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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

SEATTLE, WASHINGTON

Tuesday, January 25, 2005

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P R O C E E D I N G S**Questions and Answers**

MS. FRASER: If everyone could, please, take their seats, we will get started. One of the things I encourage you to do--I know reading government regulations is far less than exciting, but the first part of the Rule, if you go on our website, answers a lot of the questions that we received on the Proposed Rule and also answers some questions where people weren't quite sure what we meant or why we were doing something. So, if you don't read anything else, I encourage you to read the comments and the responses to comments because many of the questions that you may have could be answered already.

For these different sessions we have seven outreach meetings planned. This is our second. We did one in College Park. There is one here today. There is also one in Chicago today. On Thursday, there is one in San Francisco and another one in Orlando. Then, next week--I think it is next week, I don't remember where I am half the time but it is

Philadelphia and Boston. What we are doing is compiling the questions that we receive. We will be posting the answers on the website, but we will also be doing question and answer guidance documents. So, to the extent you raise a question and we have already answered it in the Rule, then I can tell you what the answer is, or if it is sort of a straight application of the Rule.

We also get questions that we haven't thought of and they are sort of specific to a particular industry. We got a lot of questions in College Park on what does it mean "per sample" and what are we going to do with those. Another question had to do with transporters. If you are a contract transporter which company are you keeping records on? So, we need to think about those because the answers we give--and the reason we put them in guidance documents, is we actually have a pretty significant vetting and clearance process for all of the questions and answers we have in the Rule. They have gone through the appropriate centers. They have gone through our Chief

Counsel's Office. They have gone through our Commissioner's Office. So, this is the view of the agency. This isn't Leslye's view or someone else's view. So, the new questions that come up that we haven't addressed yet we need to give that same level of scrutiny to so you will see those coming up in guidance documents as we get time and ability to issue them.

Again, if you are on the list service, whenever we publish a guidance document or an update to a guidance document--you know, we get a collection of questions; we publish it, we keep working on the next one; we publish an update. If you are on the list service, you will get a notice to that effect.

What we also have on our website--you can actually get hard copies of these if you want; you can request them--I call these "The Cliff Notes" version of the Rule. They are about eight to ten pages long or short. They explain the Rule in more plain English. We try to write the rules in plain English but these are much more straightforward,

what you need to know. There is one "ready for registration," there is one for "prior notice." "Registration" is an option for registration over the Internet which we encourage. "Prior notice" you are required to file electronically either through our system or the custom system.

But if you also go on our website you will see tutorials. There is lots of information that will walk you through registration, how do you register a facility; how do you set up an account; how do you file a prior notice. There are lots of question and answer booklets on there. So, I encourage you to look for those as well, and all of this can be downloaded. The Power Point presentations that we have done are on our website. This one that I did today, if it is not there yet, it will be in English, French and Spanish. These materials are also in French and Spanish so we usually stick with the three World Trade Organization official languages.

These two are coming. "The administrative detention of food" will probably be out soon, and

we are working on "The Cliff Notes" version for this Rule as well. So, those will be on our website and there will also be shiny, glossy books. We will have these tutorials on CDs that we can send out to people and you can distribute. You can watch them on-line as video stream. So, there is a lot of information there when you don't get a live body. There are relatively few of us and there are hundreds and thousands of you. So, I know people get frustrated when they feel like they have a question and they aren't getting an answer. We are doing the best we can as fast as we can, but you far outnumber us and so, you know, we are trying to do as many of these meetings as possible.

With that, I guess I have a couple here in my hand that I will start with. Then whoever wants to go to the mike, can go.

The one point I did want to clarify is that the food that is subject to records is a food that is under our jurisdiction and it doesn't matter whether the food is going to be consumed in the United States or not. So, if you have food

that is under our jurisdiction and you are manufacturing, processing, packing, holding, transporting, distributing, receiving or importing it, even if you are importing it to export it, you are subject to these requirements unless you meet an exemption. That is different than registration. Registration is only for food that is going to be consumed in the U.S. So, you need to look at each of the rules very carefully because the exemptions aren't exactly the same; the applicability isn't exactly the same and you do have to take them one regulation at a time, just as you do all the rest of the regulations.

We are a bakery that currently does not assign lot codes to finished products sold wholesale fresh and frozen. Do we have to start assigning lot codes to finished goods in order to be in compliance?

No, we don't require you to change business practice but, to the extent lot codes are available and you do have lot numbers assigned and you are a manufacturer, processor or packer, then

your records must contain the lot number or other identifier. Some other companies may not have a lot number but they have a company code and we would require that to be recorded as well.

How would we apply retention period requirements when we produce and sell wholesale bakery items fresh with a 7-day spoilage, and frozen which could last, if properly stored, 12 months although once stored subject to 7-day spoilage?

The record retention applies to the food as you receive it so your records for what you receive--it would apply to the state of the food as you receive it, as well as for records that you produce for products released, the food in the form that you release it. So, for the products that you are selling here, 7-day spoilage would be the 6-month record retention time period because it is less than 60 days. The frozen, which you say can last, if properly stored, if you are selling it in the frozen state. Then between 60 days and 6 months would be the 1-year retention and greater



than 6 months would be the 2-year retention. So, your product, if properly stored is 12 months, it would be the 2-year retention for that product.

Will retail be covered if food is not primary sales? For instance, a gift shop that sells mainly nick-knacks but also chocolates?

