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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

SAN FRANCISCO, CALIFORNIA

Thursday, January 27, 2005

San Francisco Downtown Courtyard
San Francisco, California

[TRANSCRIPT PREPARED FROM A TAPE RECORDING.]

02N-0277 TR5

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P R O C E E D I N G S

Questions and Answers

MS. FRASER: I have several here and then we will see who wants to be the first brave soul to go to the microphone. This one says we are a distributor. We use our own trucks to deliver products to retailers and restaurants. Do we need to comply with the non-transporter as well as the transporter requirements?

No, you are either one or the other. If you are a manufacturer or a distributor with your own trucks, then you are a non-transporter because, again, a transporter is one that has custody, possession or control of the food for the sole purpose of transporting it. If you are a distributor you do not just have the sole purpose of transporting it; you are probably breaking down pallets or rearranging pallets, or something else. So, you are either one or the other and you need to look at the definition for transporter and non-transporter to see which bin you fall into.

This brave soul says to assist all of us

to assess the business value of compliance, what are the penalties for not complying--

[Laughter]

I won't tell you his name but he is brave enough to put it here--for manufacturers, transporters, retailers, etc?

You don't really expect me to answer that! We assume, as with all regulations, that you will be in full compliance. I think the costs that are in the economic analysis section are the costs of actually complying with the Rule, which are the costs for establishing and maintaining records above and beyond what you may not be doing now. One of the reasons the average was less than $1000 is we assume that a lot of the existing business records could be used and that you only needed to supplement them for the difference, as well as have provisions in place to make sure you can meet the 24 access requirements. We also assumed a lot of records were retained longer than the one or two years that are specified in the rules or six months in the rules because for IRS purposes you can get

audited, I think, up to five years. Or, you may have contracts that you want to be able to litigate if someone is not in fulfillment of those. So, those are just the costs of complying with the Rule.

The costs of non-complying include legal fees if we bring an action against you. So, however much your attorneys may happen to charge you is in there. I think it is a lot more than $1000 average to comply. But that is probably as much as I will say on that one.

The next one is will California have their own title rule? I am not quite sure I understand that. In terms of whether states have their own similar trace-back requirements, some do maybe or some have their own kinds of record-keeping requirements. Again, we try to just specify what has to be in the records, and you may already be keeping records to comply with other FDA regulations, other state regulations, local regulations or just good business practice. There may be manufacturing records and, to the extent the

information that we require is in those records, you do not have to create a duplicate set. You can use those records to meet both objectives. To the extent that the other records may have some of the information but not all, then you can choose just to supplement them with the missing information. So, we don't require you to create a brand-new set of records and have everything in one place. You just have to have, with whatever system you come up with, the ability to give us access within the "as soon as possible, not to exceed 24 hours," however you compile it, whatever format. Even if it is a shoe box, you need to be able to pull out the right shoe box within that "as soon as possible, not to exceed 24 hours." And, that might be the small mom and pop who decide to keep bills of lading if that has all of the information. Maybe you work out with your suppliers your bill of lading doesn't have all the right information but you work it out with them that they start adding what you need so that you have a record delivered with the product. But we leave to you how to make sure you have the

right information.

How will FDA determine compliance proactive or reactive? That is a great question and we are still wrestling with that ourselves. Part of the issue goes to interpretation. You know, we have the right to access records when there is a threat of serious adverse health consequences or death to humans or animals. So, clearly on the reactive side we would find out if we are in a public health emergency and somebody doesn't have the records they are supposed to have. That is a prohibited act and it is probably the least of our problems right there, especially if it is a terrorist attack and we are trying to make sure we get all of the tainted product off the market.

How we can do it proactively is really I think working in cooperation with the covered entities. We do not at this point, under our guidance, have mandatory access to those records. You may have inspectors who are willing to work with you on a voluntary basis and maybe participate

in a voluntary run with you and say, okay, I will randomly pick a date and I will randomly pick an outgoing product and let's see what this time frame looks like for you and us, with no penalties associated with that but trying to work with you on it.

I am not real sure. I think we are still trying to figure that out ourselves in terms of do we have the legal authority or the ability to proactively look at the records. But right now all that we specify in our guidance is the mandatory access provisions in the public health emergency situation. If we come out with a different approach we will certainly put it out in writing for comment beforehand. So, it is not something we are doing right now.

Let's see, if a pallet of ingredients is received with multiple manufacturer lots on it and an internal control lot code is assigned to the pallet, does one need to record the manufacturer's original lot codes, or is it sufficient to record the ingredient, manufacturer contact information

and the internal lot code for the pallet lot received?

We really ask for lot numbers to be recorded to the extent they are reasonably available. So, if there are, let's say, ten lot numbers on one pallet and the pallet has a separate lot number on the bottom of it, presumably somebody has the code that deciphers the one to ten ratio. If not--maybe it is the manufacturer, whoever put that together and put the pallets with the lot numbers--that is one I guess we have to think about. We say to the extent it is reasonably available. The point and the intent is, again, to try to focus the investigation as quickly as possible, and to the extent that there is something we are detaining because it presents a significant health threat, we want to just detain that product that we think is implicated, not any other similarly named product or brand product.

I think, clearly, what is reasonably available is the pallet number, whether it is reasonably available to you to actually also have

the specific manufacturer's number that is within the pallet I think is one of those that is a case-by-case basis as well. To the extent you have thoughts on what we should say on that and how that works in the real world, please send it to us so we can add that to the Q&A guidance document.

If grapes are mechanically harvested which breaks the skins and releases the juice, is the location a farm or manufacturing plant?

That is still a farm. I mean, you are really talking about a harvesting activity. Unless you are capturing the juice and making juice which is a different issue, which I think would become manufacturing. But if you are really just talking about the process of harvesting grapes that are grown and you are taking the harvested grapes and selling them, that is a harvesting activity which is a traditional farm activity. It would still be exempt as a farm.

Are filter pads, membranes or filter aids, such as diatomaceous earth considered food?

Anything that contacts food, yes. There

is a pretty extensive discussion. If it is not in the record-keeping rule, which I don't think it is, it is in the registration rule. You can find that on the same website. It really talks about a distinction between products that contact the food and products that are used just to process the food but they are not left in the food. It is really detailed and specific so I would encourage you, whoever submitted that question--I know for sure it is in the registration rule and I think it is also in our registration Q&A guidance document under food contact substances--to look at it. It really talks about it from a legal perspective of what we consider a food contact substance versus something that is a processing aid, and we do make distinctions between the two. That is probably the best I can do because I don't remember the distinction off the top of my head.

