door with

the consumer, but they come back from that same consumer and get sanitized and reused. Is that consumer considered the immediate previous source of that food contact substance? Are we going to have now record every one of those consumers returning those items?

MS. FRASER: The consumer is the immediate previous source of that, and that is a question that came up--it comes up in other places, too. Bottled water. You know, you reuse the bottled water over and over again, and you know, you put your jugs out on your porch, they come by and pick it up, and bring you a new one. Those are your immediate previous sources.

Now for a retail store, you know, those are all the specifics that--the devil is in the details. You know, we thought about the bottled water and said yes, clearly we do expect that to be captured. The same principle would say it should apply to your little wedding toppers, and you probably have a record of that, anyway, because you want to make sure you get it back or you are going

to charge them \$50, \$100, or whatever the topper cost that you held as security. So it is similar to me to the bottled water, the empty bottled water gallon, five-gallon thing that you leave out on your porch.

MR. : This is still within the food contact substance. Did you say earlier that the food contact substance that the consumer receives is the one that we are responsible for tracking? So, for instance, in our manufacturing function, there may be, you know, people wear gloves to mix things by hand, let's say. So those gloves are not--even though they contact food in the manufacturing process, that's not a food contact substance we have to track?

MS. FRASER: No, you don't. The only one you have to track, if you look at all--you know, everything is excluded, food contact substance is excluded except for the records access, unless it's the finished container that contacts the food.

MR. : Okay.

MS. FRASER: So all of that other stuff,

equipment, mixing utensils, are excluded except for the container the consumer receives.

MR. : Okay. Thank you.

MS. : I first want to thank this gentleman for asking a lot of the questions that I had.

I have one specific question. You talked about the --

MS. FRASER: I need to know and where. I'm sorry.

MS. : Oh, I'm sorry. I'm sorry. I'm Valerie Waylan, I work for Flowers Foods. We are a large wholesale baker.

If we have a distributing facility, we have independent distributors, and they are considered nontransporters, can a nontransporter contract with the manufacturer to maintain their records for them?

MS. FRASER: That--you can do anything you want as a private business matter. It does not absolve you of your legal obligation to comply with this record. So how you choose to comply, whether



you choose to do it yourself through your employees, whether you choose to do it through a contractor, whether you choose to do it through one of your suppliers or buyers is up to you, but at the end of the day you still have legal responsibility for being in compliance. And if they drop the ball, your remedy is under whatever your contract says with them as a private matter, but that doesn't deal with a remedy with respect to us.

MS. : So would FDA be going to that distributor?

MS. FRASER: We would go to you.

MS. : Or would you come to us?

MS. FRASER: We would come to you --

MS. : Even though they are independent distributors?

MS. FRASER: Well, but that--we would come--you know, there's two separate questions here. They have a separate obligation because they are a different person. So your obligation is to keep track as your own nontransporter as a bakery

to keep your nontransporter immediate previous source and immediate subsequent recipient records, that's your obligation.

Their obligation as a distributor is to do the same thing. Now if they are choosing to do your records in addition to their own, that's the private matter between the two of you. When we are doing our traceback and we get to the distributor, because we are probably working backwards from the consumer, we get to the distributor and find out, well, here's where we received the cakes from, and then we come to you and you say, well, the distributor has my records, if they have your records and you can produce them within the as soon as possible not to exceed 24 hours, you have discharged your obligation.

If they don't have your records, we are not taking action against the distributor because they have given us their distributor records, we are taking action against you because you haven't fulfilled your obligation to meet those, and whatever the penalty or whatever happens to you is

basically your public name at stake.

However you handle that with the distributor is your private--you know, breach of contract, whatever else you choose to do, has nothing to do with us taking action against you because you had a legal obligation to keep these records.

MS. : So that works vice versa for the distributor also?

MS. FRASER: Absolutely.

MS. : If you go to the distributor and he says the manufacturer has the records.

MS. FRASER: Right. Absolutely.

MS. : As long as they can be produced, everything is fine.

MS. FRASER: Right. But that's--how you choose to do it is different from whether you are obligated to do it.

MS. : But legally we can enter into a contract with them to handle that?