We look at the retail with respect to the food only. So, if food is only 10 percent of your business or 5 percent of your business, then we are only focusing--this Rule applies just to that 5 percent of your business or just that food. What we are looking at is that food that you are selling directly to consumers. If that is the case, in this case chocolates, then you would meet the retail exemption. So, we are really only looking at food.

Same thing with the restaurant retail exclusion. That was my example of the Cracker Barrel. Even though Cracker Barrel on the retail side sells much more non-food than food--it sells some candy, probably mostly candy--we are really only comparing food to food sales. So, we are

looking at how much food, what are the food sales from the restaurant versus what are the food sales from the retail side. We don't care about other sales. As long as the food sales from the restaurant are more than 90 percent of total food sales, they are exempt as a restaurant retailer. It doesn't matter that they get three times as much business or sales from the non-food products. We are really just looking at food to food.

I think that is it for what I have in my hand so if anyone else has a question, if you would please go to the microphone so that we can record it and transcribe it for posting on our website? If other people want to jot them down, if you don't want to do that, then we can collect those as well. It always takes one brave volunteer to start so thank you very much, sir.

Q. I have a question on the retail side. If I am preparing foods and I am prepackaging them on the retail side, do I have to keep the records one down?

MS. FRASER: As a retailer, one down for

sales to non-consumers to the extent it is reasonably available; not one down to consumers.

Q. Okay, again, if I am making a prepared salad or I am making a bakery item and I am prepackaging it and it is going out on the shelf, I don't have to control the lot numbers coming in?

MS. FRASER: No. Lot numbers coming in, yes; lot numbers going out, no. The partial retail exclusion is just on the outgoing side with respect to sales to consumers.

Q. Okay, I want to make sure, so as far as the recipe is concerned, if I have nine ingredients that go into that macaroni salad I must keep the lot numbers on those nine ingredients?

MS. FRASER: If they come in with lot numbers, yes.

Q. Thank you.

Q. A number of us had some questions on clarifying the records from the non-transporter to the next non-transporter. Is that transfer of ownership or just movement of the product?

MS. FRASER: Let's see, if we go back, it

is really tied to the definition of the non-transporter. It is really when you are relinquishing custody and control of the product from one entity to another.

So it is one who owns food or who holds, manufactures, processes, packs, imports, receives or distributes food. So, it really is a different entity than you are. So, if you are a corporation that does a lot of different activities--you manufacture it in one facility, you pack it in a different facility that you own, you transport it to the retailer yourself that you own, we don't need that intra-corporate record transfer because it is still one entity. We need it once you relinquish it from you as a person, as covered by the Rule, to the next person who is covered or exempt by the Rule. That is what we need. So, sometimes it will be ownership and sometimes it may just be transfer of the product. It just depends on what your legal construct is, if you look at it in terms of a trace-back investigation which persons have different activities with respect to

that food.

It could be in that case that you have where you are manufacturing it and you are giving it to a different distributor that is a different legal entity and that distributor is giving it to a grocery store, then, in that case, the different non-transporter now is the distributor so you are keeping records of your immediate subsequent recipient, the distributor, because that is who is taking over that food. They may or may not own it. It just depends on what the legal contractual arrangements are, but they are a different person doing an activity with respect to that food and you have relinquished it from your activity to theirs. It is a combination of the two but it can be custody but it depends on the custody basically within the construct of how your corporation is set up and what are the different activities you are doing within your corporation. We would look at the custody as a different person, a different legal construct, different entity that is not you.

Q. Okay. So, if I transfer food to you

but I still own it and you are holding it for me under some kind of contractual arrangement but you don't own it, and then you transfer it to this fellow, over here, and then I transfer ownership to him, what I need to keep for purposes of compliance with your regulations is the transfer to you.

Correct?

MS. FRASER: Again, I think it will depend because if I am under contract to you, then I might essentially be like your employee. So, probably yes. I mean, probably if you are transferring it to me and I am a different person and I am a distributor or I am another packer or another entity then, yes, you are keeping track of records to me and I am transferring it to the next person. That is my records, keeping track of that. That gets back into the transporter question that we have to think about some more because people are saying, well, what if I have my own trucking company as the manufacturer but I am subcontracting a part of that for them to deliver it to him? You know, which records are we keeping? Am I keeping

track of the contract I have or am I keeping records of the subcontract? So, the more you have specifics on what you think the outcome should be, if you send them to us it helps us to answer it on a factual basis with examples that other people can understand as well, and also answer it in a way that reflects the real-world of what you know is happening out there and how the legal construct should apply to where you think the records make the most sense to cross over.

Q. One of the things that I am trying to get to is you have an exclusion in here for access to financial data.

MS. FRASER: Right.

Q. Does ownership necessarily fall under that or is that tied to the movement of the product, or how does that work?

MS. FRASER: I think for financial data they are looking at what are the sales data; how much sales do you make from product A versus product B. It is more in that context. The ownership of the food may be relevant in terms

of--I mean, we are looking for who is your immediate previous source of the food. You could say, well, you got it from me. You may not know whether I own it or don't own it. That is not really part of what we are asking you. We are really just trying to track, you know, where was the food; where are the points at which it could have been contaminated if we are in a trace-back. So, the ownership may be a whole separate set that you may know or you may not know, and we are not asking you to go track the ownership. We are just really trying to track where did the food move from person to person.

Q. Okay. Thank you.

Q. Hi. In your requirements for transporting you have five options. Option one has route of movement during the time food is transported. Can you tell me what level of detail you are asking for on the routing?