With that, that exhausts my paper copies. If you want to go to the microphone?

Q. If a facility is engaged primarily in research and development with food and food

ingredients and they send food out for compositional analysis, for example, or if they send samples out for animal research, is that food required to be tracked or is it exempt from record-keeping?

MS. FRASER: We do have a discussion in the Rule under samples. There is a discussion in registration and also one in prior notice. But for record-keeping purposes we make a distinction between food that will be consumed anywhere, whether it is in the U.S. or not, by humans or animals and food that is going to just be tested analytically, stability. So, if the food is going to just be tested without tasting, then there is no requirement to establish and maintain records but the product is subject to the records access provisions for any records you may happen to keep to the extent we end up with that becoming a public health issue, often not likely. To the extent that one or more persons or animals are going to be given the food to taste, then the full requirements apply.

Q. If the animal is just like a laboratory rat, is that included or is it only an animal like a pet or a domestic animal used for food?

MS. FRASER: That is a good question and I don't think we distinguish. So, again, I think if you have thoughts on whether lab rats and other animals should be included or not--I have my own reaction but it is one I probably need to bounce off other people--please send that in. Separate from the lab rats, but why the tasting by one or more people, the reason is that we have had outbreaks and we have had deaths with samples being consumed in restaurants where people have become ill because the product has not been made correctly. So, there is a reason why we find it important to cover those as well so we can see where the other samples go. But your point about lab rats is well taken.

Q. Thank you.

Q. Two questions. A mill that is generating feed for poultry, is that considered

part of the poultry industry and under the USDA, or is that mill under the regulations that you are talking about?

MS. FRASER: Animal feed is ours solely.

Q. Solely, no matter what industry?

MS. FRASER: Yes, poultry products or the bird itself is the USDA piece of it but animal feed is--well, I shouldn't say solely, but animal feed is an FDA-regulated product.

Q. Then, if the mill is wholly owned by a company, is the requirement then to track it from that mill into their ranches and so on down the chain? How is that considered?

MS. FRASER: We don't require intra-corporate transfers. For example, if we go to any manufacturer delivering to a retailer we are looking at the point that the person--so if a person is a corporation and receives the food and releases the food. So, as long as it is still within your mill to your distributor, then we don't count that as your immediate subsequent recipient. Your immediate subsequent recipient is one you give

it to, a different person that is not you.

Q. Here is my dilemma. You have these ingredients going into the feed. The feed then is distributed to ranches that create the poultry that goes into the processing. It seems that you need to be able to track that original ingredient path somehow.

MS. FRASER: We do, but do you own the ranches or does somebody else own the ranches?

Q. We own the ranches. If somebody didn't own the ranches, then I would assume that is a transfer and you would have to track that.

MS. FRASER: Right, but you are really releasing the food at that point, the bird which is not the poultry product. The bird itself is a live food animal for which we share jurisdiction. So, when you release the bird--

Q. You share jurisdiction with USDA on the grow-out farms then.

MS. FRASER: We do. USDA is the one that has primacy on the farm.

Q. Is there anywhere where we could see a

coordinated discussion between the USDA recall guidances and FDA and if there is overlapping. Are these coming together anywhere?

MS. FRASER: We are working on that. Yes, they are coming together both in terms of guidance under these bioterrorism rules, as well as generally trying to clarify things which we share and where the line should be drawn so that people can at least understand who is going to do what, where.

Q. Thank you.

Q. Several questions actually. In a manufacturing situation in the baking industry, if you are having dedicated silos but your pattern and practice is to have trowels that are not sanitized because you are keeping cultures going in terms of fermentation, say that you are not using silo A as an example, but there was some contamination that is in the trowels, how do you deal with that? You may be segregating the source, the dedicated silo source, but you still may have a contamination issue. So, say, you are using A this week and then

B next week and you are not tracking the difference?

MS. FRASER: So, you are basically saying that the problem was from your A silo and you are now tracking B week, and you may find an outbreak with the B week but it is really due to the A silo residue that is in another part of the line but not the silo.

Q. And it may even be that the silo goes straight into the manufacturing process in a dedicated way but the trowels are shared so you still have the cross-contamination issue.

MS. FRASER: Yes, I think in that case it may be that how I explain my example isn't realistic to your scenario and that for you connecting incoming ingredient with outgoing product your records still say it could be A or B or A, B or C because, while we really were flowing for this cookie lot primarily from which the valve was turned on, we do know that we haven't cleaned the plant or the facility for the last--

Q. You don't want to know.

MS. FRASER: I don't want to know! Just like I didn't want to know when I got to FDA how many bug parts were allowed in my Fig Newtons!

[Laughter]

Some things you just don't want to know! So, it may be that what your records show is more pertinent to you. Okay, it is primarily B but, you know, maybe we know it is A or you want to say A or B. But I think we didn't try to specify because it really is based on a case-by-case and you all know your facilities as to what is realistic and what should be recorded.

Q. And, in terms of prior notice, if you are considering an offshore supplier and you have either an EU or a Chinese supplier of organic raw ingredients and they have warehousing already established so that you are not actually doing the importation, do you still have to make the prior notification?

MS. FRASER: On prior notice, we don't say who has to provide the prior notice. We just say we have to get it before the food arrives. So, we

leave it to the business parties. Typically it has been--not always because you can file it yourself, but typically people have been using their customs brokers who would otherwise file entry to file the prior notice.

Q. All right. The third is in the case of a non-profit exempt where they may be manufacturing food for distribution in the home delivery context or soup kitchen but, to defray their operating costs, they are also placing food into containers and selling from their kitchen to the general public, do they then also have the recording responsibility?

MS. FRASER: They have a recording responsibility for that portion of their operations that deals with the general public. So, they would have a requirement to record immediate previous sources of the ingredients. To the extent their immediate subsequent recipients are consumers, they don't have a recording responsibility there. To the extent there are businesses that aren't non-profits, they do.

Q. Thank you.

Q. Hi. First I want to say it is a very informative, well presented program and I see why you have groupies.

[Laughter]

MS. FRASER: Thank you.

Q. We are a large retailer and have a couple of questions. One, if I am using my own private fleet to transport goods from a manufacturer or between my own facilities, what kind of record-keeping do I have to maintain about the transportation services? Again, this is my private fleet.