MS. FRASER: Legally we don't preclude you

from doing anything. And I say it that way because it's how you operate in the business world has nothing to do with us in terms of this regulation. The only persons that can get out from under from us are the transporters who meet the agreement requirements that we specified in the regulation. They are the only people that in your example, if I went to the transporter and said where are the records, and they said, well, she has them, Valerie has them, and here's my contract, and you didn't have them, I would not take action against the transporter. Then it would come against you because you have signed an agreement saying I have assumed their legal responsibility for this action. That's the only time they can get out from under.

MS. : Okay. Okay, and then I wanted some further clarification also on the warehouse and the immediate subsequent recipient. So if we manufacture product and we send it to a warehouse that is just contracted by us, and that food is held there but subsequently our person that we sell the food to is a retailer or a restaurant,

is our immediate subsequent recipient the restaurant or the retailer, or is it the warehouse?

MS. FRASER: Your immediate subsequent recipient is really the warehouse, because they are a different person. They are owned, operated by someone else.

Now I think, you know, this is again one of those, you know, should we consider the immediate subsequent recipient the retailer because, you know, we are looking at does the building belong to you or not belong to you, but you are operating it as if it were your own. That's one way of looking at it.

You know, I think another way of looking at it is, you know, does that warehouse owner--is it solely yours? I mean it's difficult for us to sit here and say, well, in this scenario it's the immediate subsequent recipient is the retailer, but in that scenario where the warehouse owner is you're colocating spaces, you're cosharing it. I mean it's probably another great question for the Q&A guidance document.

We were looking at it more in terms of personhood. So is it coming into your bubble and leaving your bubble, and if we look at it in that respect and we go to the definition of person, which is individual corporation, partnership, or association, it has left your person and gone to another corporation.

MS. : However, we still have ownership of that.

MS. FRASER: Yeah. So, you know, that's where the obligation is for the ownership piece, possession, custody and control. So you are not totally out from under because there is still--and they have custody and control, so how do those two relate is part of our challenge, I guess. And we will probably need to think about that one some more.

MS. : Okay. Thank you. And my last question is a hypothetical situation. If I have say a bag of flour that I'm getting from a grain producer and I'm actually buying it from a flour milling company, but they have subsidiary

companies that it's actually coming from. But all my paperwork and documentation says I got it from company A, but it actually came from one of their smaller companies, who is my immediate previous source?

MS. FRASER: Yours is company A, and if we went back to company A in a traceback and we said, okay, what are your immediate previous sources, then they would be the ones identifying all the subsidiaries for me.

But, you know, we are really looking at what is at the end of--what do you see at the end of your contract? You don't have an obligation to go investigate what they have contracted to do. What is at the end of your buy-sell relationship.

MS. : Right. And that also works for us because we do the similar thing where we are selling to a company, but we've got different subsidiaries who are actually --

MS. FRASER: Right. And that's in yours, so when we're looking at what left your personhood, you know, you're tracking coming into that, how you

received product. It might have come from one of five of your subsidiaries are contracted out. Where did you release that product. It went out of your--but that's part of your personhood, and you know, we're not--to do the converse would get real complicated. It would start requiring people to get into private contracting relationships that no buyer or seller would ever want to share with--you know, they don't want you to know they're getting it from John Doe down the street because then they'll say, well, I'll just go to John Doe down the street. Why am I coming to you in the first place?

So the rule isn't requiring you to look underneath what that contract says. It's requiring us to look at, you know, who did you get it from and they think--they say I got it from Valerie's company. That's what they see, that's what they write.

When we get to you, we need to know, well, where did that product come in, where did the product leave.



MS. : Thank you.

MR. : Good morning, Dr. Fraser.  
I'm Eddie Allen with Dean Foods Company.

MS. FRASER: Okay, Eddie. Just hold it.  
I think the gentleman behind you will be the last  
question, so we're coming up on noon.

MR. : Well, I'm like this  
gentleman, I have about 24, but I'll try to keep it  
to three.

MS. FRASER: You're not going to let me  
make my flight. Okay.

MR. : I want to apologize to the  
group if a couple of them are too simplistic or  
redundant, but do nontransporters have to consider  
packaging that has contact with food as a food  
item?

