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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

"WHAT YOU NEED TO KNOW TO ENSURE COMPLIANCE WITH THE NEW FDA ESTABLISHMENT AND MAINTENANCE OF RECORDS FINAL RULE THAT IMPLEMENTS SECTION 306 OF THE BIOTERRORISM ACT"

DOMESTIC OUTREACH GRASSROOTS MEETING

PHILADELPHIA, PENNSYLVANIA

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MILLER REPORTING CO., INC.
735 8th STREET, S.E.
WASHINGTON, D.C. 20003-2802
(202) 546-6666

P R O C E E D I N G S

Questions and Answers

MS. FRASER: So, with that, how does this seminar's information differ? If you currently have a HACCP or AIB program in place--Hazard Analysis Critical Control Points; AIB?

Q. [not at microphone...]

MS. FRASER: Sorry, say it again? American Institute of Bakers.

Again, we haven't gone through and determined if you are in compliance with HACCP whether that will meet these requirements. I think many of the things you may have gone through to establish HACCP in knowing what is coming in, having records of your lot numbers, knowing what your critical points are, what you need to control, you may have all of the elements that we require in this regulation. But we did not go through and do that determination. We leave that to you all to figure out that comparison based on what you are keeping, what you are required to keep under HACCP or any other state, local or business practice. We

just specify the requirements.

Part of the reason we didn't do that is if HACCP changes later or there is another new requirement out there, we would spend more time doing comparative work on what may be required if HACCP changes and then we would have to decide whether we are changing this one. This was what we thought was effective for a trace-back investigation and that is where we left the determination of whether you are in compliance or not to you all to decide.

Bioterrorism would seem easier to take place at the country of origin. What is being done to address this, especially in Third World countries?

There are a number of ways to answer that I guess. We have had intentional acts of contamination in this country and those are documented in the regulation; some of them are documented in the regulation. If you go to our website, fda.govbioterrorism, we have a risk assessment on there where we do talk about the

number of contaminations that have occurred, accidental or intentional, in the United States. We had an outbreak of over 200,000-plus people who got sick because an ice cream truck wasn't properly cleaned and the product inside was contaminated and sickened a number of people. So, there is a need to control what we do ourselves, whether it is intentional or accidental; whether it is a disgruntled employee or people trying to affect a local election, which was a salad bar intentional contamination in California years ago.

That being said, yes, there are other problems with foods that we import and prior notice. One of the other regulations in the Bioterrorism Act was designed to help us identify and target products that we need to inspect at the border before they get introduced into commerce. The information that people have to provide us includes country of origin, country of manufacture of the product, who is bringing it in, when is it going to arrive. And, we use that information to screen it against known problematic facilities,

problematic areas of the world, suppliers who may have a history of bringing in adulterated product. So, we have other tools under the Bioterrorism Act that we are using to look at imports.

As a legal matter, we do not have the authority to just walk into a facility and demand compliance in a foreign country. We can show up at your doors and show you our credentials and, under our authority, we have the right to come in and do an investigation or an inspection at a reasonable time and place. We cannot just walk into a foreign country and do that without working with the foreign government any more than those of you who are supplying food to those foreign countries can have those foreign officials just show up at your door and demand access to your facilities.

So, the ways that we work with dealing with terrorists and problematic food that may be coming in from a foreign country has to be done within the context of how you deal in the international arena and sovereign rights and that is an overlay of how we can implement food. We

have authority over food once it is within our border but just because someone is producing food for us doesn't mean we can just go in and demand access and requirements on them.

The next one--and I think I have about four or five here so you all can figure out who will be the first brave soul to hit the microphone--we have product that is returned to our plant because it is damaged, out of date, etc. This product is removed from the container and stored in a bulk tank. The tank is then pumped into a tanker for delivery to a hog farm to be used for feed. What records are required?

All of the above. You have product that is returned to the plant. That is the product that is food received and so you, as a non-transporter, you would have the requirements that apply on the slides for non-transporter immediate previous source. That is for all the food coming back in, whether it is damaged, out of date, etc.

You are storing it in a bulk tank. We don't need to know what you are doing internally.

The tank is pumped into a tanker for delivery to a hog farm. When it leaves your plant that is now food released so you are back to now immediate subsequent recipient records. So, you have to keep the records of the food that went to the hog farm because it is now animal feed. It is still food. So, that transaction--and that is where I was getting to our definition of food. It does not necessarily just stop at food that is fit for human consumption. Even if you were not sending it to the hog farm but you were sending it to waste, it is still food that you are releasing and that is something that, in terms of if we are doing a trace-back and we are trying to account for 1000 lbs. of food that we think has been adulterated with a toxin, botulism, that we are trying to make sure that we have gotten it all out of commerce. Knowing that you sent 500 lbs. of it to the waste helps complete that investigation and lets us know that we don't have to trace and find what happened to it. So, all that does apply.

The second question is since form 482 is

currently being used, will it be modified so we can tell if the records request has been authorized by the FDA district director? If not, how will we know?

The guidance document that we published was published in draft form with an opportunity for people to comment. We did get a comment on this that we are looking at and we will make a decision whether it needs to be modified or not.

Just FYI, while regulations have a certain specified period of time to comment on them and then sort of your opportunity is gone, guidance documents, at least FDA guidance documents have a never-ending comment period. So, even if we issue it in final form and you find out you don't think it is working right or we haven't covered something, you always can submit a comment on a guidance document and we will consider that comment and decide whether we need to amend the guidance. But we are looking at that specific question.

Do you consider food contact items to include manufacturing vessels, transport hoses,

etc? If so, what are your recommendations for tracking?