MS. FRASER: In that scenario we don't require you to track intra-corporate, from plant to plant or plant to warehouse to distribution site. That is all yours. We look at when do you actually release your food product. So, you would be recording incoming ingredients, whatever format they are in, that you receive from another person or another entity. In whatever form you release it, you would be recording the release. So, you

are under the non-transporter requirements and part of the requirements you have are where it says identify when you released it, the transporter who took the food from you is yourself.

Q. But just to clarify something, if I am shipping it from my distribution center to one of our stores and it is on an outside carrier, I do have to record who the outside carrier is?

MS. FRASER: Right. You would still be a non-transporter, it is just that now the name of your transporter is the outside transporter, not you.

Q. Right, okay. The second question I have is regarding the compliance dates, which in our case would be next December. Do I have to have all the records for any goods in my system, whether it is at my stores or distribution centers, as of that date or only goods that we first received as of that date?

MS. FRASER: Goods you receive or released as of that date.

Q. Goods I received or released as of

that date?

MS. FRASER: Right.

Q. All right, thank you.

Q. We are an importer and I am trying to clarify the one up/one down kind of records. I notice too that you didn't mention ocean carriers. Our cargo comes in, in sealed containers and then those containers are picked up by our trucking company and taken to a processor. Then the processor dry-heat treats the seed and repacks it and then we have trucks that pick it up and take it to our different customers. Pretty much, we have a record of all of that. But which ones are we required to--I mean, do we need to know the ocean carrier and the trucker that takes the containers to the processor?

MS. FRASER: You are in the U.S. and you are receiving your seed from somewhere internationally?

Q. Yes.

MS. FRASER: So, you are in the non-transporter set and your immediate previous

source, non-transporter, is your foreign supplier.

Q. Right.

MS. FRASER: The transporter who brought the food to you is probably the trucker that shows up at your door to deliver the product. That is all you have as a non-transporter. The transportation company now has an obligation to say from whom they received the product, in which case it may be the ocean carrier. Now, if you happen to be the one that also owns the trucks, then you are receiving it from the ocean carrier via your trucks. It really depends on who you are using, but assuming you don't own the trucking company, the one back would be the truck. But since the truck is transporting food within the United States, they are separately subject to the transporter requirements and we would find out from them their immediate previous source is the ocean vessel.

Q. Then I also have a question about the BSE. Is pet food not exempt?

MS. FRASER: Right, all animal feed,

including pet food, is subject to the Rule.

Q. You know, we have had this problem come up already. We had some stuff that was held and they asked for ingredients, and it is just the seed, it is a raw seed. It doesn't have any ingredients and it took about a month to kind of get this explained to the FDA people. I don't know, finally they released it but, I mean, there are no ingredients. Why would it be subject to the BSE rule?

MS. FRASER: That actually does not get to be me--

[Laughter]

--so I don't really know. That really is probably more with the import procedures and that is something I would say you should take up with Barbara and her staff because it really may have been something that they thought it could have been, how it was treated or the process used to make the seed, or something along those lines. With BSE that is a different set of requirements. If it was a raw seed, not treated at all, that is

one thing. But if it were a seed that was processed in any way, to which something else may have been added, or if it were dependent on how it was manufactured or the animal it came from, or whatever, that is my guess as to what is happening on the compliance side. But I am on the regulations development side and then I leave it to the enforcement people, and out here it is Barbara. They do all of the regulations, not just the bioterrorism one but they have all of the regulations under their purview.

Q. Actually, this comes in through New York. So, I guess I will try and find--

MS. FRASER: On our website, if you go to fda.gov, you can find all the names of the district directors so you can find the one for New York. And, if that doesn't work you can always contact headquarters, Office of Enforcement.

Q. Thank you.

Q. I have a couple of questions. On seed in particular, is seed that is going to farmers for planting or packets of seed that would be used by

home gardeners being brought in, sold, moved through commerce, is that subject to this Rule?

MS. FRASER: No. We don't include seed for planting as food until it is actually a plant.

Q. So, it does not include seed if it is going in animal feed then?

MS. FRASER: Yes.

Q. Back to my two questions, the first one is with regard to animal feed. We have many pre-mixed plants, mineral plants and things like that, medicated feeds, in the feed industry. Some of these ingredients come in in sacks as opposed to bulk. In the case of medications, minerals, vitamins or things like this, each inbound sack of ingredients will have its own lot number. This individual sack, depending on which thing it is, may end up in ten different mixes, a hundred different mixes, a thousand different mixes on the outbound side. With regard to tracking lot numbers, where in this process, and to what extent, do these lot numbers need to be tracked in terms of being outbound?

MS. FRASER: The requirement to link incoming ingredients to outgoing product is with the immediate subsequent recipient of your final product. So, as you are relinquishing the finished product to the different entities, then your list of incoming ingredients very well may be the seed or the vitamins--let's use vitamins that were added to ten different batches or a thousand sacks of seed. That is where the linkage would be so if there were a problem with that bag of vitamins we would know there are a thousand sacks of seed that went out that we now, in doing the trace-down, may have to identify and recall if that is where the problem is.

Q. Okay. My last question, in California, with regard to day-to-day feed inspection, feed contamination incidence, quarantine loads and things like this, of course, it is handled by the California Department of Food and Agriculture typically on a day-to-day basis, except in isolated instances, BSE in particular there may be an FDA inspector that comes out. As

far as these rules in particular--I just lost the acronym, the determination of immediate threat to animal--

MS. FRASER: SAHCODHA.

Q. Thank you. Who is going to make that determination? Is this strictly FDA authority? Is it going to be a shared authority? Or, how is that going to work down the road?

MS. FRASER: This is an FDA authority but there are other provisions in the Bioterrorism Act that say that if we do have a SAHCODHA threat--which we would do anyway but the Act actually specifies that we have to communicate that to the state in which the product is located. If we are detaining a product we also would work with the state. But the authority to make a finding under the Bioterrorism Act is FDA. We may gain information from states or from anybody in terms of making that determination, but it is an FDA determination.

Q. And will remain so? So, there may be some inter-communication but not necessarily a

shared authority.