MS. FRASER: Yes.

MR. : A half gallon ice cream --

MS. FRASER: Yes.

MR. : Okay. The second one--and  
this, I do not what numbered slide, but it was on -

-

MS. FRASER: If you're putting the food in contact with the finished container only.

MR. : Yes, ma'am. On records for nontransporters have to establish his immediate previous source. You mentioned something when you were going through the slides that shouldn't be responsible for transactions to which we are not a party.

Let's say that we have a particular ingredient that we need for a product that we're going to manufacture next month. We order that ingredient from whomever that we are purchasing it from. They have responsibility for making arrangements for transportation, and they may send it LTL. So it may go to--it's on the other side of the country, it may go to seven different locations, and you know, three or four different transportation companies, and we receive it from an LTL carrier that we did not have any responsibility for setting up.

MS. FRASER: What is LTL?

MR. : Less than load. You know,

the ingredient may be sitting beside a piece of mechanical equipment going to someone else.

Do we have to have the records for that truck, that LTL carrier that backed up to our dock, that we took that ingredient off of?

MS. FRASER: You can choose to do the transporter that brought the food to you, I guess, in one of a couple of ways. I think the easiest way that most people would do it is when you contact the person you are buying the ingredient from, you would say, okay, you know, I'm purchasing it from you, I need to know the transporter you are using to get it here, and they would probably say, here is our transporter. Whether it's gone through that convoluted chain, that's the transportation's obligation to keep those records. But that's the most likely way you would get it.

Alternatively, it may be you choose to comply by having someone record that information on the bill of lading as you receive it from the person that delivers the product to you, and you know, it may say Ace Trucking at the top and that's

your record, and you say here's my--it's in my records, I received this ingredient from Ace Trucking.

Either way, we would get to the same place on a traceback, if they are all complying.

But it's the transporter that brought the product to you. We don't necessarily require you to go through figuring out--but I've heard people saying they are going to comply in one of those two ways.

MR. : Okay. So if it had a bill of lading, and that bill of lading had a number, a telephone number or Web site, would that satisfy the name and contact information of the transporter? Or would we have to have names of responsible parties at that transporter's --

MS. FRASER: That should, but let me-- that's a good question.

MR. : Okay.

[Pause.]

MS. FRASER: It could be. I mean they are all case specific as to how the transportation is

arranged. If the customer is actually doing the driving themselves, or you are doing the driving to the customer, you could be in multiple places. I think the question is more tied to is all I know is I purchased the ingredient, and I don't really know how it's getting transported to me, what do I have to show as the transporter, and I'm saying you have to show something, and I have heard people say I may use who shows up on my dock, and use those records, or I may ask if I'm purchasing let's say from Kraft and say, okay, Kraft, how are you sending me this ingredient and Kraft is saying I'm using my company truck or I'm going to send it UPS or--I mean we just need--we don't want to preclude either of those from being waived that can work, if it's the transporter who brought it from you, it's going to be specific to the business relationship.

MR. : (off microphone)

MS. FRASER: Yes. Well, let me let him finish, but I'm really--I do have to catch a plane, so--

MR. : (off microphone)

MR. : My last question is one that really I need clarification on because a couple in my group, we have kind of understood it to be explained maybe different ways.

But does a nontransporter, fully integrated, or vertically integrated, and I'm assuming those are synonymous --

MS. FRASER: I have heard vertically, but I will assume, sure.

MR. : Okay. Does a fully integrated nontransporter, manufacturer, have to consider each retail location as an immediate subsequent recipient? And an example would be we bottle--we use a code date on milk as the number that we track, but Super King Foods has a thousand retail locations, and we are servicing them all, do we have to have each--are each of those individual retail locations considered the immediate subsequent recipient?

MS. FRASER: Well, I'm assuming in your vertically integrated, you are a Super King manufacturer, too, so --

MR. : No. No.

MS. FRASER: Well, then, you are not vertically integrated. Vertically integrated is you own everything. You own the manufacturing facility, you own the retail store.

MR. : Okay. So fully integrated. We manufacture and we distribute. It doesn't leave our control until we walk in Super King Foods retail store and we put that bottle of milk in there.