Yes, they are considered food contact items under our statute. In terms of what is required for this record-keeping rule, those products are generally only subject to the records access provisions to the extent we thought they were implicated in a trace-back investigation. And, it is only if you are placing the finished food product in contact with the food contact substance, and the way we use it there we are really talking about the cereal going into the cereal liner bag; the strawberries going into the clam shell; whatever it may happen to be. It is only those products that are subject to the immediate previous source requirements if you are the person putting that food into contact with the food contact substance. So, while, yes, they are food, the manufacturing vessels, hoses, etc., they are not subject to these record-keeping requirements.

If we have multiple pieces of equipment

such as mixing vessels with multiple uses, do we need to track uses per product?

Not for purposes of these rules. You may want to do so as part of your good manufacturing practices or something like that, but this Rule doesn't require that level of detail. We really are tracking the movement of the food, the immediate previous source of the food and food ingredients and the immediate subsequent recipients of the food or food products. So, we are not really tracking your internal manipulation of the food as part of this regulation.

When receiving bottle caps and milk jugs from a supplier in plastic bags do I need to track the source of the bag or only the caps and the jugs?

You only need to track the source of the caps and the jugs. That is really what we are looking at because the food contact substance is what is touching milk. So, it is going to be the jug and it is going to be the little plastic liner that is inside the cap. So, if you are the person

actually putting the milk in with the cap on it, then, yes, you have to track the milk and the jug. If you are anybody else in that distribution chain you don't have to track that but we would have access to the records if necessary.

Will FDA permit bracketing of lot numbers for purposes of compliance? Example, production codes of bottles will be required to be maintained, however, refillable bottles have an 18-month to 3-year life cycle.

Send that one in with a suggested answer but that is one we will answer in guidance documents. You know, I think when he says bracketing, can he say this was lot numbers 1 through 1000 as opposed to specifically tied to a product? I think when we wrote the Rule we were envisioning, you know, what is the lot number that is on the can or the bottled water as you receive it, not it could be 1-1000.

I received a related question in Seattle. Someone said, well, you know, we may receive a pallet of products that has one lot number on the

outside but a 1000 or 500 different lots numbers on the inside, and which one do we have to track? Can we track the one code on the outside or can we track the 500 on the inside? So, that is another one where I suggested he send it in. You know, how often does this occur? I mean, to me, there is a difference. If you look at the lot number requirement, it is if it is reasonably available. If you can get the 500, if that is what it is, on the inside easily because it is coded from the one on the outside, that is one thing. If you have to break apart the pallet to get to the 500, then that is not reasonably available. To me, reasonably available some people don't like because it is not clear; it doesn't provide as much clarity as they would like. Other people don't like it because it is not one size fits all. So, it depends on your perspective.

I did that one I think. That is it up here. So, again, if you would step to the microphone? We are recording the questions and the answers to put in our guidance document so that is

why we ask you, so the gentleman over there can get our tape and then it will be transcribed.

Q. Our business deals not only with foods as defined by the agency but drugs and cosmetics as well. Of late, we have had several imports challenged dealing with the drugs and the cosmetics. We have had to provide BSE type of statements, the 1000 guideline statements for cosmetics. Will this record-keeping then apply to the drugs and cosmetics eventually or right now as well?

MS. FRASER: It definitely does not apply now. This only applies to foods. This would not apply to drugs and cosmetics without Congress amending the statute. The authority in here was only for food products under FDA's jurisdiction.

Q. Thank you.

Q. I read in the comments a response regarding direct store delivery that says it is exempt from the lots and coding. I just wanted to make sure that that was part of the final regulation.

MS. FRASER: That is because the direct store delivery--the obligation to record lot number or other identifier only applies if you are a manufacturer, a processor or a packer. So, if you are just the delivery person at the retail store, it does not apply. If you happen to be doing the packing and the direct store delivery, then you are subject because you are the packer.

Q. But will we have to record codes to every store that we deliver to?

MS. FRASER: No, not on the receiving end. No.

Q. Thank you.

Q. I have several questions if you can indulge me here. From a transport standpoint, if I get a delivery order to go to the pier to pick up a container and deliver it to a facility, do I need to know who the supplier from that foreign company is, or is my one down the pier, you know, for record-keeping?

MS. FRASER: Right, we really are looking in the record for who you received the food from.

Now, if you say you received it from the pier, that is fine. If we are doing a trace-back we then end up at the pier and they have now imported the food so they are also subject to the record-keeping. They would have to tell us I received it from foreign supplier X.

Q. So, I would be able to provide the container number; we got it from, say, Port Elizabeth, and that is good enough?

MS. FRASER: And the contact person and all of the other information specified, yes.

Q. On that same container in regards to lot number--I think you answered my question as far as reasonably accessible. A lot of these containers do not have, from a delivery order standpoint, a lot number on them. So, I wouldn't need it. Correct?

MS. FRASER: The lot number is only required if it exists and if it is reasonably available. But I want to hesitate on the container because as a transporter we don't want to just know you are delivering food. We want to know that you

have iceberg lettuce in there. So, it may not have a lot number on it. But if it does, if inside that container there are lot numbers because there are canned vegetables and there are lot numbers 1-1000 on those canned vegetables, then your business practices need to be such that, because those lot numbers do exist on that product, you are not just looking at I received a container full of canned beans because we know canned beans, low acid canned food, have lot numbers.

Q. Yes, but I wouldn't know that. I am taking a container from the pier and I am going to company A.

MS. FRASER: You may not know that today but you have the ability to work with your suppliers to make sure that is a reasonably available piece of information. While you may not have to go in, your business relationship is such that that is something that can go through--well, let me back up. As a transporter you are not a manufacturer, processor or packer anyway. So, you don't have the lot number obligation. So, for you

it doesn't apply but generally for other people--

Q. Who I am bringing it to, once they open that container, they have to keep track of that.

MS. FRASER: Right.

Q. Good. One last question from a warehousing standpoint. I cut a bill of lading to release food from the warehouse. A lot of the customers will give me the details of where it is going but they fail to give you a carrier. A lot of it is just customer pick up, which we then abbreviate as CPU. Am I supposed to now refuse those types of requests and demand that I know exactly the carrier that is coming in because you don't get that information all the time?