MS. FRASER: Right. Now, that doesn't mean that the state wouldn't be operating under its own authority to take action. When you look at the detention authority, before the Bioterrorism Act was enacted FDA didn't have any authority to detain food. They could seize food in court but often what happened is that while we might have identified a threat, while we go to court to try and get it seized, the unscrupulous person has moved the product or it has disappeared, and all we have had to work with is the state to actually detain the product under the state authority. So, there was a loss of time. The states really wanted to know why you are actually going to do something; are we going to be stuck with this food on our hands because you have changed your mind due to resources, or whatever? So, the detention authority was to give us our own ability to take action without having to use the state resources. But the states may still choose on their own initiative, under their laws, to detain food

products separately and there is nothing that precludes them from doing that in the Bioterrorism Act.

Q. Thank you.

Q. Hi. I am from the New Zealand Trade Commission. We are ostensibly part of the New Zealand embassy.

MS. FRASER: I can barely hear you.

Q. Sorry. I am from the New Zealand Trade Commission. We are part of the New Zealand embassy. From time to time we have companies in New Zealand who send us sample products which we then forward on, for example, to retailers for trialing or for trade shows. Are we required as a diplomatic post to maintain records as somebody who stores or holds food products?

MS. FRASER: For activities that you are doing for yourself or products that are coming in a diplomatic pouch, those are not subject to requirements, or things that you are doing in an embassy facility that is part of foreign property. Even though it is physically here within the 50

states, that is counted as New Zealand land.

Q. Generally it is not sent through a diplomatic pouch and the product does end up with a U.S. retailer.

MS. FRASER: Then that would be subject to the requirements both on the prior notice side, as well as the record-keeping side but, you know, it really hinges on are you a foreign person transporting food in the United States or are you acting in your diplomatic capacity.

Q. I think we will err on the side of caution.

MS. FRASER: Right, I think you are more in the foreign person transporting food.

Q. My second question is in relation to foreign food manufacturers, for example, who physically bring product for trade shows. They bring product samples and they are required to submit prior notice if they bring that product in their luggage. Do they also need to then keep records as a person who is transporting food within the U.S.?

MS. FRASER: Yes, they would because they are actually transporting the food in the U.S.

Q. Right. Thank you.

Q. Hi. I had a couple of questions. I wanted you to expand on the aspect of samples and record-keeping. I work for a consulting product development firm so we have lots of ingredients, lots of different products. We may formulate with ingredients coming in from suppliers or go to the retail store with the food technologist who is whipping this stuff up and tasting it. Do we have to track every lot that they are trying, or is that considered personal consumption?

MS. FRASER: If you are doing it for a business it is not personal consumption. Personal consumption is really you in your individual capacity, something you would do at home with family, friends. So, if you are mixing it up and the intent is to sell it you are really acting in a business capacity. The personal consumption would not generally apply. In terms of product samples, they are food under our jurisdiction and to the

extent that you are providing food that will be consumed somewhere, whether it is in the U.S. or abroad, whether it is a small sample or a large quantity, unless it meets some other exemption, then the record-keeping requirements would apply.

Q. So, let's say you have ten different little bottles of flavored soda and you are putting a different flavor in each one, you are just trying it and then you are tweaking it a little bit here and there, they would have to have a record of each little one?

MS. FRASER: The way the Rule is written now, yes. Now, to the extent that you have thoughts that we should--and I will say there is some discussion in the Rule on samples. I would ask you to read that, and to the extent that you think that is not quite it or that there should be another interpretation under what we have provided, then please send it to us because, again, in terms of the real-world practicalities of what people are doing in labs or with samples or what the common distribution is, that is something we definitely

can think about and see whether it makes sense to do something different. So, see whether what we have said addresses it or, you know, if you think we have missed the mark entirely or it doesn't answer another set of scenarios.

Q. Thank you.

Q. Hi. I represent a food processor. I was wondering if you have ever evaluated or done a correlation between the requirements of FDA and HACCP.

MS. FRASER: Well, HACCP are some of our requirements too and they are also USDA requirements. Again, to the extent that you are keeping records for HACCP that meet these requirements, then that is fine. We didn't really look per se at each set of regulations and say, okay, here are the infant formula regulations, here are the HACCP regulations, here are the low acid canned food regulations. We approached this regulation by starting from the perspective of trace-backs and recalls that we view as failures in whole or in part in areas where the investigation

was delayed, where we weren't able to continue it, where it stopped, and what were the problems. Some problems, it was lack of records; some problems, it was incomplete records.

Then we went to what were the things that we think would have made for an effective investigation. What are those records we think we should have, or the contents of those records. Even then we made some trade-offs. Like, for transporters we limited it to a year even though two years in the ideal world would have been better but there were cost trade-offs there.

The third piece we did was say, okay, now that we have a list of what we think is required we won't specify any format. We will allow people to decide on their own with whatever records they may happen to be keeping, whether it is for HACCP, whether it is for low acid canned foods or anything else, do they meet these requirements and, if so, then they are done. If they don't, what do they need to supplement it. So, we have left the burden to others to figure out what meets their needs

based not just on HACCP, and that way as HACCP changes we don't have to come back and say, well, now we need to amend this rule because we told people HACCP worked but it doesn't because they have added or they have deleted. So, no, we didn't do that side by side comparison because our approach to the regulation was different.

Q. Thank you.

Q. Good morning. I am from Dole Food Company and I have three areas of questions. The first one is the area regarding foreign persons. Your explanation earlier helped but it didn't quite answer all the questions. We have U.S. operations that grow food, pack food, process food. It is covered within the regulation. We also have those same type of activities going on in foreign locations--bananas and pineapples, let's say.

My question is those foreign operations, are they considered foreign and are they excluded? Or, the fact that they are a subsidiary of a U.S. corporation and that U.S. activities are included, does that make the foreign activities also

included? For instance, would the FDA come to our corporate offices in the U.S. and ask for records regarding operations in Latin America or Asia?

MS. FRASER: No, for records--let's just talk about records, your foreign operations are included in prior notice most likely.

Q. Yes.

MS. FRASER: But for record-keeping purposes we count foreign persons as including facilities and foreign countries. For example, Costa Rica--

Q. Yes.

MS. FRASER: I actually toured one recently on a cruise tour, but the operations there would not be covered by the record-keeping rule because that is a foreign facility even though it may be U.S. owned or a U.S. subsidiary.

Q. Yes.

MS. FRASER: For your operations here, you know, you are sending let's say your bananas from the Costa Rican facility here. Whoever is receiving those bananas, their immediate previous

source would be the Costa Rican name with the contact information there. But that is part of their records as immediate previous source. It is not the obligation of the shipper or the Costa Rican facility to keep those records for this Rule.