MS. FRASER: In this one we are really looking--and it may be in records that you already retain as sort of a transfer point so if it is a



truck coming into a hub, a terminal, and you are moving it from one truck and going to another truck, then we would want to know the route of movement. It went from state A to terminal facility and then it went to state B or whatever the distribution point was or the endpoint was. If your route of movement also meant that one company owned multiple vehicles, then we also want that route of movement to indicate that it went from a truck to a plane to a truck within the same company. So, we are really looking at places where food may have transferred from one vehicle or one mode to another such that, again, if there is contamination, not that this only applies to intentional contamination but we could be doing a trace-back where it is a naturally occurring toxin or bad manufacturing or agricultural practices, but if you look at it as where are those various nodes at which something may have happened intentionally, that is kind of what we want to be able to pinpoint.

Q. So, you are not looking for the road

mapping or anything like that which depicts where they stopped or ate?

MS. FRASER: I don't think we are but that is a good question for us to clarify in guidance as to what does route of movement mean. Again, if you have thoughts on what that should mean or what you are already keeping records on in terms of that--you know, what specificity makes the most sense. I don't think we are looking for you were on Route 15 and then you went to this route. It is more transfer and custody. Again, it is sort of the custody and control. You know, who had custody throughout these various periods of time. Was it the truck? Was it the plane? Was it another truck? Was it trucker A and then it went to trucker B, on a different truck because you shifted the load or split it up? That is sort of the information we are thinking of in terms of route of movement.

Q. I have a couple of questions for clarification. If a manufacturer ships a product to a public warehouse and then releases that

product from the warehouse to a retailer or a second owner, when the product is in the warehouse the manufacturer still has the ownership. So, in this case, the manufacturer charts the record up to the public warehouse and it is up to the warehouse to chart the record to retail? Would that be correct?

MS. FRASER: Yes.

Q. Even if the public warehouse doesn't have ownership of the product?

MS. FRASER: Correct, because the warehouse is receiving food and releasing food. The Rule is applicable to persons who do an activity subject to the Rule. So, the warehouse is doing the activity of holding food or receiving food and distributing food. But the warehouse is responsible for its activities with respect to the food whether it owns it or not.

Q. The next question is if the manufacturer doesn't have his own storage area and is sitting next to a public warehouse and uses the public warehouse as their storage area and their

activity is moving the product in and out from that warehouse, going to operation and going back to the warehouse, does that mean each time when there is a product movement they have to follow that regulation of record-keeping requirements?

MS. FRASER: Yes, because it is food that is released to the warehouse and, again, I am not using intention as the only thing that can happen but it is easier to use as examples, if someone who wants to do us harm comes into the public warehouse and contaminates the product or releases a toxin, we need to know what food was there for that period of time; what wasn't there; what other food may have been there. So, yes, the in and out tracking is important for being able to do that.

Q. My next question is regarding the co-mingled ingredients. If a manufacturer has three suppliers for the same ingredient and also has three suppliers for one food contact or packaging material and they have no way to track which particular supply goes to which product but they know for a particular product it comes from

three suppliers, will that be sufficient record-keeping?

MS. FRASER: Again, it is going to depend on what the setup is of your operation. The Rule doesn't require you to revamp your manufacturing operations but it may require you to pay a little bit more attention in terms of what you record than you may be doing now. So, you know, co-mingling can be done in various ways. Flour can be co-mingled in a silo and, yes, A, B and C are sufficient. Tomatoes can be co-mingled in a truck picked up from five different farms and that would be sufficient because they are not separating them per se, but if they are coming in to you in bins or crates and you are dumping them in, knowing that a crate was labeled farm A, it really is going to be dependent--the same thing with the food contact substance. If it is coming in as a roll--you know, when I was a summer student eons ago I worked in a Saran wrap plant. They produce rolls in big sheets, big rolls of these that they ship out. If that is how it is coming in and you are getting

some from Dow and some from another company, then it seems like you would be able to know that you are using the Dow roll at a particular run, but if you are dumping in the raw polymer into a bin, then maybe you are not.

So, it really is not a global answer and that is why it says it is a case-by-case determination of what is it you are doing in your operations and what is reasonable to record. In some cases you may not be recording it but with a little bit of effort you could be. In other cases, just because of the way things mix or the way of the natural course of shipping and delivering, that is not reasonably available for you to record and it is going to have to be specific to what you are doing and what you reasonably can do.

Q. My next question is regarding the electronic data. Is any specific format required by the record-keeping regarding using electronic--

MS. FRASER: No, and that is a good question. Thanks. Generally, FDA has a regulation in 21 CFR, Part 11 that governs electronic records

and it specifies the format and requirements for those records. There is an exemption in this Rule for Part 11. So, if you are keeping electronic records just to comply with this Rule, then you don't have to comply with the Part 11 requirements, or if you are using existing records to comply with this Rule you don't have to comply with the Part 11 requirements. However, if you are keeping records to comply with another FDA regulation, let's say low acid canned food that does require Part 11 and you want to use those records here, this will not get you out of the Part 11 for the low acid canned food piece. But there is a Part 11 exemption.

Q. Thank you very much.

Q. Our company can produce a substantial amount of USDA product. My question is the USDA is exclusively produced for USDA so the product itself would be excluded but the packaging would have to be--the inbound packaging that touches the product would have to be recorded?