MS. FRASER: When you receive the food you would know who--

Q. When I get it I know who brought it to me. It is either me or some outside source. Fine. I am talking about now I am releasing it. So, you own the food and you send a release to me--I am a public warehouse so I represent many different

companies. So, now I get a release for some salt, let's say, out of my warehouse and they may just say, okay, it is going to ship on February 3 and, you know, have 500 bags ready to go, and it is going to ABC company. But they don't tell me the carrier. They may not know. Maybe it is a collect shipment and the customers make the arrangements to send a truck to me and the supplier may not even know who the carrier is.

MS. FRASER: Yes, but your obligation is to have in your records who is the transporter who took the food from you. So, whether you want them to tell you that and make sure you know it from what they are giving you, or you want to make sure that whoever is on your loading dock loading those bags--

Q. We have that information.

MS. FRASER: --puts it in the record, but it is your obligation to have that information.

Q. So, you definitely need that. It can't just stay as customer pickup. We need to know who that carrier is.

MS. FRASER: Right.

Q. I am done. Thank you.

Q. Hi. Pertaining to returned product, specifically plastic containers, if the product is returned and designated scrap and you sell it to a recycler for non-food use does your tracking end there?

MS. FRASER: If you are just moving plastic containers with no food in them, you don't have an obligation to create records to track at all.

Q. We are talking specifically dairy orders. They are shipped to dairies to be filled with milk, beverages. I know there is a tracking obligation. What I am saying is, say, we get returned product for cosmetic reasons or performance reasons--

MS. FRASER: That has food in it or empty containers?

Q. No, they come back empty but they do return for something that has nothing to do with the food contact--cosmetic; they have holes in them

for example.

MS. FRASER: If they are returned empty you don't have a tracking obligation. The only person who has the obligation to track the container receipt is the person that is putting the food in contact with the container on the incoming side. On the outgoing side they are not tracking it separately but they are saying I shipped off, you know, 1000 cartons of milk or 1000 bottles of juice. If they are returning those containers, that is not part of that tracking obligation for the container, no.

Q. Thank you.

Q. I wanted to know, as a manufacturer, whether I have responsibility to verify that my suppliers, my transporters and my receivers are properly complying with the Bioterrorism Act? I also wanted to know whether FDA inspections that we currently get will now include checking our paperwork to make sure that we are complying properly with the Act.

MS. FRASER: You don't have an

obligation--at least FDA has not imposed on you an obligation to ensure that other people are in compliance with the Bioterrorism Act. You are only responsible for your own activities.

That being said, you will see a number of both industry and guidances that go out that just say in terms of protecting the safety and security of your food supply and your business practice, it is good to know the people with whom you are doing business and to know that they are in legal compliance with everything they are supposed to be in compliance with. But that is a business practice as opposed to a legal obligation.

With respect to what the inspectors will do when they show up, you know, our inspectors, when they come into your plants, may ask for you to voluntarily show them various records in terms of seeing whether you are in compliance. They can ask to see are you registered. They can ask are you registered and you can say yes or no. They can run that on their own against the database and check your name and the address of the facility and see

if you are registered.

In terms of the record-keeping, they cannot demand access and have it a mandatory right to access to those records unless we are in a public health emergency. Whether they request voluntary access, like we do, and work with facilities to see if they are in compliance is another matter, but not on a mandatory basis, no.

Q. Thank you.

Q. My question applies to the one step back, one step forward requirement. You had a flow chart that showed hand-offs from the manufacturer to the store and ending there. But there are about 350 facilities around the country, reclamation centers that collect store returns. They collect them for the purpose of creating invoices to bill back the manufacturers for the returns, and those items are then sold into the secondary market or returned to the manufacturer or their representative. Can you explain how the one step back, one step forward applies when it ends at the retail store?

MS. FRASER: A reclamation center generally is a separate entity, or some of them are affiliated with the retail store itself.

Q. Right.

MS. FRASER: But there is not an exemption, there is not a full exemption for retail stores. Retail stores have to keep track of--well, let me back up. Retail stores with ten or fewer employees are exempt so we will take them off the table since they are usually not the reclamation entities. All other retail stores have to keep track of immediate previous sources. So, if you are a reclamation center you are keeping track of your immediate previous source of the food. Retail stores only have a partial exemption, if they have more than ten employees, if they are distributing food to consumers. They still have to keep track of distribution to other businesses to the extent it is reasonably available.

So, the reclamation center that is giving food to another business, sending it back to the manufacturer, whatever they are doing, that is a

business and that traceability is required.

Q. Thank you.

Q. We have a manufacturing facility and we use a lot of farm ingredients which are all purchased from domestic distributors, which have already passed customs and everything. You talked a while back about the HACCP and, you know, we keep track, like, of lot numbers and we check all ingredients when they come in. I know there is no prior notice that I need to do because we are not receiving it in the country, but is there anything else, any other paperwork that we need to take care of for that?

MS. FRASER: You are a distributor?

Q. No, manufacturer.

MS. FRASER: You are a manufacturer?

Q. Yes.

MS. FRASER: Well, if it is a farm ingredient from a foreign farm somebody has filed the prior notice because it wouldn't be here otherwise.

Q. Yes.

MS. FRASER: So, that is fine. But you are subject to the registration rule because you are a manufacturer within the U.S., and you are subject to the record-keeping rule. The exemption for farms is only applicable to farms; it is not an exemption for farm products. It is just an exemption for the facility that happens to be the farm itself. So, you are subject to the full requirements here for a manufacturer as a non-transporter.

Q. Also, you know, if the product is shipped out in plastic containers or plastic bags, those lot numbers for each shipment--we have to know the lot?