MS. FRASER: The only piece that you may tie in is if we were doing a trace-back and we ended up at headquarters and we said, okay, we have a concern about this shipment coming in, it would only be to find out, well, the immediate previous source was a particular farm abroad. As far as those records, that is the extent of what you have to maintain. We now may work under other authorities, working with the Costa Rican facilities to kind of figure out what that problem is but that is not a record-keeping obligation at that point.

Q. Okay. My second area question is at Dole we also own our own shipping vessels and own an ocean cargo division. We have situations where a third party will be bringing containers in. At the transfer point the third party, or the company

that owns the product in the containers will have another third party come in and do fumigation of that product before they pick up the shipment. Our question is regarding us as a transporter, do we have any type of record-keeping regarding what that third party fumigation service does, or does the fumigation service or does the owner of the contents have that record-keeping?

MS. FRASER: Well, you actually now have a facility at whatever point that is occurring. You have a facility that is performing a manufacturing activity because we count fumigation as doing something to the food and it is a type of manufacturing activity. So, the obligation to register the facility goes to the owner, the operator or the agent in charge of the facility.

Q. It is a registered facility.

MS. FRASER: So, you may be the owner. The person coming in and fumigating may be the operator. It is one of those where it is a shared responsibility. Somebody has to register the facility and if nobody registers the facility, all

three are responsible. The same with record-keeping, you have a manufacturing activity taking place at that facility. Somebody needs to be keeping records of that activity and it should be the person who is performing the manufacturing activity who should be responsible for keeping that activity. It gets into what is your responsibility. You know, are you the owner of the facility? It kind of gets into the legal responsibility versus the actual activity but we expect that there should be some record-keeping kept. It could go to both. I would just make sure somebody is doing it.

Q. Okay. My third question, I think I may have misunderstood an answer you gave earlier. Someone was asking about when they do a transfer from their warehouses to their retail units using their own private trucking do they need to record that or not. I had thought that that would be an intra-company transfer that would not need to be recorded.

MS. FRASER: If they own the retail

facilities also it is an intra-company transfer. If they don't own the retail facility, then they need to record immediate subsequent recipient which is the retailer. They also need to record, as a non-transporter, the transporter that took the food from them, in which case it would be themselves. So, they are recording it there. So, it depends on whether the retailer is theirs or not but intra-company transfers we don't require to be captured under the Rule.

Q. Thank you.

Q. Leslye, we manufacture fruit and vegetable salads and during the manufacturing process a lot of the plant material, unusable material goes up into a waste stream. That is contracted by an outside entity to pick it up and he may choose to use it in one of three ways. One is to take it to a landfill, to use it as a compost material or, three, as feed for animals. In that situation, what is our obligation as a manufacturer in terms of record-keeping? Since our products are perishable, the way I understand the Rule right now

is that we would have to maintain the records as a non-transporter for six months. If the outside contractor or the entity that is taking the waste material is using it as an animal feed, do we then have to maintain the records for one year on the waste stream?

MS. FRASER: Well, if it is food you are releasing, then you should be recording that food you are releasing, who you released it to, quantity and so forth. So, that is your obligation. The retention periods are based on the state of the food when you receive or release it. In your case, you are releasing it as a perishable product and your retention period is six months.

You know, there are two sets of records. There are records for immediate previous sources and it is tied to the condition of the food when you receive it, and immediate subsequent recipients that is tied to the condition of the food when you release it. It is not based on whether you know they are going to make it into a longer-term product or not. It is just based on what is the

food when you get it and release it.

Q. Maybe I confused the question. I need some clarification. What I am looking for is when we make the salads we know that it is going to be used as animal food. The waste material that is being picked off, I don't know how that is going to be used.

MS. FRASER: It doesn't matter whether you know or not. It is just what is the perishability of the food. You don't have to know what they are going to do with it. You just have to keep records based on whether you meet the criteria for 60 days or less, 61 to 6 months or more than 6 months. In your case, it sounds like 60 days or less. You have 6 months regardless of what they are doing with the food.

The same like with somebody making tomato paste. They may get raw tomatoes. Even though they know it is going in as tomato paste, the records for the raw tomatoes are tied to six months; the tomato paste is two years whether it is them or somebody else. We just look at what is the

condition of the food when you receive or release it.

Q. Thank you.

Q. Hi. Good morning. My questions actually are similar to ones the gentleman from Dole asked regarding a foreign manufacturer wholly owned subsidiary and the intra-company transport of those goods. I understand the requirement if you use a common carrier to move those goods from the foreign manufacturer to the U.S. recipient. Does that also apply for a contract carrier? Would the same essential rules as for a common carrier apply then?

MS. FRASER: Will you help me understand?

Q. Basically, a contract carrier would be one that you engage. It is an outsourced transportation unit that you treat similar to an in-house carrier. In other words, you don't own the trucks; you don't own the tractors; the drivers are not your employees but you contract with them exclusively for the transport of your goods, not in a common carriage arrangement.

MS. FRASER: I think we would look at that as still a different entity. They are their own company with their own requirements and the fact that you contract with them to buy, sell or move goods is still a separate person. So, they would have their own obligation as a transporter.

Q. All right.

MS. FRASER: So, they would have transporter records. That is not you. Whether you contract with them or not, you don't have the same ownership, the same title or whatever.

Q. Okay. Well, the title stays within the organization. There is not a transferred title--

MS. FRASER: No, I meant the company. It is not your company.

Q. Okay. Then finally, again with the private in-house carriage, that is something that you have to keep a record of, the fact that you gave it to your trucking company subsidiary? Is that correct?

MS. FRASER: Right, because they would be

a different person. If you look at, you know, association or corporation, they are a different entity.

Q. All right. Thank you.

Q. Good morning. I am with the California Department of Food and Agriculture and we have a number of entities that we license through the state. We license both pet food importers and pet food processors. For record-keeping purposes the importer, whether it is coming from another state or another country, that would be their immediate previous source?

MS. FRASER: Correct.

Q. And the processor they are delivering it to would be the recipient? Correct?

MS. FRASER: Correct. Well, whoever is importing the food, their immediate previous source is abroad. Whoever they are delivering it to is their immediate subsequent recipient.

Q. That would be our licensed processor plant.

MS. FRASER: Right.

Q. Now, in the case of our processing plants, their immediate previous source is going to be the importer?

MS. FRASER: Correct.

Q. And then--

MS. FRASER: Their immediate subsequent recipient.