MS. FRASER: No, if it is a food product that is exclusively USDA's then, even with respect

to the packaging, you wouldn't be subject.

Q. How about a transporter?

MS. FRASER: No, any food that is under USDA's jurisdiction and the packaging that is touching the USDA food, as long as it is exclusively theirs, you are out from under this Rule.

Q. Thank you.

Q. I have another question in reference to the packaging. How would you handle a recall if you didn't know the lot number? If you knew that there were three suppliers, what would be recalled?

MS. FRASER: Well, let's break it up. We could have required lot numbers and in the proposed rule one of the reasons we required lot numbers was so that we could, with specificity in our case, administratively detain just that product or ask the manufacturer to recall the product. Recalls are not mandatory. They are only voluntary on behalf of the manufacturer, with strong encouragement from the FDA. But we don't have authority to make you recall any product. That was



in part, I think, why we got the administrative detention authority. It was an ability to hold the food in place while we went to court to seek an injunction or a seizure action.

But in the final Rule, a lot of the comments came in and I would say lot number was the number one "let's see red" issue for many commentators, and a lot of it focused on how cost prohibitive it would be to require lot numbers from the warehouse down. So, we balanced our ability to pinpoint with that specificity against the cost and the burden, and chose not to require lot numbers. What that means is that we may end up detaining more product than we might otherwise have to under a detention or requesting more product be recalled than actually would be limited, which is the case now for products that don't have a lot number. You know, for fresh fruits and vegetables, which often don't have lot numbers, you may just end up with a wider recall or a wider seizure action. So, it is going to be however much information we have specific to the public health risk and concern that

we have, and that will be the way we end up going.

Q. Thank you.

Q. Where do parties such as brokers and sales agencies that represent the sales of the transaction but don't handle the product or manufacture the product--where do they fall in, the transportation side and the product side?

MS. FRASER: Yes, generally brokers are acting as the agent for somebody else who does have the food. So, there is a question in the Rule that talks about customs brokers, for example, and they are not subject to the Rule per se because they really are filing the paperwork on behalf of someone else. You know, on the import side they are filing the paperwork with customs on behalf of someone who actually is taking custody or control of that food even if they don't have ownership rights.

Q. I guess I am still confused on ingredient traceability. We may on a given day use, like, 1600 different ingredients and I am sure I can tell you where the manufacture was and all

their contact information, but I don't know that I can tell you today each individual lot number and trace that. So, is that or is that not a requirement? I can tell you the manufacturer of the ingredient but he may have, you know, three or four different lot codes on any given day. Do we need to keep track of each one of those individually?

MS. FRASER: Yes, to the extent that you are receiving product that comes in with a lot number as a manufacturer, packer or a processor, then, yes, you will have to start keeping records of the lot number. Part of the reason we extended the compliance dates by six months from what was in the proposed rule was because people said they needed more time to be able to enhance their records or get more information from the suppliers in ways that they could easily record it. But to the extent lot numbers are provided, they will need to be recorded, and to the extent you can link it with an outgoing product and that is reasonably available, then that is something else we require

as a manufacturer.

Q. Thank you. And one follow-up, as we receive our FDA routine inspections after the law takes effect, they will not be coming in to test the waters on us and doing, like, mock recalls or things like this to test our capabilities unless there is cause? Is that correct?

MS. FRASER: All I can say is I have not currently heard any plans to do that. I am on the developing the regulations side of the house and my counterparts are in the Office of Regulatory Affairs who do the enforcement and have the inspections. So, while we talk sort of on the broader level of what is required, I have not heard of any exercise in that regard.

Now, one of the comments that came up at the College Park meeting, one of the people in the audience suggested that, you know, with some volunteer companies and FDA staff, we do a mock run to see how this would actually work so that if we were in a public health emergency and we did have someone contaminating the food supply we would

actually be able to see how the kinks work, how our system worked, how well it worked with the manufacturers. So, that is something that has been suggested to us and we will see what happens, but I haven't heard as part of a routine inspection that we are asking anyone to show us records in 24 hours. I think it is something you all should do on your own.

Q. Agreed. Thank you very much.

Q. I would like to expand on a previous question regarding the USDA product, and that would pertain to meat, poultry and eggs. Correct?

MS. FRASER: Egg products.

Q. Egg products. So, if you had a product, let's say milk or dry milk that is being graded by the USDA and labeled under the USDA labeling, that would still come under this Rule. Is that correct?

MS. FRASER: It would because the USDA exclusion is only if it is exclusively USDA's and there are products we share jurisdiction over. So, if we share jurisdiction you are under this Rule.

Q. Okay. Thank you.

Q. Would the manufacturers of product contact packaging materials fall under all of the rules of the non-transporter?

MS. FRASER: They fall under this Rule but they are excluded from the duty to establish and maintain records. The only thing that we have them subject to is the records access provisions for existing records. So, you don't have to keep any of those records that we have specified but if there were a public health emergency that related to the packaging material and we could meet the stand of saying there was a reasonable belief that the packaging was the source of that contamination, then we would have access to those existing records you would have and you would have to meet the "as soon as possible, not to exceed 24 hours."

Q. But they wouldn't be required to record lot numbers?

MS. FRASER: No. No, you don't have to. The whole section that dealt with records a non-transporter has to maintain to identify an

immediate subsequent recipient and immediate previous source doesn't apply to packaging manufacturers.

Q. And would Charles Breen be willing to tell us what we might expect from a compliance standpoint when his people are in our facilities?