MS. FRASER: Right, for the plastic containers that you are putting your finished product in, if it comes in with a lot number then what we would like to see on the finished--whatever you are sending out the door, is the lot number of that finished product which, your case, may be the one that is on the container or it could be another one you are putting on yourself. But that comes

into linking incoming ingredients with outgoing product. If it is a different lot number going on, let's say, the canned string beans but there is an incoming lot number for the can itself, then your linkage would say this batch of string beans that went out the door used these cans with this lot number on it.

Q. Thanks.

Q. This is a follow-up to an earlier question. If you are a vertically integrated company and bottle a beverage and also own a distributorship, if the warehouse does direct store delivery is that route truck then required to record lot numbers delivered to each retail outlet?

MS. FRASER: Probably not, but that is one of those we are going to put in the guidance document. You know, it is sort of like things we have answered just in segments but we haven't answered it as one big collection of questions, which is this one. We basically say that only lot numbers where manufacturers, processors, packers--and I think in our thinking at the time we

were envisioning all those people as being different entities. Then, in another place we answered the vertically integrated question that said if you are a manufacturer who also delivers your own product to the retail store, using your own trucks, we only need to know what receive and release if you happen to be the transporter for yourself but we don't need to know when it moves from your manufacturing facility to your own distribution facility A to distribution facility B to the retailer. We don't need intra-transfers. We didn't match those two up.

My sense is we will likely come out in the guidance with something along the lines of being equitable and saying if you were different entities we would impose the same type of requirements. So, you may want to have lot numbers going into your distribution facility, which is what you would have to do if you were separate. But just like that distributor doesn't have to do to the retailers, I don't think we would require the manufacturer to do to the retailer either.

Q. Thank you.

Q. A follow-up on your example of waste. If you have a manufacturing facility that generates a lot of waste and you collect it in a co-mingled bin and then you ship it off either to an animal feed or landfill, would lot numbers of all the various waste be mandatory?

MS. FRASER: If you keep lot numbers as a manufacturer, yes. If you don't keep lot numbers we are not requiring you to create them. But, if you put all of that in a bin and you have labeled it and your practice is it is lot number whatever, then as a manufacturer your records would require you to keep the lot number when it went to the animal feed manufacturer or to the landfill. That is where the traceability of those lot numbers is. So, it depends on what your practice is and whether that has a lot number already. This Rule requires lot numbers to the extent it is reasonably available but that is assuming a lot number exists, not that you have to create one.

Q. For persons that are excluded, except

for the provisions under 1.361, the record availability, what are the specific records that are required under that section?

MS. FRASER: It is not records that are required. If we are in a trace-back investigation and we are trying to track immediate previous source and immediate subsequent recipients and we have met that reasonable belief in the SAHCODHA standard, then we would have the authority to access any records you may happen to keep on your own that could identify immediate previous sources and immediate subsequent recipients, subject to, you know, those financial data sales being excluded.

So, you don't have to keep any different records. We would just be looking to come to you and, you know, maybe it is your bill of lading records, maybe it is your invoices but we would be looking for those--

Q. We would still have to make those available within 24 hours.

MS. FRASER: Within the as soon as

possible, not to exceed 24 hours, yes.

Q. Thanks.

MS. FRASER: So, that is the key, for those who are just subject to records access, making sure you have provisions in place to do that 24 hours or less provision.

Q. We are a manufacturer and we are registered. All our sources are registered and most of our customers are registered. Do you plan to have the transporters register? If not, how do we ensure that they are complying with that one step forward, one step back and that they are maintaining the records that you need? What authority do you exercise over them?

MS. FRASER: Transporters do not have to register and we do not have the authority to require them to register. This provision, the record-keeping provision, is the only provision in the Bioterrorism Act that applies to transporters. Detention applies to the food so it doesn't matter who has the food, so indirectly it could apply to the transporters. But specifically in terms of a

duty to do something, this is the only requirement for transporters. We don't have the authority to require transporters to register.

While you know your customers and your suppliers are registered, and that is great, there is no obligation on your part to make sure that they are, other than good business practice. There isn't a legal obligation. For us in terms of how do we verify people are in compliance, that is something we are trying to determine now within the agency. We know we clearly have access to records when we are in a public health emergency. What other ways can we have to make sure people are in compliance short of that? To the extent we come out with a different view, it will be in a guidance document or regulation that we would publish for comment beforehand. So, you would hear from us ahead of us showing up.

Q. I have two questions. The first one is since there is no 21 CFR requirement on electronic signature data, is there any authentication requirement or is it essentially

just the report?

MS. FRASER: Well, there isn't an authentication requirement because there isn't really any duty for you to submit the records. These are really your records. I mean, there is no more an authentication requirement than if it were on microfiche or paper copy. So, no. But when you are turning over your records if we are accessing them under this authority, you essentially are representing that these are the records that were created and established to document these transactions. So, that is where you are either providing accurate information to the government or you are providing false information to the government. And, to the extent you are providing false information, there are separate statutes that govern your liability for doing that, which people get caught at tax time all the time on.

Q. Sure. One other question, is this presentation available electronically for education?

MS. FRASER: It will be. In fact, it

actually could go up when I get back. I thought it would be up. I think they are waiting for the Spanish and French versions to be ready so they can post them all at the same time, but this one can go up. If anybody needs it ahead of time, send me an email but it will probably get up in the next week.

Q. Thank you.

Q. Just a point of clarification, we have raw materials coming in that we combine to make food and we ship them out. Our record-keeping requirement is not the manufacturers of the different raw materials that came in but the actual trucks that brought them in. Correct?

MS. FRASER: It is both. As a manufacturer, in your list of data elements you have the non-transporter immediate previous source, which is the manufacturer of those ingredients, as well as the transporter immediate previous source, which are the trucking companies or whatever else brought it to you. So, you are capturing both as a non-transporter.

Q. And going out?

MS. FRASER: The same thing going out.

Q. The actual truck we put it on?

MS. FRASER: Right, exactly.