Q. --it is going right back to the importer because what they do is process it, break it down and return it to him for distribution.

MS. FRASER: Right.

Q. So that would be how that would work. Now, under processing, we have retail processors that we license. Some of it is custom processing, some of it is retail. The custom is for the owner of the meat that is brought in, the smoked, cured, dried, processed, whatever, returned back to the same customer. What records would be required to be kept there? The same thing?

MS. FRASER: The same thing. I mean, putting aside the issue of meat for the time period since we have an issue that we still have to

resolve on state licenses that are not USDA facilities--so let's not make it meat. Usually the immediate previous source is whoever it may be and even if you are doing an activity and returning it to the same person, your immediate subsequent recipient and your immediate previous source can be the same entity if that is what it happens to be.

Q. We don't allow that as retail sale in California though. That is strictly between the processor and the customer. But now when they take a USDA approved source and process it and put it in their retail sales counter, does that exempt that portion of it because it is a USDA approved source?

MS. FRASER: It is whether the food product is exclusively regulated by USDA. So, if the food is exclusively regulated by USDA, the record-keeping requirements do not apply.

Q. But if it is one that is regulated under our license, even though the source is USDA, it still requires--

MS. FRASER: That is the question we have to come back and answer, how does the state

licensing piece fit in when it is a meat product.

Q. So, that is going to apply to both processing and slaughter?

MS. FRASER: Right. That is the global question.

Q. All right, we will deal with that a little later then.

MS. FRASER: Right.

Q. My question is a follow-up on the lot number question. I know we had the one earlier where the question came up if they had a lot or a pallet that came in with multiple lots and they put the lot number on it, would that be acceptable. You gave us an answer but I don't believe that that is probably an acceptable answer because we have either 6 months or 12 months or a year and a half, depending on the size of the company, to be in compliance and I think we need to know when we will be in compliance and when will we not, and I think we also need to be able to tell the people that we sell our products to, because we do put a lot number on them, what is going to happen to them if

they are out of compliance on following a lot number that is reasonably available.

MS. FRASER: Well, on the lot number question, that is one we need to come back to on the pallet and the lot number on the pallet being different than the lot number of what is in the pallet. So, that is one that if people have thoughts on, please send them in and we will get them into a guidance document and address that.

In terms of your compliance dates, it is either 11 months from now, I guess, now--17 and 23, but our intent as these questions come in is to get them out in guidance documents as quickly as we can. The lot number issue is one in terms of what is reasonably available. To the extent you all have thoughts on whether that should be more clearly defined or even defined, or not quite defined but examples given to help people understand what the parameters are, we would welcome that.

Some of the most helpful guidance documents are, you know, here are situations and

how we think it plays out. We did not put it as a mandatory, flat-out requirement that lot numbers must be recorded in the Rule because we recognize that there are different situations where what may be reasonably available in one instance is not reasonably available in another.

You know, people say, well, that is not clear to me; you should have made it a lot more specific. The only way I know really to make it a lot more specific is to say it applies across the board as a manufacturer, processor or packer, or it applies in these ten situations and then you forget situation 11 which looks exactly or close enough to 10, so the 11 gets off and the persons who are in the 10 scream that it is not equitable because you didn't include those people. So, it is a difficult one to address. So, to the extent that you really do have thoughts on what does this look like in the real world, you know, when you are talking about a pallet that has one situation, how is that compiled; how is it broken down? Is it reasonable, cost effective for people to actually record the

internal lot numbers versus the external lot numbers? And, what are the factors that you would think about in terms of deciding something was reasonably available or not would be helpful to us because we are trying to make it as real-world without being so specific that we have left out people who should be covered, or been so prescriptive it becomes cost prohibitive.

I know that wasn't a complete answer to give you any more clarity but it really was left to try and make it case-by-case.

Q. Well, the way it is written, if it is reasonably available then we have to document that and be able to follow that through. So, that would say that if it is on the bag, is that reasonably available? I would think it would be in my judgment. But we need to know what the judgment of FDA is because the inspector is going to come in and he is going to give us a citation that we are or are not in compliance. So, I think we need to know what is reasonable. If it is in all cases if it is available, if it is on the bag, then we need

to know that and we need to be able to tell everybody that.

MS. FRASER: Right, and I agree. I think to help me answer that in a way that gives you that clarity, it is helpful for me to know are we dealing with a typical scenario, a pallet that has one number on the outside and there are five numbers on the inside that are easy for people to see? Or, are there a hundred numbers on the inside and the bags are all stacked together and they are shrink-wrapped so you cant really see those numbers at all? So, for me to say, yes, it is reasonably available for you to record the hundred lot numbers on each bag, you are going to say I can't do that without breaking apart the pallet.

The facts really help me answer what we are talking about. So, I can say in one instance it is reasonably available to take the one on the outside. In another case, if you tell me no, the pallet is a packing slip that tells you all the hundred numbers on the inside of this pallet, then I would say, well, that looks reasonable. It

really gets to specifics to make this meaningful in a way that does not really become something that requires you to break down a pallet under a reasonably available standard.

Q. But I would take it that if it is reasonably available--and we still need to come to a conclusion as to whatever that is--if it is reasonably available, then we do have to follow that--

MS. FRASER: Yes.

Q. --and all subsequent people will have to follow that on the new lot numbers--

MS. FRASER: Right, manufacturer, processor, packer, always, yes.

Q. My question is a carry-on to the lot number and I am specifically talking about a three-tier distribution system where you have a manufacturer, a distributor and then a retailer that is going to receive the product. I am focusing on the distributor and that lot number where the manufacturer would have the lot number available. Is that distributor required to track

it one up/one down at that point?

MS. FRASER: If the distributor is packing a product, yes.

Q. Not packing, he is just putting it away and then selling it on to the retailer.

MS. FRASER: No, then he is not a manufacturer, processor or a packer. No.

Q. So, he is not required to do lot tracking.

MS. FRASER: No.

Q. Good. Thank you.

Q. I was understanding that you didn't need to track transfers within a vertically integrated company, but let me just make sure I understand. If we are distributing products--we are a manufacturer and we are distributing to our own stores but we are using an outside carrier, then we need to track the carrier that is used when we release it to the carrier and our stores need to track the carrier that brought it? Is that right?

MS. FRASER: Yes.

Q. Thank you.

Q. I have a couple of questions regarding, again, the distribution area. First of all, is a public warehouse classified as a transporter or non-transporter?