MS. FRASER: Charles, would you be willing or unwilling?

MR. BREEN: Actually, it is very easy--I don't have a clue!

[Laughter]

MS. FRASER: I will say we started with the outreach with the regulated entities and we have tapes and other things going on. Next month we are doing training for the field and a lot of that will be interactive videos, both on the requirements of the Rule, the access provisions and the access limitations, and Charles will be in there too. But that really is directed at a lot of the inspectors so we are developing the training to underscore the confidentiality, the trade secret protections, etc.

Q. I wanted to say thank you very much for putting this on for all of us. It is very helpful.

MS. FRASER: Thank you.

Q. Also, a question for a transporter. If you are an airline carrier and people, say, are fishing in Alaska and they want to transport their fish home, do we have any obligation or is it their obligation since they will be using it for their personal consumption?

MS. FRASER: Yes, for personal consumption neither one of you have an obligation for that. We don't worry about food for personal consumption. You know, if they start bringing in loads and loads of fish, customs will also start looking at it if it is coming in from another country but they may start looking at whether that really looks like a personal consumption or a business enterprise. You don't have an obligation for personal consumption.

Q. Okay. Then also for an airline transporter, does each city that is involved in transporting need to register separately?



MS. FRASER: Each facility?

Q. Yes, each city has its own facility.

MS. FRASER: Yes. Well, each--no, let me see, on the transporter side, no for registration. The registration rule only applies to those who manufacture, process, pack or hold food--

MS. FRASER: --and when we first issued the registration rule we counted "hold" as everybody who might have a warehouse and a transportation hub and then, after we got beat up and told to think about that some more, what we have in guidance for the registration rule is that transportation hubs do not have to register because that is part of the normal course of transporting food. It is just an intermediate transfer point. So, to the extent it is a place where you are just exchanging food from one truck to another or one airline to another, they don't have to register. To the extent it becomes a warehouse that is actually sitting there, holding the food until, you know, maybe the local truck comes to pick it up, then they do have to register. So, it is like is

it more of a transportation hub? No. Is it more of a warehouse? Yes.

Q. Thank you.

Q. I have a few questions. My first question is if a foreign, non-transporter imported a food into the U.S.A., would the foreign non-transporter be required to comply to the non-transporter requirements set out in this Act?

MS. FRASER: Not this Rule. The person that has to comply is the person in the U.S. who is actually importing the food. So, the person in the U.S. importing the food would tell us who the immediate previous source is which, in that case, would be the non-transporter in the foreign country. So, that is where we would find out the name, at least for these records, of that person over there who is providing the food. But the person over there doesn't have to do anything for the record-keeping rule. On the prior notice rule, somebody, whether the person in the foreign country or the importer here, is going to have to provide us prior notice of the food before it arrives,

which will have some of the same information that this record-keeping rule will have. That was another reason we did not include foreign persons or foreign manufacturers in the Rule because a lot of that information is already captured in the prior notice information we get when the shipment comes in.

Q. Great! My second question is in establishing and maintaining records regarding the non-transporter when they release a product, is that considered as a positive release type system, or would like a shipping manifest do the same job as far as when we release, say, a product that is going for shipping somewhere else? Or, would we actually have to keep a record and sign something saying that it has been released?

MS. FRASER: Well, we only tell you what information you have to keep. We don't say what form you keep it in. So, if your shipping manifest has all the information that is listed under what the non-transporter has to have for immediate subsequent recipient, that is fine. If it has six

of the eight elements and you want to add that to your manifest or keep those other two elements in a separate file, that is fine. You just have to figure out and make sure that whatever records you are keeping, whether it is one record or a compilation of different records, it meets all of the elements that we require and is created at the time the transfer happens, unless it happens to be like a bill of lading you are receiving or some other existing record you are relying upon.

Q. My last question is would products produced in the U.S.A. but processed for export only be exempt from this or not?

MS. FRASER: No.

MS. FRASER: No, they are exempt from registration because registration is only required for food that will be consumed in the U.S. Prior notice, record-keeping and detention don't have that limitation. It just applies to food in the U.S. under our jurisdiction.

Q. Right, great! Thank you.

Q. I have a couple of questions too. In

the event that the FDA will require records, how will you contact us? Will it be through the facility registration emergency contact number?

MS. FRASER: For those who are registered, most likely yes, or it could be through the name and the contact person that is listed, you know, when we go back up the chain. So, if the retailer told us in their records who their immediate previous source is--farm name and contact information, we might start there. So, it could be one of the two. But registration only is half of who is subject to the record-keeping rule so we are not going to have an emergency contact point for every person that is subject to the record-keeping rule.

Q. Okay. For a retail establishment, currently most of the stores don't require the manufacturer to provide them on the bill of lading with all the lot codes. They are saying tell us what you have shipped to us and the quantity. We, the manufacturer, keep those records and there is a link-back through purchase order number or shipping

order number. Will we now be required, because the lot codes are available, to provide those bills of lading with code information to the retailers?

MS. FRASER: Well, the retailers don't need that information because the requirement to record the lot number only applies to the manufacturer, the processor and the packer. So, unless the retailer happens to be doing the packing also, which is not typical, they don't have the obligation to record lot number but you would have to record lot number for the sources that you ship or the product you ship out, if you have a lot number available.

Q. Thank you very much.

Q. I have a quick one. Remember the example I gave you about macaroni salad?

MS. FRASER: Yes.

