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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

BOSTON, MASSACHUSETTS

Thursday, February 1, 2005

Hilton Boston Back Bay
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P R O C E E D I N G S**Questions and Answers**

DR. BERU: Thanks, Gail. One thing about questions, as I said, the preamble to the Rule where we have addresses some 220 comments, our rationale and so on, that is a good place to look because you will find many things are answered there.

The other thing, as I said, because there is such a huge number of entities covered here, there are always situations that we may not necessarily have thought of or addressed. This Rule lays out the general record-keeping establishment and maintenance requirement, records access, but there will be some nuances, and so on, that we haven't looked at. So, those not directly answered and codified or in the preamble we will be issuing questions and answers for. The first one will come out, hopefully, soon. It is certainly going to be way before the compliance date even for the large firms. As we get more questions, we will be posting additional questions and answers similar

to the way we did it for prior notice registration and administrative detention.

We do urge you to send in questions through our web link. It wasn't up as of a week ago but it should be now. I was given information that it probably is up and running. So, submit questions, as much as possible real-life situations for us to consider and we will be issuing those questions and answers.

With that, I would like to open up for questions. Please use the microphone because I believe this is being recorded and, as much as possible, identify your name and affiliation so we will have it in the record.

MR. BOWDEN: Good morning. My name is Sam Bowden. I am with Polar Beverage, and my question is about returnable water bottles. I am a little confused with all the reading as to really what is the correct way of handling bottles coming back into our facility.

DR. BERU: You are a bottler, I take it? You bottle?

MR. BOWDEN: Yes, we do.

DR. BERU: That falls within the realm of packaging material that contacts the food. Water is food. So, you would be responsible for having in your records the immediate previous source of that bottle that you are using to bottle water.

MR. BOWDEN: If we send a bottle to a particular store and the consumer takes it to another store, are we to track it by bottle?

DR. BERU: Well, we have said, first of all, when you get the bottles from the bottle manufacturer, even though the bottle manufacturer is not required because they are not bottling water per se and they are just making the bottle, they will be subject to the records access provisions of the Rule. They will not have to record the immediate previous source and immediate subsequent recipient.

In your case, when you get those bottles from the manufacturer, you would have to have in your records the identify of the manufacturer from whom you got the bottle as well as the date you

received it, and so on. Now, your question specifically asks about water bottles you send out that are then returned to you, a reuse bottle.

MR. BOWDEN: That is right.

DR. BERU: That is one that we haven't specifically addressed in the codified or preamble.

MR. BOWDEN: It is subject to too much interpretation.

DR. BERU: Right, and those are the type of things that we want to clarify in questions and answers. This will be recorded, of course. We will be taking those questions and that is why we are recording it but if you want to clarify with more specific examples of your situation, please do send in your question in writing.

MR. BOWDEN: I have one other question. How do you address a product that comes back in, let's say a glass product that is damaged? It is reworked and there is more than one lot put into a case and then it is sold back into distribution?

DR. BERU: Remember, connecting the incoming product with outgoing, you have to keep

that information to the extent that information is readily available to you. There are situations, and we are aware of those, where a product comes into one container and so you don't necessarily know where that came from. You are taking product from that and bottling in your case. So, it may not always be possible to link the incoming with the outgoing. In that instance, I think what is reasonable is to have in your records the sort of sum total of where the product could have come from.

We want to be able to identify in tracing back if, God forbid, this should be the situation, coming back to your facility. FDA getting information from you saying that the water in this bottle could have come from so many different sources isn't terribly helpful for us because then we will have to look at everything to be able to trace back the one place where the contamination may have taken place. So, that is why we want linkage of incoming to outgoing product. But we fully understand that there are situations where

your business practice is such that it is not always possible to do that and the only thing you may be able to tell us is that the bottle that was shipped out on this date could have come from these sources.

That is what the Rule asks for--to the extent possible, connecting incoming with the outgoing. But if that is not your normal business practice, the Rule doesn't mandate that you re-engineer your process in order to be able to do that. It does not mandate, you know, costly re-engineering of your process.

MR. BOWDEN: Thank you.

MR. SIEFER: I am Alan Siefer, from Harris and Tweeder Supermarkets in Matthews, North Carolina. I have a question on direct store deliveries. We have over 100 stores and we have many different vendors, such as Frito-Lay, Cola, Pepperidge Farm delivering to our stores. I understand we have to track the company we are getting that merchandize from. But my question is a lot of these companies have franchisees such as a

Pepperidge Farm bread company that is like an independent contractor. Do we have to track that person as a transporter of the product or is it good enough to track the company it came from, such as Frito or Pepperidge Farm?

DR. BERU: Good question. Remember, the intent of this Rule is for FDA to be able to follow the movement of food backwards and forwards. In the case of contamination we want to be able to get to the source of the contamination.

While the big corporate name and address may be useful, that is not where the food came from. So, the Rule would require where you obtained the food from, in this case the franchisee as your immediate previous source, not the big corporate. While it is possible that that extra step for that information can be had by FDA, the intent really is to do a speedy--you know, in food emergency situations we won't have the luxury of lengthy trace-backs before serious damage is done. So, it would be the immediate previous source.