MS. FRASER: It depends on whether a warehouse, public, private or otherwise, meets the definition of holding. So, holding is basically storage of food. If food is stored in the public warehouse, then they are a non-transporter.

Q. If the public warehouse also has a trucking function, would it at that point become a transporter or is it still considered a non-transporter?

MS. FRASER: It is non-transporter because it does not have the food for the sole purpose of transporting it. It is storing it also.

Q. Also, in terms of how a person is defined, and this gets into some of the questions about internal distribution, am I correct in understanding that for record-keeping purposes common ownership of separate legal entities, those are separate persons? That would include,

obviously, a subsidiary or brother/sister companies?

MS. FRASER: Correct.

Q. Thank you.

Q. In the food broker realm, if you are a company that takes title from a food broker and the broker has gone out to companies A, B and C and bought fresh vegetables, are you, as the company taking title in your distribution facility, required to know who the immediate previous supplier is, i.e., who produced, you know, celery boxes A, celery boxes B and C? Or, is the food broker enough for the record-keeping purposes?

MS. FRASER: Are you just taking paper title or are you actually doing something with the food at a facility?

Q. We actually bring it into our facility and then we turn around and sell it to the retail customer, let's say.

MS. FRASER: You are responsible--and this applies to anybody, not just a broker--for tracking immediate previous source of food contact

substances, like the celery boxes, if you are the one that is placing the celery in the box. If you are receiving the celery already in the box, then what you are responsible for recording is I received celery packed in ten ounce cases or cartons from X person. So, the only separate duty to record the food contact substance is if you are the person placing the product into the box itself.

Q. So, we can just put the food broker who never actually does anything with the box, except they get 25 cents, 50 cents per box, whatever their commission is?

MS. FRASER: Yes, if all you are doing is receiving boxes--I mean, you are moving the boxes from point A to point B but you are not putting the food in the box there is no duty to do anything.

Let me find this, if you go back to this chart, you are basically receiving finished container that contacts the food. This is the third one down. If you are the person that places it into direct contact, you are subject to all of the requirements. The bottom one is anything else,

if you are doing anything else with that container you are only subject to the records access provisions. You have no separate establishment and maintenance provisions.

Q. Great! Thank you.

Q. One follow-up question to the one earlier about the brother/sister companies, could you talk a little bit more about that, just different ownership or entities within a corporation and how that affects what is an intra-company transfer or not?

MS. FRASER: I think if you look at the definition of person, it is an individual, a corporation, a partnership, an association. So, to the extent you have established different corporations, whether they are subsidiaries, brother/sister, whatever but your corporate structure has already defined them as separate persons because they are corporation A, corporation B, corporation C, those are no longer intra-company transfers because we are looking at an intra-company transfer as something that is solely

within corporation A to anything under the A umbrella.

So, I think to the extent that you have already established separate persons, we would count that as a transfer from person A to person B, no differently than you transferring it to me when we are separate entities. So, it really goes to what is the structure of your corporation and whether this is truly intra or inter. If you set them up as separate entities, then they are separate entities.

Q. And what I am thinking about is probably more in line of acquisitions that weren't intentionally set up as different type of legal entities but, through how they were acquired and for legal purposes, they may be treated one way. From an operational viewpoint it may be integrated into our supply chain and we don't manage them as a separate entity.

MS. FRASER: I guess, again, this is one that I would say you could send us a comment on what is the scenario and how you think we should

interpret "person," but if I go back to the definition of how a person is defined in our statute, which is an individual, a corporation, an association, a partnership, it seems to me those already have legal terms and how you choose to operate is being all friendly, in the same box together, from a legal perspective my guess is that you are filing taxes separately. You are treating them as separate legal entities and that is the same situation we would have here. That is not consistent with how you are treating them and if there is some other interpretation you think we should give to the definition of "person" than what is in the regulation then, you know, you could send that in. But my initial reaction is it is a legal structure and it is a legal term.

Q. Thank you.

Q. I need a little more clarification on a food distributor as far as they are excluded, yet, you are asking that you have to have access to records.

MS. FRASER: They are not excluded.

Q. A distributor is not excluded?

MS. FRASER: No, persons who manufacture, process, pack, hold, distribute, receive, import, transport.

Q. So they must be one up and one down?

MS. FRASER: Right. What they are excluded from is the requirement, unless they are packing, to record lot number as one of the required elements in their records. But it is not a complete exclusion from the Rule.

Q. So, if they are receiving products they are going to have to record lot numbers?

MS. FRASER: Only if they are packing.

Q. We are not packing.

MS. FRASER: Then they don't have lot numbers.

Q. So, what record are you going to be looking for then?

MS. FRASER: These are the records that apply to all non-transporters including distributors. So, they all have to keep non-transporter and transporter immediate previous

source, firm name and contact information; description of the food received; the date the food was received.

The next one, the lot number is the one that does not apply to them because they are not a manufacturer, processor or packer, but everything else on this list does apply.

Q. Most companies would then just take the bill of lading and take that as a record, and would that be acceptable?

MS. FRASER: We don't make that call for you. We just say if your bill of lading--because some do and some don't--if your bill of lading contains all of the information we have here as to what is required, then, yes, it would be acceptable. If your bill of lading is missing some of these data elements, then, no, it would not be acceptable. So, it is for you to determine whether the information you are getting on your bill of lading meets the requirements listed in the Rule.

Q. Thanks.

Q. I have a question on the distributor.

Basically, we just bring boxes and ship boxes, however, we break down lemons, 50 lb. case and we put them in 5 lb. bags. Is that considered something that we have to have lot tracking going out for? Because we do get a lot--

MS. FRASER: If you do get a lot number and you are packing, yes. If you are breaking them down and there is no lot number, you don't have to create a lot number.

Q. Are there any regulations regarding the physical security of a manufacturing facility or the access that people have to those facilities?

MS. FRASER: We don't have regulations in place. We do have guidance documents in place that apply to manufacturers, processors, transporters, importers. Then I think there are some specific ones, but they are all on our website under food security guidances. There is quite a number, and they were developed in conjunction with industry in the wake of 9/11. USDA and the American Trucking Association, I believe, also just recently issued a joint guidance document that applies to

transporters. So, we do have guidance documents. Guidance documents are not binding. We cannot enforce them against you, but they do have some excellent recommendations on how to govern the security of your plant, including access not only from visitors but also from people within the plant; whether you really should have employees able to freely migrate and visit their friends who work in a different section, can they go over there or do you have some knowledge of who is moving in your plant where, and have limitations. So, yes, I encourage you to look at that on our website.