Q. If she is supplying the product and I need a lot number, how do I get it?

MS. FRASER: You are a retailer?

Q. I am a retailer but I am making salads--

MS. FRASER: Yes, but you are still a retailer--

Q. --and she is supplying me the product.

MS. FRASER: Yes, but you still generally don't have a requirement to keep lot number because, under the retail definition, a retailer can manufacture and process food as long as it is food they are selling directly to consumers. So, you don't end up losing your retail classification, in which case you still don't have an obligation to record lot number here.

Q. That clears that up because in the first place I thought that I would have to keep a lot number.

MS. FRASER: If you look at retailers, we recognize that--

Q. See, I am talking only about one down now. I am not talking about the one up.

MS. FRASER: But there are about like three different things at play here. In the retail definition we define a retailer as one that sells food directly to consumers or whose sales to

consumers is his primary function. I think that is really the definition. Primary function means that more than 50 percent of your sales go to individuals versus businesses. As long as you meet that definition of a retailer where 51 percent is consumers, you can manufacture and process. You know, many grocery stores have delis in the back. They are doing the combination salads and all of that. You are still a retailer. So, now that you are a retailer, you don't have an obligation to record lot numbers. Only manufacturers, processors and packers have that obligation.

If you don't meet the retailer definition because your sales are more to businesses than consumers, then, yes, you are a manufacturer and you would have to keep the lot numbers to the extent they are available, and if she has them and she can give them to you, that is part of your business transaction to say I, now as a manufacturer, have to keep lot numbers on the products that you are providing me that have a lot number, so you need to work out how you get that



from her.

Q. If I am a retail establishment and I have a central area where I am producing those salads or bakery goods that are being distributed and sold through 25 or 30 different stores in that particular region, do I now have to track one up/one down?

MS. FRASER: Yes.

Q. Okay.

MS. FRASER: Because you are now a central kitchen and you are not selling food directly to consumers. You are like the host Marriott, sending it to the airplane.

Q. Thank you.

Q. Just a little additional clarification, as a non-transporter we will occasionally ship products through an express courier, like FedEx, that type of method. Our responsibility for tracking is simply for that carrier to pick it up and make the delivery, not necessarily the hubs that that carrier may route through? Is that correct?

MS. FRASER: Correct, and it is their responsibility to tell me. That was the transporter route of movement that the other gentleman asked about.

Q. I just wanted to be sure. Thank you.

MS. FRASER: Just generally, you are responsible for the activities you do. So, you are responsible for keeping track of food you receive, food ingredients you receive, packaging material you receive if you are the manufacturer putting the food in contact with that food contact substance, and foods you release. You are not responsible for what another entity does. That is their responsibility. So, that is the one up/one back. The only thing you are responsible for is making sure your records tell us who is that one up and who is that one down so that when we are doing the trace-back and we get to you we know who the next person is up the chain, and when we get to them we know who the next person is up the chain. So, it literally is a step by step trace-back, not that we come to one person at the end of the chain and make

sure you tell us everybody up the chain.

Q. When a retailer buys, let's say, a bulk pack of 20 lbs. boxed fish and they prepare the fish into 1 lb. to put it into trade and then sell a product at this point, when they do that, are they under the packer definition?

MS. FRASER: It depends upon whether they meet the retail definition. If a retailer is selling 51 percent to consumers of its food, then it can do those various activities, but if it is not meeting that definition--so, it really is going to depend on if you meet the retail definition then you are a retailer and you don't have to do the lot numbers.

Q. Even if you take the product out of the box, repack into a smaller container with a food contact packaging material, does that fall under packing?

MS. FRASER: With the food contact material, yes, that would because on that chart--I am sorry, I misunderstood your question--with respect to the food contact substance, then you are

on this third one, down here, finished container that contacts the food. You are placing the food directly in contact with its finished container so you do have to keep track of the material that you use to do the shrink-wrapping or the repackaging, yes.

Q. So, even the retailer?

MS. FRASER: Even the retailer. This is any person who is doing that activity, yes.

Q. Thank you.

Q. As a custom cold storage, we frequently receive product like, say, X LA Cold Storage for a consignee. Now, we don't necessarily know who the owner of that product was. Is LA Cold Storage the supplier in our case? We don't know the owner.

MS. FRASER: You just have to tell us who you received the food from.

Q. Meaning LA Cold Storage?

MS. FRASER: That is who you are receiving it from?

Q. That is who shipped out to us and--

MS. FRASER: Right, that is who you are recording.

Q. And, likewise, when we are shipping product out, if it is to LA Cold Storage we don't know who it is going to eventually--

MS. FRASER: Right.

Q. --is that adequate?

MS. FRASER: Right.

Q. Good. Thank you.

Q. Hello. Under the exemptions to access you state that personnel data is excluded. Is there somebody else who is going to be looking at that?

MS. FRASER: Maybe the state. I don't know, but not us. I mean, under this authority--and, again, this is when does the FDA have the authority to demand access to records in a situation where you would be in violation of refusing it. Under this authority, we cannot demand access to personnel data. Now, whether states can do that under state law; whether we can request that you voluntarily supply it and you

could say yes or no, but we cannot demand mandatory access to personnel data under this authority.

Q. Thank you.

Q. We have about 300 full-time year-round employees and during our processing seasons, which are only a few months out of the year, we have up to a thousand. Would we need to be in compliance by December or would we have 18 months?