MS. DOWD: Good morning. My name is Mary

Ann Dowd and I work for Continental Airlines. As an airline we cater 50 percent of our own flights out of six facilities throughout the country. The employees who receive, pack and deliver the product to one of our employees which is another flight attendant on the airplane--it is all one company, all one chain. Would we be required to keep any additional information, other than the arrival information from the transporter?

DR. BERU: No, in this case you are directly putting it on the plane where it is consumed. It is your own firm, and we are not asking companies to keep records within company or within corporate transfers. So, you would have to keep the immediate previous source of the food that is coming to your catering facility but you are not really giving it to another entity, which is the situation in many cases and that is the main reason we did not exclude interstate conveyance caterers because they may prepare the food and then hand it off to another company to transport it, to distribute it and so on. In this case you are

doing the whole thing. You are essentially providing it to the consumer on the plane as part of that company. So, you will be required to establish and maintain the immediate previous source of the food.

MS. DOWD: When we do this for other airlines and we are trying to get over to another airline employee, would we be required to keep track of all those components?

DR. BERU: Yes, that is a different entity so the rules would require you to keep the subsequent recipient in that case.

MS. DOWD: And track it throughout whatever ingredients are within the facility into our other recipes.

DR. BERU: Repeat that, please, again.

MS. DOWD: Well, let's say, for example, we get a gallon of olive oil. Do we have to keep track of every recipe that gallon of oil goes into by the lot number?

DR. BERU: No. Well, if you manufacture food you have to track lot numbers of your products

that you manufacture provided you already do so. I mean it is to the extent the information exists. The Rule doesn't say that, all of a sudden, you never did that but now you have to track with lot code. But, yes, if you are making a finished product, whether it is a sandwich or a meal, the Rule requires you to identify the sources of the ingredients that go into that finished product. To the extent available, we want you to be able to tell us this is where the ingredients came from that made that product.

MS. DOWD: And one last question, looking at your economic impact, it seems just a little low--

[Laughter]

--when the Rule was originally written it stated that if the economic impact to an organization was considered to be a burden you could ask for an exclusion. What steps would need to be taken to become exempt if that were the case?

DR. BERU: You know, I had that question in Chicago as well, and the statute clearly says

take the size of a business into account when you issue these regulations. We may have said that in the proposal. The proposal is now a year and seven months ago. So, I don't particularly remember that line. Was it from the proposed rule?

MR. DOWD: Yes, it was in the initial rule.

DR. BERU: Right. We got comments from industry, many comments from industry, but we felt that, unlike restaurants--the reasoning was we are like restaurants so we should be exempt like restaurants. We have defined restaurants as those that prepare food and sell to consumers for immediate consumption. We simply didn't think you fell in that category as caterers because there are other intermediate steps before it gets to the consumer where contamination can take place. That is why we haven't excluded that.

Now, at the same time, your comment said, you know, you have the ability to trace foods in the distribution chain, and to the extent you are doing that, then really there may not be much else

you need to do. I mean, existing records that enable you to trace, provided they have the elements of the information that we are asking for, you do not have to recreate records. Existing records can be used to comply with there regulation. I mean, to the extent that information is here and information is missing, you may have to supplement those bits of information but you do not have to recreate records to comply with this regulation. Existing records are fine, whether paper or electronic, and whether the piece of information is on several pieces of paper or one piece of paper.

MS. DOWD: Thank you.

DR. BERU: That is how we have tried to reduce the cost of compliance with this. Now, with respect to economics, I really would urge you not to just look at those two slides. As I said, half of the document really is an economic analysis and our economists have done I think a wonderful job of addressing all comments. The numbers do seem a lot at first blush but I am confident the numbers are

right.

MR. WAGNER: Hi. My name is Jim Wagner. I have a question about food contact substances. Can you give us some examples of food contact substances that may be exempt?

DR. BERU: Okay, food contact substances are substances that go into the manufacture of packaging material. Those are food contact substances and legally those are defined as food. Now, those are exempt with respect to the establishment and maintenance part of the regulation but they are not exempt with respect to the records access. So, whatever records you are keeping now as a matter of normal business practice or because you are complying with some other regulation, we would have access provided we meet the threshold and we determine that a food is adulterated, and so on. So, we have record access with respect to existing records. But you are exempt from the establishment and maintenance part.

Now, finished packaging that contacts the food, there are two components there. There are

substances that go into making it and then the finished packaging itself that contacts food. If you are making that, distributing it, and so on, again, you are exempt from establishing records, the one up/one down records. However, you are still subject to the records access provision.

If you do package food with that food contact substance, if you are the packager of the food, then you have to maintain the one up with respect to the packaging. Of course, when you package the food you have to maintain the one down records as well.

MR. WAGNER: Thank you. So, food contact substances would not include such things as disposable utensils like spoons, knives, forks?

DR. BERU: In what setting? This is a manufacturing setting?

MR. WAGNER: I am thinking in particular about a commissary where we would produce food for distribution to our own retail stores and we line, say, baskets for bakery goods with a parchment type paper. Is that something that would be covered as

finished packaging?