Q. Thanks.

Q. Leslye, this may be a question for Barbara and I would like to get your thoughts on it. During some of the most recent inspections at our facilities, the inspectional personnel came in and said they have access to the records. Did I interpret that incorrectly, or did they have statutory authority to ask for records and make copies of records?

MS. FRASER: That probably is a question

for Barbara. I don't really know.

Q. Because they were quoting the bioterrorism regulation.

MS. FRASER: If they were quoting the bioterrorism regulations and we weren't in a public health emergency, then--

Q. It was a routine inspection.

MS. FRASER: --yes, they don't have mandatory access to records. You will have inspectors that voluntarily request access to records as part of an investigation to see whether you are in compliance. There is no prohibitive act from precluding that. We also recently did a food--as part of the Counter-Terrorism and Homeland Security, we did have a number of targeted investigations on foods that were of particular concern and people were requesting voluntary access to records, but they should not have been invoking the Bioterrorism Act. I think I see Barbara standing in the back.

Again, we will be, starting next month, doing some training of the field to make sure they

do understand when they can invoke the mandatory access requirements under circumstances in which, if you refuse access, you are committing a prohibited act, which is different than what inspectors regularly do in terms of working with compliance and requesting voluntary access, which the Bioterrorism Act doesn't speak to.

Q. Thank you.

Q. We buy raw materials directly from a foreign source and we go through a custom broker. In that case, the transporter that we have to record is the trucking company? Or, is it the shipping vessel or just the custom broker that services us to bring it to our door?

MS. FRASER: One of the questions and answers in the Rule does address custom brokers specifically. So, you can read this answer in more detail. But generally we do not count the custom broker as the immediate previous source or immediate subsequent recipient. They are really just the agent doing the paper transaction for you. So, in your case, as a non-transporter, your

non-transporter immediate previous source would be the foreign supplier. The transporter immediate previous source would be the trucking company that brought it to you. Then that trucking company would have an obligation to keep their own up/one back and they would get the shipping vessel on one hand and they would get you on the other hand.

Q. How about when the foreign supplier has an agent here, in the States, and we just buy directly from that? You know, we just place an order to that agent and they deliver it to our door? In that case, the non-transporter would be that agent?

MS. FRASER: I mean, to the extent that you know the immediate previous source is really the foreign manufacturer, that is what we would like you to record. If all you know is the agent or the distributor and that is all you see, then that is your immediate previous source.

Again, when you are looking at what makes sense for your records, if you kind of keep it in the context of where we would be using these

records in an emergency to do a trace-back/trace-forward investigation so what are the effective records that let us know where did the food move so that if any one of those points was--again, not that this is only terrorist but if you think of it in terms of terrorist it kind of helps clarify the answers. You know, where are those points where the terrorist might have contaminated the food supply? That is really what we are trying to track. You know, what are those different nodes? Who was the immediate previous source so that we can keep going back up and back up the chain?

Q. Thank you.

MS. FRASER: Any others?

Q. Given that there are 700,000-plus of us out there, are there any software tools that you know of that the FDA has been working with the software companies to try and facilitate this kind of compliance that has some artificial intelligence involved with that?

MS. FRASER: Actually, there are a couple

of them here in the room who I am sure would be happy to identify themselves to you afterwards. Again, we specify the requirements. You know, back in the olden days when federal government did regulations and they did what people called "command and control," they said not only here are the requirements but here is how you will comply and everybody screamed. So, we have become a little more enlightened. So, we don't really get into the "here's how you must comply."

That being said, I think there are a number of private entities, and I think the market will bear more and more coming up where people are developing the radio frequency technology, having different software programs that can link products from the farm even, farm grain all the way through the grain elevator to the bakery to the retailer. So, I think there is a market for those out there. I think the best place to find information on that is through your trade associations because I think that is where a lot of people come and try and find out what the needs are. But we try to stay out of

the private enterprise aspect of it.

Q. You know, to have some reasonable cooperation with tool makers, whether they are small or large, seems reasonable. Obviously by my questions, I am not just thinking of one enterprise but they are questions that your excellent presentation raised for me. Even in a small setting where you have a small local manufacturer of tamales, as an example, where you have certain ingredients that are USDA regulated or there may be a raw vegetable ingredient, I am even asking myself why wouldn't you just have 2-year record-keeping, period. If you are going to go to the trouble of setting up a record-keeping protocol, given that 20 percent of your ingredients may be excluded and the other range of ingredients may be 6 months on the inbound or 2 years on the outbound--I don't understand. It seems like you are really setting people up to be vulnerable to potential criminal or civil liability.

MS. FRASER: Well, I think it is a difference between what we mandate as a requirement

and when you can be in violation of a law versus what people may choose to do because it is easier to do two years across the board and I don't have to figure out six months, one year, two years. We had different retention requirements, that were pretty similar to what you just suggested, in the proposed rule. If it was a really short shelf-life product, seven days or less, it was one year; if it was anything else it was two years, except for animal feed which was one year, and really the distinction with animal feed is it doesn't tend to stay in our cabinets as long as all those bulk products we buy and leave in the back of the cabinet and forget we purchased. Pet food tends to move a lot faster and animal feed does as well.

But we got lots of comments that said this is ridiculous. It is cost prohibitive. It is inconsistent with the DOT. So, again, it went more to what would we mandate and leave it tot he business community to decide, well, okay, I know I am not in violation; I don't have to keep it for two years but it is easier for me just to have the

same requirement across the board.

Q. It seems too that in the current environment where product innovation is really a competitive necessity, you could be throwing off 20 new products a year, all of which may have ingredients that have different recording requirements even if you are a small vendor.

MS. FRASER: I understand, but we were there at the proposed rule stage and a lot of people didn't like that requirement and we ended up balancing mandated versus what you would voluntarily do.

Q. I just want to make sure I am clear on this recipe idea. We have a list of ingredients and we have lot numbers. Do you need to know the quantities and the process?

MS. FRASER: No. We need the list of ingredients. We need lot numbers. We don't have a need, as part of a trace-back, to know the quantities or the instructions on how you made it. What is critical for us is tracing the ingredient because it is typically the ingredient that is the

problem, or the finished product that wasn't manufactured properly.

Q. Thank you.

MS. FRASER: Going once? Going twice?

[No response]

Thank you very much.

[END OF TAPED RECORDING.]

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