MS. FRASER: You actually have to go through and calculate--somewhere in the Rule where it talks about compliance dates it will tell you how to calculate whether it is based on number of employees, the hours that they are working, time, total hours that you have people working in a year, and then you will figure out what the equivalent would be. Full-time equivalent means if all these people were working full-time how many people would you really have or, you know, if you added up all the part-time people to make a full-time person I guess is really the way to say it. So, I don't know because it is going to depend on how many total hours each of those thousand people are

working to see whether you make it over the 499 mark or not.

Q. And that calculation is in the Rule?

MS. FRASER: It is in the Rule if you look under compliance dates. It is either under compliance dates or definitions for a full-time equivalent employee.

Q. Thank you.

MS. FRASER: Actually, the other thing about the Rule, if you go on the website, you can search it. You know, if you put in FTEs you don't have to read the whole thing, it will jump you right to that spot. Probably by the end of the day it also will be bookmarked so if there is a particular section you want to read up on, you can actually just link to that section of the Rule. They are adding the bookmarks. In fact, they may be done now. They were starting this morning to add the bookmarks to the Rule.

Q. If I register a facility that I have determined today from your presentation may be exempt, is there a consequence to having registered

it and can you unregister?

[Laughter]

MS. FRASER: The consequence to having registered, you know, the fact that you registered is fine. There is no penalty, other than you might decide you don't like FDA knowing about you when we don't have to and, yes, you can unregister. Right on the same website, when you go in to the website and you click on, if you go to the bioterrorism page, you will see register facility and if you click on there you can either register a new facility, cancel a registration, which is what you want, or update a registration. So, as information changes you have an obligation to update. So, you can go in to cancel the registration and with your password you can cancel the registration.

Q. Then if, in fact, a facility is exempt what is the process, or is there a process for claiming exemption? Or is it just when Mr. Breen's group shows up?

MS. FRASER: It is just when Mr. Breen's group shows up. I mean, this is like any other



regulation. You have the obligation to comply and FDA has the obligation to say you are in violation or prove you are in violation if that is what the case is. So, we would have to come and say you are supposed to be registered and it is our burden to prove that you are supposed to be registered. But you could easily say, no, I am a farm; I don't have to register. So, no, there is no penalty for being registered or penalty for cancelling. If you are not subject to the Rule, you are well within your rights to do that.

Q. Thank you.

Q. I have a question regarding the traceability requirements for what I would call kind of obscure subsequent recipients. I am thinking, for instance, if we collect flour dust from our dust collection system and we sell it to an animal feed producer or we distribute samples to our employees, what would be the requirements around those?

MS. FRASER: The flour dust going to an animal feed is an ingredient so that is a food

product subject to the Rule, and your immediate subsequent recipient is the animal feed manufacturer so you do need to keep track of records for the dust, and that animal feed manufacturer would have you as their immediate previous source and they would have to keep track of records for the flour dust that they receive as a food ingredient. And your second question--my brain just disappeared?

Q. Samples distributed to employees.

MS. FRASER: Oh, samples. In the Rule, and you could search on samples, there is an exemption for the requirement to establish and maintain records for samples that will not be consumed. So, if a sample is coming in just to be tested--you want to see what the stability is; what is the color; what is the pH--then you don't have to establish and maintain records for those samples. But if the samples are being distributed for anyone to consume, whether they are consuming it in the U.S. or consuming it somewhere else, then the record-keeping requirements do apply.

We have had outbreaks and we had people die from samples, samples consumed in restaurants or test marketing of product, and we have had situations where the product has not been manufactured properly and so that is the reason that it becomes a trace-back situation like any other.

Q. Some manufacturers have employee sales. Are they under the regulation or are they exempted from the regulation?

MS. FRASER: I am sorry?

Q. For employee sales, if a manufacturer has employee sales.

MS. FRASER: To the employees? Well, the employees would be consumers so you would treat them as any other consumer. So, to the extent that you are selling a product to a consumer you don't have to keep records--that exemption for sale to consumers was not just the retail partial exclusion, it was for anyone selling to consumers.

Q. So you see your employee as a consumer?

MS. FRASER: If your employee is buying the food or getting the food in their capacity as an individual under the family and friends plan, as I call it, yes, they are consumers. If you are selling it to an employee who happens to be giving it over to uncle Joe who has the grocery store then, no; then it is a business. But, basically, if it is like Wonder Bread selling in a company store to employees, that is a consumer.

Q. Thank you.

Q. Leslye, when we talk about trace-back/trace-forward and lot codes, unique identifiers, does the FDA care what is considered a unique identifier?

MS. FRASER: No, we don't. We were just recognizing that some companies use lot numbers; some companies have their own code. Even if you have a unique identifier and the key is locked up somewhere--you know, you know the key that breaks the code, that is fine as long as you can provide within that "as soon as possible, not to exceed 24 hours" the code so that if we do need access to the

lot number or the unique identifier we can actually figure out what that is.

Q. So, if we are moving a thousand pallets of coke or a thousand pallets of PMG or something like that, if we have a unique number that specifies that, then we can get by.

MS. FRASER: That is fine.

Q. That is very important, by the way.

MS. FRASER: Yes, that is fine. That addition was in response to comments that people sent in. It is not just lot numbers that they use, they do use unique identifiers.

Q. I just wanted to comment that I think your estimate on the cost of implementing this Rule is probably very, very conservative--

[Laughter]

--and I am not sure--

MS. FRASER: Low or high?