DR. BERU: That would be finished packaging that contacts the food but again, here, you are exempt from the establishment of the one up/one down records. You are subject to existing records that you have.

MR. WAGNER: My understanding was that as a commissary we would be viewed as a manufacturing facility.

DR. BERU: No, I misunderstood your question. I thought you were a manufacturer of the utensils. As a commissary you are exempt. That is where food is prepared and sold directly to consumers, I take it?

MR. WAGNER: No, it is sold through our franchise network through their own retail stores. So, it would be a central production location that would produce donuts or bagels, baked goods, delivered to retail stores, and from the retail source or restaurants they are sold from there to consumers.

DR. BERU: Now, in this case you are

covered under this Rule.

MR. WAGNER: So, under this Rule, in our commissary if we have a basket for baked goods and use a piece of parchment to line a basket, would that fall underneath the Rule? Would we need lot control for parchment paper?

DR. BERU: If it is contacting the food, yes, you are required to keep track of the immediate previous source of that food contact, the packaging that is contacting the food.

MR. WAGNER: Thank you.

MS. WIERBICKI: Barbara Wierbicki, of Tomkins and Davison. With respect to entities that are subject only to the access requirements, are you going to publish somewhere something which will confirm that this is only the records kept in the ordinary course and not the record-keeping requirements that you have in the Rule?

DR. BERU: Well, the Rule is clear about that. I mean, it says --

MS. WIERBICKI: No, not really. I mean it says you are subject only to access of records but

it doesn't say what records.

DR. BERU: There are two things. As I said at the outset, record access means records you are establishing under this regulation as well as the records that you have with respect to manufacturing, distribution, and so on and so forth.

But if you are exempt from the establishment and maintenance of records--well, let me put it this way, if you are not exempt from the one up/one down record establishment, then the record access applies to those records as well as records you happen to have pertaining to manufacture, and so on and so forth.

But if you are exempt from the requirement to establish the one up or the one down, then record access applies only to records that you have, you happen to have, not to the one up/one down. I think we made that very clear--

MS. WIERBICKI: In the discussion. So, if I am importing water bottles that somebody is going to buy and he fills it with water himself--I am not

going to fill it with water but if I am importing water bottles and I am going to sell it to a retailer, I am only subject to the ordinary course records. Right?

DR. BERU: Right, yes. I was just going to say to the extent that is not clear in the preamble or the final Rule, do send us questions and we will clarify that but I think that is very clear.

MS. WIERBICKI: So, the same would apply to people who import dishes and glasses?

DR. BERU: Yes.

MS. WIERBICKI: Thank you very much.

MR. LONG: I am Jim Long, from Hudson Valley Food Works. I am going to confuse you now. I operate a food business incubator. There are only 20 places like mine in the country. We currently have 44 different manufacturers operating out of my facility. Basically, what we do is we rent kitchens to small manufacturers. We help them get started, help existing businesses as well. They bring in product. They take out product. They

store product, finished product. They store ingredients in our facility. What is our responsibility? Do we have to track everything that comes in and out of the facility in spite of the fact that each manufacturer will be doing that?

DR. BERU: As I understand it, you are renting out a facility to a manufacturer who is then carrying out the covered activities?

MR. LONG: Right.

DR. BERU: Well, in this instance you do not own or have custody of the food. It is the manufacturer who has rented your facility that. So, it would be the manufacturer who is renting your facility essentially because he is the one who is manufacturing, processing, holding.

MR. LONG: It is stored in our warehouse and in our freezers.

DR. BERU: Remember, you do not have to own the food. If you have possession or custody of the food, and that sounds like holding to me and storing in your warehouse, then you are responsible for establishing and maintaining the immediate

previous source of the food that you are holding and the immediate subsequent recipient of whoever you deliver the food to.

MR. LONG: But basically that means that everything that comes into my facility I have to track.

DR. BERU: If you are holding food, you have to, yes.

MR. LONG: Well, I might only be holding it for eight hours. It is delivered the day the manufacturer comes in and tomorrow he manufactures the product. He either stores it there or he takes it with him.

DR. BERU: Well, as written now, you are covered. However, let me say this, we did get similar comments from trucking terminal points who say they hold food briefly for the purpose of transferring the goods from one transporter to another. We have said in the preamble that in those instances you are really not holding food. You are only temporarily holding it for the purpose of transferring it from one transporter to another.

So, even though you are a warehouse, you don't come under the purview of these regulations. However, we haven't addressed your situation, and it seems to me your situation is somewhat analogous to that and we would have to clarify it through questions and answers.

As I said at the outset, these are the types of specific examples, real-life examples that we really would like to get in order to better clarify the requirements.

MR. LONG: I will complicate it a little bit further. We are not for profit.

DR. BERU: As I said, submit those questions because, as I said, we have kind of covered it in a sense with respect to the transporter because that is where we got the comments. I don't recall getting comments along the lines that you just provided and so we haven't addressed that comment in the preamble, and we will. I mean, just give us a real-life situation. Remember, this new Q&A is now going to be vetted through a process, just like we did in responding

to the comments to the preamble, through our Office of Chief Counsel before we put them out on the web so that everyone will have the same information at the same time. But, please, do send in those comments. In addition to the fact that we already have it recorded in this session, but if you have specific examples to clarify it, do send those questions in.