Q. And the customer receiving it?

MS. FRASER: And the customer you send it to.

Q. Thank you.

Q. I have a couple of different questions. Is consumer complaint data accessible through this regulation to FDA? It is not a record you would specifically exclude?

MS. FRASER: I can't say necessarily yes and I can't say necessarily no. I mean, I think generally what we are looking for in a trace-back investigation are those records needed to identify immediate previous source and immediate subsequent recipients. How likely is it that consumer complaint data will actually be really helpful in an investigation? I would think probably less likely but, to the extent that it ever could be, it may be. But I don't see that really playing a big part in a trace-back.

Q. When maintaining records regarding your immediate previous source, let's say we are buying from a company that has ten different manufacturing locations for that particular ingredient, are we required to know which facility that specific lot of product came from? There was something in the preamble that sort of talked to, well, you don't list the headquarters address but you need to list the actual manufacturing location. So I wondered about that.

MS. FRASER: I think if you actually know it came from plant A in Kansas, that would be helpful, again, in the trace-back but, by the same token, if what you gave us is it came from manufacturer X, then when we got to that company they would have to be able to tell us, well, we shipped from this plant these products.

Q. Because it could come from different locations at different times.

MS. FRASER: Yes. You know, this regulation is to assist with the trace-back, not just with terrorist attacks but any kind of serious

public health risk with food. But sometimes in thinking about what should be the answer, it is helpful to think about it in a terrorist context. If we are dealing with somebody coming over and contaminating something with botulism, anthrax, whatever it is, what would help us move as quickly as possible as the FDA? What would help you identify the product that might be implicated as the manufacturer or the distributor? So, the more specifically you have that information, and if you knew it was plant X as opposed to a company that had a hundred different manufacturing facilities, that is both useful I think for you and definitely useful for us.

Q. Right. One last question related to consumer test products, as we manufacture products that we place with consumers for them to evaluate, you know, I would assume they are considered consumers and we don't need to maintain information about them as the immediate subsequent recipients, but we obviously have to have information about the product as we manufactured it, etc., etc. So, is

that a true statement?

MS. FRASER: Yes, that is another one that we spent I think over 15 minutes on samples and overlap between consumers, in College Park, and it was not pretty. But, yes, there is the exemption for distribution to consumers so you would not have to keep track of those. What we got into in College Park was, well, what if we give it to a business, and now we do have to keep track of that and, yes, that is the way the regulation was set up. Then they said, well, but it might just be one person. Well, we created a partial exemption for consumers. I will note that we have had outbreaks and deaths with samples, samples consumed in restaurants. So, you will see in the Rule that we do have an exemption for record-keeping for samples that will not be consumed by anybody, if they are just for laboratory analysis and so forth. But if they will be consumed by anybody, consumer distribution aside, that is different. But generally we do look for the records in business to business transactions.

Q. If we engage a third party to, say, place that product in ten different geographic locations, do we need to keep records related to the transfer of that product to those third parties?

MS. FRASER: Yes, because that is not a consumer; that is now a business to business transaction.

Q. They wouldn't have to keep records, would they, because they are sort of holders of the food?

MS. FRASER: Well, in that case they are more like a distributor of the food and they would have to keep records, except they don't have to keep records for distribution to consumers.

Q. Right. Thanks you.

Q. Hi. We are a manufacturing site. We fall under HACCP and under AIB but we have a sister company that is also a fund raiser, and we have our own trucks. Would they have to be required to keep track also of the school, or would the school be required to keep track of all of the products that

they sell?

MS. FRASER: Well, if they meet the definition for a non-profit, they do not. If they don't meet the definition for a non-profit, they are subject.

Q. Would the school also have to then?

MS. FRASER: Well, the school is probably more in keeping with distribution to consumers. I mean, if they are selling it in the school--are you getting into like candy bar sales in school? That becomes more--

Q. Meat and cheese.

MS. FRASER: Meat and cheese? That is probably one I need to think about in writing with some basis for what we are talking about and what that entity looks like. But we are running into whether you fit within the retail definition, where we define retail as sale of food to consumers, and we define primary function as 51 percent of your sales going to consumers as opposed to businesses. So, as long as 51 percent or 50.1 percent--more than half--goes to consumers you are a retailer.

So, there is a bunch of different exemptions that may apply but if an exemption does not apply to you, then you would be subject to the requirements.

Q. Hi. We are a manufacturer/importer of food materials and chemicals. Some of those chemicals are DEA-listed chemicals. From experience, I know the DEA has their own set of rule-keeping and record-keeping regulations. Which would apply to a company like ours that would even resell those types of chemicals?

MS. FRASER: Again, if these are products that are being used in food or you have a reasonable belief it is going into food--

Q. Correct, they are.

MS. FRASER: Then you are subject to making sure your records contain the information we have here.

Q. Some of the examples that were used trying to get as specific as possible, for example the cheddar cheese versus cheese and the iceberg lettuce versus lettuce, when it comes to grains, raw material commodity grains--corn, rice, wheat,

do we need to get into the varieties of those? Or, is just a statement that it is corn or rice or wheat adequate?

MS. FRASER: Are they viewed as different like cheese and cheddar?

Q. At the farm they might be but at our use point they are not.

MS. FRASER: I think really, you know, to the extent these are viewed as different commodities--you know, cheese has an umbrella of different uses and that is the specificity we want. To the extent that the product is typically a co-mingled product, then no. But it is really trying, again, to focus on investigation and, if necessary, if we have to go out to the public and say this is a problematic food shipment, to be able to not just say it is cheese or all grain but a specific type. Even to the farmers with animal feed, it is a specific type of grain. So, it is partly what is customary in terms of are these unique products.

Q. Thank you.

Q. I am a processor and have products delivered to me in an overseas container for the account of the importer. Is the previous source the origin supplier? It is not the transporter.

MS. FRASER: You are a processor and you are receiving something from overseas basically.