MS. FRASER: Well, in that case, if you don't own Super King, your immediate subsequent recipient is all of those retail stores. And the vertically integrated company, they--Super King would own the manufacturing facility, too, in which case when it leaves their personhood, it's to a consumer, and so their immediate subsequent recipient is a consumer and there's no obligation to record sales to consumers or transactions to consumers.

In the case where you are distributing to Super King that you don't own, that is not the

vertically integrated model. It leaves your personhood the minute you send it to the--whether you are delivering it and stocking the shelves or not, it has now transferred to a different person at the retail store level, and that is what you are capturing is each of those retail stores.

MR. : Okay. Are y'all cool with that?

MS. FRASER: Probably not, but that's --

MR. : (off microphone)

MS. FRASER: As the manufacturer, yes. But the duty to--and that's part of this wrinkle. But as written now, the duty to record lot number is on the manufacturer, processor, or packer, and the minute it left - when it left your personhood was at the retail store level, and that obligation, as the regulation is written, is for if you are a manufacturer, processor or packer, is to record the lot number.

What you are really getting at, which is still kind of the same question that comes up in different ways, vertically integrated, fully



integrated, is should we count you as a manufacturer at that point, or should we count you as a distributor. And should your obligation to record lot number stop at some point, whether it's your distribution center or some other place, and that's the question we need to answer. Because we didn't think of that model. We just said if you are a manufacturer, we are assuming it's going to some place else. We didn't count how far down the chain that that should go.

You get to be the last question.

MR. : Well, I guess that's an honor. I'm Steve Rogers. I work for a company called Feed Management Systems. We provide manufacturing software for the livestock feed industry. We assume that we're going to have to record lot numbers on our own ingredients that go into livestock feed if they came to the manufacturer with a lot number.

MS. FRASER: Correct.

MR. : The bags, of course, touch the feed, may or may not have a lot number. Can we

resolve that issue? If they have a lot number, we would be obligated to record that as well.

MS. FRASER: Separate from --

MR. : If the bags that --

MS. FRASER: Right, the bags that you are putting the product in to send out, yes.

MR. : And that needs to go along with the --

MS. FRASER: Because in that sense, since you are putting the food in the finished container, the bag is considered just like the food ingredient coming in.

MR. : Then the additional way that food is sold is in bulk containers, 20-ton trucks. Will we need to record the truck that that feed was transported on and keep that as part of the documentation?

MS. FRASER: The truck itself, like the truck number?

MR. : Truck number or other identifier.

MS. FRASER: That's not part of the

requirement. It's just the transporter that took the food from you. We don't require the truck ID as part of that obligation.

MR. : The truck really isn't considered part of the package?

MS. FRASER: Oh, I see what you're saying. We have not considered the truck number to be the lot number.

MR. : Good. Good. We're glad of that.

MS. FRASER: I made somebody happy. That's a good place to end.

MR. : Thank you very much.

MR. : One thing you just said, we don't have to--a container, a lot number on a container does not become part of the lot number of the finished product? We do not have to--all we have to trace is the lot number that came into the plant of a package. That does not have to trace through.

MS. FRASER: Well, you're talking--you know, those are two--as I understood his question

on truck number, which I didn't count as the container number, those are--those may be two different things.

MR. : Let me give you a scenario. We bring in an empty gallon container that has a lot number. It comes in on a truck, it has a lot number. That's where that lot number stops, when we receive it. We do not have to trace that through the manufacturing process and that lot number becomes part of the finished product.

MS. FRASER: You do have to trace it because you do have to link incoming ingredient to outgoing product. As the manufacturer. I mean as someone--you do--if you go back to--wrong way. You are a nontransporter, the records must include all information reasonably available to you to link incoming ingredient to outgoing product.

MR. : The key word is reasonable. Okay. Thank you.

MS. FRASER: Yes. Well, thank you all.

[Applause.]

MS. FRASER: If I didn't get to your

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questions or if you think I didn't--you know, if there are some that we really do need to answer, in your packet is a place where to send those questions. The more fact specific they are, you know--try not to make them so specific they only apply to you, but the more facts you can give us that would help us answer your questions in a --

[End of recording.]