MS. PAVELCHEK: My name is Kathleen Pavelchek. I work for Steinhouse Inc. and we import food products. I have a question about the importer of record, I guess. If our foreign manufacturer is the importer of record and uses third-parties to warehouse and transport to the ultimate customer, what I am hearing from today's session is that foreign manufacturers are not covered by this Rule.

DR. BERU: The foreign manufacturer is not covered by this Rule.

MS. PAVELCHEK: However, if my company, which is a domestic company, is the importer of record, then we would be?

DR. BERU: You would be required to identify that foreign manufacturer as the immediate previous source, yes. You would have to have the contact information, the description of the food, how the food was packaged, etc., together with information about the transporter who brought the food to you.

MS. PAVELCHEK: That is incredibly clearer than I thought it would be. Thank you.

MR. PERRONE: My name is Don Perrone, with Finished Trade Networks. We would be regulated as a transporter. I have two questions. First, regarding food contact substances, oftentimes we are transporting items such as polyethylene bags and we may not know whether it is a food contact substance or not but we would still be subject to the records access requirements?

DR. BERU: Yes, as the Rule is written now, if it is a food contact substance, even if you are not putting the food in contact with that substance, then you are subject to the record access requirement.

MR. PERRONE: So, we could be transporting something as a transporter and not really know whether it is a food contact substance, but we would still be subject to the access requirements?

DR. BERU: Well, you know, it applies to substances that are intended to contact food, not to others. I mean, to the extent you don't know whether it is one or the other, again, I don't know whether you can get that information from the shipper or the company as to whether or not they intend to use it for food. The Rule clearly applies to food contact substances that are food contact substances, not anything else.

MR. LONG: If I may ask another question regarding the records requirement, the 24-hour requirement, do those 24 hours start from confirmed receipt of a request, and what form will the request be in? Will it be delivered in person?

DR. BERU: The clock essentially starts when an FDA investigator comes to you, shows his credentials and hands you your written request for the records.

MR. PERRONE: Thank you.

MS. MURPHY: Hi. Pat Murphy, Adirondack Beverages. As a manufacturer of beverages we sometimes donate to charitable organizations. I realize they are exempt but are we required to maintain records of what lots of beverages or goods we send them?

DR. BERU: A good question. No, and the reason is this, we have clearly said in the preamble that charitable organizations, such as the ones you described, stand in for the consumer. So, similar to the fact that you don't have to keep track of consumers, then you do not have to keep track as the immediate subsequent recipient of the charitable organizations. The reason for that--actually we did get a lot of comments such as yours that said, well, you know, that is a heavy burden. We would like to donate food, and it is not our intent to deprive needy individuals of access to such food. So, we have not only the charitable entity exempt from the establishment and maintenance of the records; they are still subject

to records access, but your operation, if you are donating to a charitable organization you do not have to keep track of that transaction.

MS. MURPHY: Thank you.

MR. WHITE: Tome White. We also import processed foods and, naturally, the foreign manufacturer is a registered facility. But this issue of recipe got me thinking. Are we required to have on file for each of the processed foods that we bring in from this manufacturer not only the ingredients but also the process for production of each of these? Or, is it enough that the registered facility maintains that?

DR. BERU: No, you are not required. I think in your case you are obtaining finished product. Right?

MR. WHITE: Yes.

DR. BERU: So, you would be responsible in your records to say I got it from this foreign manufacturer, the identity and contact information and description of the food. The ingredient part is if you are manufacturing food. If that

manufacturer had been a domestic manufacturer, then the expectation of the Rule is that they would maintain records of the ingredients that go into their product. But you are the importer. You are just required to establish and maintain records with respect to the finished food.

To answer the second part of your question, I want to make it clear that access with respect to recipes, would we need it and should we meet the SAHCODHA threat, is for the list of ingredients only, not for the instructions and not for the amounts because the recipe is all three things.

This is because we received a lot of comments saying, well, the statute exempts recipes so you have no access to recipes, and since ingredients are part of a recipe you cannot have access to the ingredients. We feel that deliberate food tampering can take place through supply of ingredients and we need to be able to access records to the immediate previous source of the ingredients. So, if you are a manufacturer, then

you have to provide us a list of the ingredients, not the instructions nor the amounts that go into making that, which could be considered confidential business information.

MR. WHITE: Also I want to be sure that I understand it correctly, that we don't have to keep track of of detailed lot records of all the transactions going out since we are not manufacturing.

DR. BERU: No. No, you are not. The lot number requirement is for manufacturers, processors and packers.

MS. DEMPSEY: Good morning. I am Nancy Dempsey, I am also with FedEx Trade Networks. During the time period where you were rolling out the prior notice and the facility registration information, from the time of the proposed rule to the final Rule for registration transporters kind of fell off the radar screen because it was determined that they would not need to be registered if their sole purpose was to transport food.