Q. Yes.

MS. FRASER: And your importer is your customs broker?

Q. No, they are the owner of the goods.

MS. FRASER: You know, on one hand, again, is it a paper transfer versus where is the food moving? The better data for us would be the manufacturer of that product, even if it is owned on paper by somebody else who really just did a paper bill and sale. But if what you know is I bought it from distributor A or exporter A or importer A, then that is your immediate previous source. We now have to go to that person to get the information.

Q. I do not own any of the goods. The importer of record, would that be my previous

source and then they can go back to where they purchased it?

MS. FRASER: Ultimately, you know, the Rule doesn't really speak to ownership per se. I mean, when we say immediate previous source we are really trying to trace where did the food move, not necessarily where did the paper title move. So, to the extent that the food moved from a facility in one place to a facility in another place and you know that information, that is what we really would like to know. To the extent that that is not something you ever would know because the importer isn't going to divulge his sources and that is part of his business, then your immediate previous source is your importer. But, again, as I say, think of it in the context of if we are doing a trace-back the faster we can go back up the steps, some of it is going to be dictated by what your business transactions really are like and what information you have.

Q. But if that is confidential information--

MS. FRASER: And many importers, all they will tell you is your immediate previous source is the importer because they are not going to tell you who their suppliers are. Then that is sufficient.

Q. Thank you.

Q. We are a finish refiner of vegetable oils so we import from various parts of the world and then refine and send out to different companies that would manufacture for confectionery chocolates and baked items. We don't unload the ships. The ships come into the port. They are unloaded by another company and then those materials are sent over to us essentially by pipeline. The previous person, would that be the company that unloads the ships, or would it be the various companies that we buy those products from?

MS. FRASER: Your immediate previous source is really the company you are buying that product from. That is your immediate previous non-transporter. Your immediate previous transporter is the trucking company or whoever actually gets it to you physically.

Q. It comes to us by pipeline.

MS. FRASER: Well, that is an interesting one. I always think of trucks, planes.

Q. See, the company that unloads the ships is a separate company. It is not part of our business. They are a totally separate company.

MS. FRASER: So, who is putting it in the pipeline at the other end?

Q. They are.

MS. FRASER: Then that is who your transporter is. But I think when we are looking at the non-transporter immediate previous source, and if you know you bought it from foreign company A, B and C, that is really who we would want to know.

Q. Okay. Now, we ship out primarily by tank, truck and rail car. Is that considered packaging?

MS. FRASER: Yes. Well, if the product is going in the tank car, that would actually be a food contact substance, touching the food.

Q. Right, that I am aware of.

MS. FRASER: Yes. You are not in

packaging. In that sense the transporter and the food contact substance kind of merge into one. So, I don't know that there is a different requirement that is really applying there. I mean, are you asking should you keep track of the tank car number--

Q. Exactly. Do I have to log tank cars as packaging? I am going to consider them as transporters.

MS. FRASER: That is a good question. Again, send me that one and what you think about it. My top of the head answer would be it is a food contact substance, sure.

Q. That was my thought too. You addressed lab samples a second ago, and we periodically send samples out to different companies. A sample might be 5-gallon pails or a pallet of 5-gallon pails that would be used to make, like, test coatings and things like that so they are actually making products. They might be making a cookie or chocolate chip or something like that. Does this apply to samples that we send out

that might not go out for human consumption but we don't know?

MS. FRASER: Yes, they would apply. Again, if there is a reasonable belief that a food would be consumed or a product--I mean, there are some products that are used for drugs, cosmetics and food. Starch might be one. If you have a reasonable belief that that product could be used as a food, then you should be keeping those records to the extent you are transporting it or the distribution of it. So, the same thing with the samples, to the extent that you are delivering it to a business and that product can be consumed and, again, if people are getting sick or dying which we have had happen, and we are doing a trace-back we need to figure out what was the distribution of that sample up the chain and where else those other samples may have gone.

Q. Currently, any of the oils that come back to us are held and then, obviously, we ship them off for disposal at a facility, and about the time that we are going to be required to keep

records we are going to have a co-generation facility constructed on our site to burn these oils as fuel and generate electricity to power our facility. Do I have to keep records of the oil that we maintain for fuel in the co-gen facility on site? Because there will be a discrepancy in what we take in and what--

MS. FRASER: Right. You don't for our records because by the Rule, the way it is written, we don't require that intra-company transfer. I think it probably would be helpful for you and us if you kind of had that complete loop but in terms of actual requirements of the Rule if it is an intra-company transfer and you are using it all internally, then there is not a requirement to keep track of transfer to that co-gen facility, assuming it is still owned by the same lead entity.

Q. Next question, and just to kind of confirm my thought, in determining the size of our company, we are a foreign company and we have facilities worldwide, do we only consider our U.S. operation in counting employees or facility size or

every company within our corporation?

MS. FRASER: That is a good question. I would say it is the U.S. entity because we really were looking at who is subject to the Rule and what is the ability to comply. But we haven't really thought about--in part, it is really looking at who has the capacity to come up to speed quickly. So, that is another one I will have to think about because there are equities on both sides. On one hand, you are a large company and it shouldn't matter that some people are here and some people are there. On the other hand, you could say, well, it is only the people that are here that are subject to the Rule so that is what we should be measured against. So, that is one that the lawyers kind of have to help me decide where it falls in terms of how we have structured the Rule.

Q. I can send you these in writing?

MS. FRASER: That would be perfect.

Q. Thanks a lot.

Q. You touched a little bit on raw agricultural commodities. I realize farms are

exempt from record-keeping but if we are users of raw agricultural commodities and the fact that they are typically co-mingled in large storage facilities, is it a matter of keeping track of the storage facilities or do you have to take it back to the farm?