--well, let me ask this question, how many of your businesses have bookkeeping staff who will cost you \$216 for maintaining these records? The reason I am bringing that up is that I am a little

bit befuddled as to why you would exempt foreign manufacturing operations. In order to keep a level playing field--we are seeing so much global pressure, especially agribusinesses and other ingredient manufacturers, it is going to be a significant cost to us, and it seems that to keep the playing field level we would want to make that a requirement for our overseas competitors as well.

MS. FRASER: A couple of points: First to get to the cost, the cost estimates are really average cost estimates. So, if you read the economic analysis it is not to say it is going to cost \$750 \$800 for every person. It was averaged over the entities that are subject. Many commentators said--well, two points: What we tried to do was start with the Rule and just look at trace-back investigations that have failed and why have they failed. Where were the missing data elements and what did we need? So, what we put in the Rule were those things that we thought were the minimum requirements necessary to do an effective trace-back. Some things we thought might be in the

minimum that we did not include, like the lot number all the way down, because of the cost effectiveness or the cost prohibition on doing so beyond the packer. So, I guess the first point is that that is where the requirements came from.

The second point is that many commentators said that a lot of those records we have already, whether it is bill of lading or whether it is shipping, and so they may not keep all of the data elements but they keep them ready for manufacturing purposes, for sales purposes, for income tax purposes. They have that information, maybe not in the level of detail needed, maybe not applied to each production run. So, it wasn't starting with a blank sheet; it was an incremental cost on what was already being kept.

Then, we took into account the comments that we received and, you know, I can't speak to that; I think our economists tried to do the best they could with the data they had and the comments they had.

With respect to the foreign side, a couple

of points there. One, the foreign suppliers say already that they have a rule that none of you all have, unless you happen to be a foreign manufacturer. They have a prior notice requirement so on the other side they scream that we have created a trade barrier and a disproportionate impact on the foreign suppliers because they now have to provide information earlier to their brokers, and most of the brokers are charging more money to do so, but they have to file the prior notice requirements. They don't have the retention periods, and so forth, but some of the information that we require in that rule is more detailed. They have to tell us the manufacturer, the country of origin, the country from which it was shipped, when the food is going to arrive. It is pretty specific as to what the foreign entities have to do.

The second point, as a matter of practicality and international law, is that we don't have the authority. We can walk in with a presentation of credentials and, upon proper



notice, Charles Breen and folks can walk into your facilities and do an inspection. We don't have authority to do that in a foreign country any more than even if you are supplying food from your facility to a foreign country they have the authority to walk into your plant here.

So, as a matter of practicality, to enforce the requirements, to do a trace-back we have to work with the foreign governments to gain access to those entities, which we do currently when we are doing a trace-back. So, between the prior notice requirements, the practical realities of having a rule in place where we don't have the ability to demand access within 24 hours to a facility that is not on U.S. soil, that is where the judgment was made.

So, I understand the point about the level playing field but you have to look at the bigger picture of the Bioterrorism Act as a whole and, you know, we think we have implemented the authority in a way that is cost effective to implement and gives us the additional tools we need on both the

domestic and the foreign side.

Q. Clarification on tracking lot numbers directly to the customer, we manufacture food service products. We distribute through a direct distribution chain directly to restaurants. Now, restaurants are excluded so would we be required to record specific lot numbers delivered to those restaurants?

MS. FRASER: Yes, you are required to do that because you are the manufacturer. The fact that they are excluded doesn't really impact that. They are excluded from the requirement to keep their own set of records or give us access to records, but you are subject to that because you are the manufacturer of the product so you have to keep the lot number with respect to anyone you sell to that is not a consumer.

Q. Even though we don't currently have that business practice, that would be a business practice that we would have to institute to do that?

MS. FRASER: If you are producing a

product with a lot number, then yes. If you have a food product or fruits and vegetables, whatever, that don't have lot numbers then we are not requiring that you do maintain it, but to the extent that you have it then, yes, we do.

Q. I hate to beat a dead horse but for a retailer, are they required to keep records regarding their immediate previous source?

MS. FRASER: Yes.

Q. So, if I have a gallon of milk coming into my retail store it has a lot code on it of some sort. Am I required to keep track of what lot codes came into my retail store although I don't have to with what is going out?

MS. FRASER: No. Let's back up to immediate previous sources. These requirements apply to all non-transporters so that is all manufacturers, all processors, all packers, all holders, all distributors, receivers and importers--so everybody but the transporters. So, everybody in that group has to keep firm name and contact information, description of the food

received, the date the food was received.

Then the second bullet, here, is the only one that is a caveat. So, out of that group, if you are a manufacturer, a processor or a packer, you also have to record the lot or code number. If you are not one of those three you don't. But then you still have to continue with the rest of the records required for the immediate previous source which is the quantity, the firm name, etc. So, the lot number is just one data element in the immediate previous source records and in the immediate subsequent recipient records, and that is the only data element that has limitations on who has to record it but everybody else has to record the rest of the data elements.

Any other questions?

[No response]

Well, thank you very much for your attention. Again, to the extent that you have questions and you send them to us, we will get to them as soon as we can. To help us along though, questions, a suggested answer and a rationale helps

our thinking as well, whether we agree or disagree, but at least it puts things in context and gives us a starting point. So, to the extent you have a view on the question, it would be helpful to hear from you as well.

So, thank you and have a good day.

[END OF TAPED RECORDING.]

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