Now, because they have not been in the loop since that time and now that they are subject to record-keeping requirements, it seems like the outreach for record-keeping is a lot more limited than prior notice and facility registration, and that there may be a lack of awareness for transporters. Can you speak to what industry organizations you may be reaching out to to convey the new responsibility for transporters?

DR. BERU: Well, first, I think the difference between registration and record-keeping is that the registration, Section 305 of the Bioterrorism Act, says facilities that manufacture, process, pack or hold food have to register. There is no mention of transporters. In the record-keeping part of the BT Act Section 306, clearly transporters are covered because you manufacture, pack, transport, distribute, etc.

With respect to outreach, we showed the proposed regulation--let me see the date, it was back in 2003, March I believe. Clearly we signaled in that proposed rule that transporters are

covered, our intention was to cover transporters. We did not have the five options that we have in the final Rule for transporters to come into compliance, but transporters have been aware of our intent to cover them under this Rule since the issuance of that proposed rule.

True, it took us a year and seven months to finalize this. As I said, we had a significant number of comments. We had to wrestle with all the comments. And, even though we were supposed to issue the final regulation by the end of 2003, that is what the statute said. Unlike registration and prior notice, there was no hammer that even if we didn't come up with the final Rule you didn't have to establish and maintain records. Registration prior notice, remember, even if we hadn't come up with the final rule by the statutory deadline, you would have had to give the default notice of not more than five days and not less than eight hours, and you would have had to register. With the record-keeping though there was no hammer. So, it took us longer. We had more comments. We were

working arduously to try and implement record-keeping and so on.

But the point I am trying to make is that there has been a significant time period since our signal that we intended to cover transporters. Having said that, we issued the Rule on December, 2003. The shortest compliance date is for light firms of 12 months post issuance of the final Rule, which is December 9, 2005. During this year's period of time we are conducting these outreach meetings. As Gail noted, this is the fifth of seven or the sixth really because there is one going on in Philadelphia as we speak and that will be the seventh. We had one in College Park. You know, the attendance has been good and we have had folks from the transportation industry.

In addition, next week, or maybe it is this week, we are having a teleconference with FedEx and UPS and maybe with DHL, but three groups. So, we are doing our best through associations, and so on, to get this information out. We are providing those booklets, as I said, that summarize

the Rule and we distribute them widely. The first public meeting that was held in College Park was video taped and we are going to make those video tapes available on the web. So, we are doing our best to try and conduct this outreach so that everybody is aware of their obligations under this regulation and help them comply with that.

MR. NORDER: Thank you. Brian Norder with Lawn Food Venture Center. Are small manufacturers that do their own trucking and do wholesale distribution and, at the same time, may do direct store delivery of, like, shelf root sales where they go in stocks with a few units of several different codes, will they still have to lot track each individual unit that they do for direct store shelf they are stocking?

DR. BERU: No, the short answer is no. Let me take this opportunity also to talk about something else. In your case, you are manufacturing and using your own trucks to deliver. So, essentially your immediate subsequent recipient is the retail store. You do not have to record

when you put it on your truck and so on. That is considered intra-corporate.

But with respect to DSD, in the proposed rule we would have covered you. You would have had to maintain the lot or code number. But it was made amply clear to us that that was literally impossible to do at this stage. If you go to the final Rule and just do a search of DSD, you will see that we have clearly addressed that the Rule doesn't expect you to record lot numbers for direct store deliveries.

MR. SIEFER: Yes, Alan Siefer, from Harris and Tweeder Supermarkets. With regards to product returns, we have less than one percent that we process through a reclamation center, and some of that food product goes to donations. I know that is not covered, but some of it is returned to our stores internally for sale because it has been reclaimed and some of it goes back to vendors, and then some of it is sold off to salvagers who sell it somewhere else. What would be the record requirements in that situation?

DR. BERU: You are obligated to keep records with the exception of the charitable organizations. If you send it back to the stores or the manufacturer or to some other entity, then it puts it into commerce and you have to have that information in your records.

MS. HILIGEN: Hi. My name is Jennifer Hiligen. I work for a software vendor, National Distributor Systems, and I am here today because I represent people that I need to figure out what records we need to keep for them for cash and carry for wholesalers, distributors as well as manufacturers. So, I have kind of a varied bunch. So, I am just trying to clarify and understand and make sure I am providing them the right data to keep the right records. Cash and carry people are not responsible for maintaining who is the recipient because it is essentially customer? Is that correct?

DR. BERU: Cash and carry? Could you explain that?

MS. HILIGEN: Sure. You are a distributor

and you have perhaps a small distribution facility where people can come and actually individuals purchase things and carry them out with them. So, you are not making deliveries per se.

DR. BERU: As these individuals are consumers, you don't have to keep track of the one down. However, if these individuals are buying for their restaurant or for their other small store to distribute food further, then you have to maintain that information to the extent it is reasonably available to you. The Rule doesn't require you to ask every single person that comes in there whether they are consumers or whether they are really businesses. But, as I said, if you have an established account with that individual who is a business, then the Rule requires you to establish and maintain the one down with respect to that transaction.

MS. HILIGEN: Okay. If somebody is distributing and utilizing their own trucks, they are considered a non-transporter. Is that correct?