MS. FRASER: Well, let's start with the distributing. You are the distributor and you go to ten different farms and pick up tomatoes and they all get co-mingled in a truck, then your immediate previous sources are farms 1 through 10 and that would be what would have to be in those records. If they are picked up separately, you know, they already come in crates or bushels and they are identifiable--you know, we picked up this batch from farm 1 and this batch came from farm 2, then that is something we would identify. And, even if you sent them out as a co-mingled product from the distributor, what you are saying is I sent to, let's say, the manufacturer tomatoes that came from farms 1 through 3 because I co-mingled them. It is really how you receive the product. That is

what you are recording, and how you release the product is what you are recording.

Q. So whether you are buying from a storage facility, you have to keep track of that but if you are also buying from farms, those farms would be--

MS. FRASER: Your immediate previous source. You know, if you draw a box around your facility you are looking at the food that comes into that box, from where did you get it and how did it get there, and the same thing on the outside, to whom did you send it and how did you send it.

Q. Hello. I have a two-part question. First of all, if a company needs assistance in complying with the record-keeping provisions, is that something that the FDA can supply? The reason I ask this is I work for De Sales University and we are offering a web-based record-keeping solution, but does the FDA provide any assistance along those lines?

MS. FRASER: We probably provide limited

assistance in terms of I think our investigators, our inspectors, our field offices where Steven is from. I mean, they are more than amenable to working with industries and companies in their region district and answering questions. In terms of actually getting in with the nitty-gritty technology and recommending one methodology versus another, that is something we do not do. I mean, we may give suggestions--you know, you are missing these kinds of records, but there are probably many more private entities out there offering much more detailed compliance assistance than the government is able to do at that level of specificity.

Q. I was just curious if eventually there would be some type of directory that companies could go to to refer to various--

MS. FRASER: No, we do not get into that business of endorsing or not endorsing anyone, in particular because that would be a whole enterprise in and of itself just to figure out who is legitimate, who is doing a good job, who is not. And, that is not what taxpayer dollars are really

for. That is sort of the private market--

Q. Sure.

MS. FRASER: I think that is a better source of who is reputable, and in that regard it is probably various trade associations and other members in the industry but that is not something I think you will find government agencies really doing.

Q. Right. I was just thinking about companies walking out of this and figuring how are we going to do all this in one year or six months --

MS. FRASER: Oh, there are plenty of people ready and willing.

Q. Okay, thank you.

Q. I was looking for some clarification on the use of the term intra-company transfers and obligation to keep facility records accessible. Specifically, if a parent company in the U.S. has multiple food facilities in various states, if the food comes into one facility and is held there and then transferred to another facility for use, does

the obligation for the receiving facility to know what it got from the inter-company facility or the original source? Say, it was from another company or even a foreign source?

MS. FRASER: I think from our perspective on what the Rule requires, it goes back to what is the definition of "person." A person is an individual, a corporation, a partnership or an association. So, for a company, you know, you start looking at how is that entity incorporated.

Take somebody like Kraft or General Mills that may have hundreds, if not more, facilities, whether they choose to do this as Kraft as a whole I think would start getting very difficult or Kraft plant A, Kraft plant B--maybe they do. Maybe they decide, well, this manufacturing plant tends to deal with these warehouses and these distributors so that will be our enterprise. But for vertically integrated companies, it does leave the company the flexibility of saying we are still one person. We are incorporated as one entity and we can look at incoming products into that entity and outgoing

products from that entity, and it is only when they are outside of what is us that we have to record the incoming and the outgoing. So, I think it is up to the companies to figure out what is the best way of dealing with that, recognizing you have the as soon as possible, not to exceed 24 hours on an access request. If you are trying to manage the whole thing at the corporate level for all of your facilities, I just think, you know, it might be easy but it also becomes a balancing of how you are structuring it. But from a legal perspective on the Rule, the intra-company transfer is really when you relinquish it outside of who you are as an entity.

Q. So, in my example, if one facility received raw materials from a second facility, if the recipient of the goods, the raw materials, received a written request for records of the immediate previous source, then I would have to provide who that was outside of my company?

MS. FRASER: Absolutely.

Q. Not the other integrated--

MS. FRASER: Exactly. It is who sends it into your box--

Q. Person?

MS. FRASER: Into your person.

Q. Good, thank you.

Q. Hi. I have kind of a general question. My company does importing and distributing. A few months ago, after many months of putting together information and going through the long process, we were certified CT-PET through Customs and Border Protection. I was just thinking what the implications are here for all of us in doing this record-keeping. If there is any collaboration between FDA and Customs and Border Patrol in terms of sharing information. I know from doing out application for CT-PET you know a lot about us now, or at least the government does. Is there any plan to be sharing that information among agencies that might make it easier on our end to have that information in the database and make it easier for everyone?

MS. FRASER: There is much more sharing

among the agencies, and particularly with Customs and Border Protection. Under the Bioterrorism Act, the registration and prior notice rules were actually co-issued by FDA and customs, Homeland Security and HHS. So, as we work through the comments on the prior notice rule there is a lot of communication back and forth between the two agencies. There is common resolution of the issues. The prior notices that are filed can either be filed through the customs automated commercial system or they can be filed through the FDA prior notice system. But those two systems are linked.

So, in terms of imported food coming in, there is a lot of information that goes back and forth between us every day automatically over the computer. Our computers are linked so that our inspectors can look at it and CBP inspectors can look at it. We have a commissioning agreement in place so that if FDA is not at the port we now have over 8000 customs officials that have been trained to do those inspections on our behalf.

That being said, with respect to the record-keeping requirements, that is not something that is co-issued by the two agencies and to the extent that we are in a trace-back and we find it necessary--you know, maybe it is dealing with an importer or something else, this kind of information that we can access we can only share with another federal agency, like customs or Tax and Trade Bureau, only if we have a confidentiality agreement in place with them that makes sure that they have the same protections against non-disclosure that we have in place for non-disclosure.