DR. BERU: Yes. If you are a manufacturer

and using your own trucks to deliver to a retail establishment for example, you are a non-transporter for the purposes of this Rule even though you are transporting your own product.

MS. HILIGEN: And what if you are just basically a full-line food distributor so you are getting it from somebody that is larger than yourself; you bring it back to your facility and then you are basically carrying it out to restaurants, nursing homes, rural districts, etc.? You are still considered a non-transporter? Is that correct?

DR. BERU: Yes. If you are using your own trucks to pick up the product then your immediate previous source would be the establishment that is selling you the food, and then the immediate subsequent source would be who you sell it to if not a consumer.

MS. HILIGEN: And all different produce is subject to this? If it is tomatoes you have to subject it to beefsteak as opposed to plum and try to identify it with lot numbers thereof? Is that

correct?

DR. BERU: Well, lot number, as I said, apply to manufacturers, processors and those who are packing food. Everybody else is not required to have lot and code information. But you are right, we want the records to say Roman tomatoes. I mean, we have had two outbreaks with Roman tomatoes this year. We don't want to say tomatoes because when our trace-back folks go and look in that trace-back if all the information is saying I got--if we know it is Roman tomatoes but as we are tracing it back we get to a place which says, well, I got tomatoes from these sources, then we would essentially have to look at everybody else to be able to see where the Roman tomatoes came from. But that wouldn't be the case if the records contain that information. So, yes, we expect the variety and just as we said, Romaine lettuce not just lettuce.

MS. HILIGEN: So, if a customer manufactures, let's say tomatoes, we would want to know what tomatoes went in there, what the lot

number is of that tomato because it is manufacturing at that point. You would want to know what lot number, for instance, sugar came from and you would want a list of ingredients with the lot numbers where reasonably available.

DR. BERU: Yes. I don't know that all those lot numbers are available, but if you are making a tomato paste we would expect you to tell us that the batch of tomato paste that was made--to identify the source of the ingredients that went into making that batch of tomato paste if that is reasonably available. Again, the standard is reasonably available. We didn't define it. We said this is on a case-by-case basis. But if you are receiving tomatoes in this hypothetical example, and you have a large bin that is getting tomatoes from five different growers, then you are taking tomatoes from that bin as you are making your paste I think what is reasonably available to you is to say that in making this tomato paste the tomatoes came from these five sources.

This is similar to the cookie example, but

if you have separate bins for separate growers, then information as to the identity of the specific grower that went into making that paste would be reasonably available to you. So, even if you are not keeping those records now, the Rule would expect you to keep those records.

MS. HILIGEN: You have clarified it. Thank you very much.

Q. One of the things that we do, we do exactly what you said. We bring in a lot of different foods from different manufacturers and in many cases we have several manufacturers making under the same item number, which I imagine is covered under the silo rule that you mentioned earlier. However, in our case it is difficult to get lot number tracking because many manufacturers don't do that. They will do expiration codes or something of that nature. However, we do track down to a pallet level ID. Is that sufficient for meeting the requirements here?

DR. BERU: You are a distributor, you said?

Q. That is correct.

DR. BERU: Again, there is no requirement--by the way, when we said lot number, code or other identifier, I mean, the expiration date would be the other identifier. We don't want to limit it to just lot code number. Other companies may have different identifiers that identify specific food. But as a distributor you are not required under this Rule to record lot numbers.

Q. Thank you.

MR. BLISS: Dave Bliss. We do two things that come under the guidelines of this Rule. One is we distribute milk that is packaged for us to individual retailers. I take it from what I have heard that we need to keep the information about the milk but not lot codes. Correct? Keep track of the codes that went to each retailer?

DR. BERU: You are a processor?

MR. BLISS: Just a distributor in the case of milk.

DR. BERU: If you are a distributor, no,

you are not required. Again, remember, the lot code number requirement is for manufacturers/processors who pack.

MR. BLISS: The other part of our business is manufacturing and distributing ice cream. For manufacturing ice cream it means we need to keep track of all the codes that went into making a particular product. The problem we have with that is we make probably somewhere around 150 different varieties of ice cream, sorbets and so forth. But on the outgoing side we distribute probably 99 percent of what we make to the final customer, in our case generally restaurants and their scoop shops. Because we are manufacturing the ice cream in a 3-gallon can and it goes to a retailer who is a scoop shop do we have to identify the lot code that went into the scoop shop?

DR. BERU: As a manufacturer, if you have lot numbers and you, yourself, are delivering it not through other companies--

MR. BLISS: Correct, yes.

DR. BERU: Then, as a manufacturer you

would be required to have in your records the lot number of products that went to that grocery store versus that scoop shop. The ingredients that go into the ice cream--you may make several different kinds but your records have to identify what ingredients went into making the finished product and, to the extent possible, we would like the identity of the source of that ingredient that went into making the specific batch.

MR. BLISS: Including the lot number?

DR. BERU: Well, if a lot number is available, yes. But you are making product and you are assigning it a lot number. Right?

MR. BLISS: Right. Envisioning how this is going to impact us, that is probably the easy part. The problem that I can see is on the outgoing side, making a delivery of 75 3-gallon cans to a customer. The driver is out there, puts the order together in 20 below zero weather and has to identify the lot code of every single can, every single flavor that is going to go out with that delivery slip.

DR. BERU: Again, this is one question we haven't really specifically addressed. In this sense of a normal transaction a manufacturer of ice cream, such as yourself, may sell it to a distribution center which then sells it to a retail facility. In that instance we have said, you know, it is very difficult because the distribution center is breaking up lots and combining products, and so on, as it fills an order for a retail store. As the technology stands now, recording code information in that operation is impossible. That is the standard we use for exempting or for saying that lot code information is not required at that stage. Send us the question--well, we have recorded it but if you can clarify the actual situation and, again, I emphasize real-life type situations, we will be happy to explain that in questions and answers.

MR. WEST: Tom West. I have a couple of questions. One is we are a wholly owned subsidiary of a foreign company but we are chartered in a U.S. corporation. So, when we import stuff, I presume

that under this we are not considered a manufacturer. Is that correct or not?

DR. BERU: You are importing finished products?

MR. WEST: Yes, we import--well, we bring in stuff like bags of citric acid which our company makes overseas or in Canada.

DR. BERU: No, you are not. You are not a manufacturer.

MR. WEST: Secondly, we do have some toll manufacturing done in the U.S. Are we considered a manufacturer for that?

DR. BERU: Say that again.

MR. WEST: Toll manufacturing where we hire a company to perform some manufacturing operation on some product and return it to us.

DR. BERU: Then that company would be the manufacturer. Since that manufacturer or that company is taking possession even though it doesn't own the product but is taking possession and control of that product for the purpose of doing the manufacturing, then it would be subject to this

Rule. It would have to establish and maintain records as a manufacturer.

MR. WEST: Thank you.

DR. BERU: Any other questions?

MS. ALEXANDROU: I am Stella Alexandrou, from TJX Companies in Framingham, Massachusetts. We are an importer and retailer that sells food in our stores nationwide. The product is physically received into our distribution centers throughout the U.S. Our home office, here in Framingham, is responsible for the import process and record-keeping of all of the documentation and the import piece from the distribution centers throughout the domestic network. Could you elaborate on the record-keeping requirements for the product moving through these third-party providers, the distribution centers, the trucking companies and then on to our retail stores?

DR. BERU: And the distribution centers and the transportation are all?

MS. ALEXANDROU: Third-party providers.

DR. BERU: Well, you don't--you own the

food, right?

MS. ALEXANDROU: We own the food.

DR. BERU: You own the food but you don't have possession of it. But that doesn't exempt you because if you have custody or possession you are required under this Rule. In this instance, you know, I would make sure that your distribution centers are establishing and maintaining records as the food is coming in, the date it was received, the identity, the amount, etc., and how it is packaged. Then, when it is being delivered to the retail stores, also maintain that information as the one down.

MS. ALEXANDROU: With regard to the records being available on site, because the bulk of the import documentation is maintained at home office, the documentation for the distribution centers, the one up/one down record-keeping, is there any provision or exception or possibility to have those documents be held at home office or in an off-site location in conjunction with the others?

DR. BERU: We did say records must be maintained on site or at a reasonably accessible location. Now, I think the standard there is can you meet the as soon as possible, not to exceed 24 hours? I imagine some of these records are electronic.

MS. ALEXANDROU: Yes.

DR. BERU: And they could probably be accessed from the distribution centers as well as from headquarters?

MS. ALEXANDROU: Possibly, but not as of today.

DR. BERU: Right but, remember, we are giving for large businesses a year to come into compliance and to the extent that that can be done, it can be done. Again, the standard is as soon as possible, not to exceed 24 hours with respect to records access.

One thing I would like to mention on electronic records, we have in Title XXI, Part 11 of the Code of Federal Regulations specific requirements for electronic records. Electronic

records have to be maintained in a certain way. However, of the purpose of compliance with these regulations, electronic records do not have to meet the requirements of Part 11, Title XXI. You know, there are specific requirements. But if you have electronic records for the purpose of complying with this regulation, then you do not have to comply with the requirements in Part 11.

MS. ALEXANDROU: Just one more question, we are not a party to any of the manufacturing of the product. Would we need to have ingredient level information?

DR. BERU: No. I think you are getting finished products. Right?

MS. ALEXANDROU: Finished product.

DR. BERU: That is the information you are required to have.

DR. BERU: Any other questions? One more?

Q. We receive product at two separate warehouses and we distribute it to 145 different stores. The question is on internal movement of products, say we ship something from our warehouse

to our stores on our trucks and then we transfer it back on our trucks to another store, is there any kind of record-keeping involved with that since it is internal movement?

DR. BERU: No, we have said that you do not have to. Again, if you want to look at the specifics of what we said, the term we used in there is vertically integrated company. We have clearly said you do not have to track movement of food within your own company.

Well, it looks like we are winding down. Oh, there is one more.