So, there is a lot more working together. I think if you look at the FDA before 9/11 and FDA after 9/11, it is a different place. We have classified security clearances we never had before. We have daily conversations with CIA and FBI. It really is a different world. Even the focus on food safety and security, and a lot of the work we have done with industry and guidance documents on how you can better protect the food supply was not

something the agencies--I mean, we dealt with wholesomeness of food and bacteria. It wasn't what are targets and what do we need to do to eliminate the vulnerability.

So, yes, there is a lot further we need to go. In terms of CT-PET, that is something we are looking at as to whether it should impact time frames for prior notice. Should people in CT-PET, because we know more about them, should they get reduced time frames for prior notice than other people bringing food products in? That is one area under consideration for the final Rule.

So, yes and no. Yes, there is more sharing in some places where it makes sense to do more sharing and in other places, where we really do have separate missions, there isn't as much of a need to do that.

Q. Thank you.

Q. This is just a clarification regarding packaging material. If you are a bulk manufacturer, are you required to trace back the packaging material that is then being transported

to another customer that is then packaging the product into the liner that would be then sold to the consumer?

MS. FRASER: No, if you are a packaging manufacturer you don't have any obligations, except to make sure you can meet the access provisions for any existing records you may keep, which is as soon as possible, not to exceed 24 hours.

Q. But if you are a manufacturer of a bulk material that is using liners, that is using tote bags?

MS. FRASER: Bulk material? Bulk food product material?

Q. Yes.

MS. FRASER: Yes, if you are the manufacturer of the bulk food product material, then they have to keep track of the packaging material. They have to tell us in their records they received the packaging material from you, along with whatever lot numbers you may have had on that product. But you don't have to do anything different. It is their obligation to do.

Q. So, both the actual bulk manufacturer and the person that is actually making the finished good that is going to the consumer has to keep track of the packaging material?

MS. FRASER: No, the bulk manufacturer--well, let's see.

Q. It is not manufacturing of the goods.

MS. FRASER: Of the goods?

Q. Like a wholesaler.

MS. FRASER: Right, the wholesaler has to keep track of the incoming product. His outgoing product is really the food in the package. So, he is not keeping track of the packaging material anymore; he is now saying I shipped out--

Q. Lot number such-and-such.

MS. FRASER: --a thousand cases of juice, and those cases were bottled with lot numbers--you know, bottles 1 through whatever from this manufacturer. But that is the bulk manufacturer of the food product obligation; the bottle manufacturer doesn't have any obligation other than giving us access to records if we find out the

bottles happen to be contaminated with cyanide, or something.

We have about five more minutes.

Q. The FDA's enforcement of compliance is only going to really be during an emergency situation. When you go in and do an inspection you are not going to be looking for these records on an enforcement basis?

MS. FRASER: Let me see, that is a question we are wrestling with because we clearly have the right to demand access to records in a public health emergency. Finding out you are not in compliance at that time is probably the least of our problems because we are really talking about something that presents a threat of serious adverse health consequences or death to humans or animals.

So, our need is to make sure people are in compliance. That being said, right now the only times we have said we will demand access to records in our guidance documents is in that public health emergency. I think inspectors still may ask to voluntarily see records and people could say I am

not showing them to you. But whether we are going to try and figure out are there ways that we can get access to records just to see if people are in compliance is something we still need to work through. To the extent we come out with a different solution that, yes, we could have access to records to spot check to see if you are in compliance, we would at minimum have to say so in guidance and possibly have to say so in regulation. But that is still not a question that we have addressed. So, as of now, yes, we can only demand access but for me, as a regulator, it sits a little uncomfortably to say the only time I know you are in compliance is when I absolutely critically need it because people are dying or are sick. That just doesn't seem the best situation for us or you.

Q. I am a food manufacturer. The bulk of my items fall under USDA. We have a small percentage that falls under FDA guidelines. I was in Washington last week at a USDA meeting where they actually had an FDA speaker and they told us that we are going to be asked by the FDA to

reassess our HACCP plans to include bioterrorism threats and make adjustments to the HACCP plans according to those assessments. Does that have anything to do with what you have here or is that totally separate?

MS. FRASER: That is totally separate. You know, probably it is another arrow in our quiver, another way of protecting the food supply related to countering bioterrorism threats, but it is not this.

Q. To repeat something that was said by the lady from the FDA, which puts us as an industry in an awkward position, her comment was that the FDA is trying to work more with the USDA to streamline the requirements so that those of us who fall under both jurisdictions can have one set of rules that we play the game by. Now, this is something else that we are going to have to do. Fortunately, the records are already kept under HACCP.

The other big topic of discussion down there that I haven't heard anything about today was

country of origin labeling. That is also part of this that is going to become law on June 7th, is it not?

MS. FRASER: People have varying views on that, but currently that is what is supposed to--I mean, depending on who you talk to, I hear folks in industry telling me, oh no, Congress is going to change that. Yes, currently that is the state of play. I think that country of origin labeling also is a different requirement than this. That talks to the labeling that goes on your product itself. Yes, maybe to get there you will have to keep certain traceability records so you know what the country of origin was of the product or the ingredients but that is not part of this.

Q. As part of traceability, don't you want to know the country of origin?

MS. FRASER: We do get that. For imported foods we already get that in prior notice. We do get that. We don't get it on the label, we get it in the notification that comes before the food arrives.

Q. Also, is my list of ingredients on my product label sufficient to tell you what is in my product?

MS. FRASER: If your list of ingredients is everything in your product, that may be sufficient. But that is not often everything that is in the product because the secret herbs and spices are often not required to be on the label.

Q. They would be listed as spices.

MS. FRASER: But that is not sufficient.

Q. If we can go off of the label and give you a breakdown of the spices that are in that particular product?

MS. FRASER: Then that would be one of those ways you could supplement the records, yes. Going once, twice? Thank you very much for your attention.

[END OF TAPED RECORDING.]

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