MR. DENIO: Good morning. I am Bob Denio with Trader Joe's Company. I thought I understood the process going from our warehouses down to our retail stores in terms of not having to track with lots and detailed record-keeping since we are breaking lots going from the warehouse down to store level. However, I thought I understood you to say in a previous question that that, indeed, would happen and I thought I heard you at times saying that we would not have to do that. So, I

just hope you can clarify this.

DR. BERU: I think the answer is you will not have. As distribution going to a retail store you do not have to have lot code number information in your records. I am sorry if I confused people but you do not have to.

MR. DENIO: We just need to have that recorded coming into our warehouse.

DR. BERU: Well, no. Actually, if you are not the manufacturer or processor who is packing the food you do not have that requirement as a distributor.

MR. DENIO: Okay. Thank you very much.

MR. STADELHOFFER: David Stadelhofer. This is not a technical question but do you have any indications of bioterrorism threats?

DR. BERU: You know, I really can't discuss that question. We have conducted threat assessments and so on, and a lot of that information is classified.

MS. GALLAGHER: Susan Gallagher, BNM Beans, in Portland. I had a question about the

business size. My manufacturing facility is under 500 people but the company that owns us is a lot bigger than 500 people. Where would we fall?

DR. BERU: You would be a large business for the purposes of this requirement because we have said, in calculating FTEs for the purpose of compliance periods, it is the aggregate corporate size that counts, not the individual facility.

MS. LEYBURN: Martha Leyburn with Norwood Distribution Services. I have a question on your request for records. Assuming that the threshold has been met, what would happen after hours or on the weekend when your representative couldn't find anybody at the facility? How would you go about contacting someone that the records were needed?

DR. BERU: Good question. To the extent we can, we will. I mean, if the only time to contact is during business hours we will be there first thing in the morning I guess. But I don't know if our field investigators have contact information outside of work hours. I don't know.

PARTICIPANT: Depending on the emergency

that is presented, it is not unusual for us to get on the phone and try calling presidents if companies if we have their numbers. But if they are not there we have to wait until they are open for business.

DR. BERU: Right.

MS. LEYBURN: Well, I guess my question is would you call the contact person? We are a registered facility so would you actually call the contact person and start there?

PARTICIPANT: Sure.

DR. BERU: That is a good point. I forgot, but at the proposal stage we said actually contact information of the responsible individual to be able to contact them. But part of the reason we deleted that is that a lot of that information would be available as part of the registration information. Thank you for reminding me of that.

MS. HILIGEN: Jennifer Hiligen, National Distribution Systems again. Just trying to think of all the potentials of my customers, obviously meat packers, poultry packers and egg product

people are not involved in this because that subject to different rules.

DR. BERU: Yes, these products, to the extent that they are under the exclusive jurisdiction of USDA, are not covered by this Rule.

MS. HILIGEN: What if you manufacture something that would contain a meat product or some sort of egg product? What would you be required as far as lot number? Nothing? If you are making a tomato sauce--to go back to that--and there is some sort of meat in it, you don't have to require anything?

DR. BERU: Well, it depends. If that food, in spite of having food under a different jurisdiction, is considered a USDA product then the Rule wouldn't apply. But if it a product that has within an FDA-regulated and USDA-regulated, then you would fall under this regulation with respect to the FDA-regulated product but not the USDA-regulated product.

MS. HILIGEN: But meat packers in general are not subject to any of this?

DR. BERU: No.

MR. HILIGEN: And if you put, say, shelled eggs in something you are manufacturing, like a bakery good, you would have to put the lot number of shelled eggs because that would fall within this? Correct?

DR. BERU: Well, to the extent that information exists, yes.

MR. HILIGEN: Thank you.

MR. DIPIETRO: Hello. My name is Mark DiPietro. I am with Dunkin' Donuts. I just kind of want to get back to the question regarding commissaries. In this specific example our particular franchisees which may own a network of 2-100 retail locations also, in fact, own the manufacturing plant or the commissary. They own the transportation vehicles as well. Given this example, what specific requirements with regard to the one up and the one down, particularly with lot codes, are they responsible for?

DR. BERU: Well, the one up would be the supplier or the manufacturer because that is when

it is first coming in. Presumably you are buying from other companies. So, that would be the one up. The manufacturer, to the extent that information is available, will need to be able to link incoming products with the donuts that are being manufactured.

The one down would be when it leaves your business. The retailer is the same?

MR. DIPIETRO: Yes.

DR. BERU: So, essentially you are vertically integrated company.

MR. DIPIETRO: Correct.

DR. BERU: You sell directly to consumers.

MR. DIPIETRO: From the retail location, yes.

DR. BERU: From the retail location, and you do the transportation by your own company?

MR. DIPIETRO: That is correct.

DR. BERU: Again, I urge you to go to the Rule and read about the vertically integrated company. Essentially, you do not have to track food within your own once it enters your corporate.

You have to have your immediate previous source and then the immediate subsequent recipient. In this case it is consumers and it doesn't apply.

Well, it looks like we have come to the end of the Q&A. I really want to thank you for coming to this session. I hope it was useful. If you have additional questions, please do not hesitate to access our website and submit those questions in writing. Thank you again for coming.

[END OF TAPED RECORDING.]

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