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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

CHICAGO, ILLINOIS

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P R O C E E D I N G S

Questions and Answers

DR. BERU: With that, we can go to the question and answer session. I think our break is supposed to start at 10:15. I can take a few questions now or we will break now and come back.

Q. Can you define what FDA means by serious adverse health consequence under SAHCODHA, and can you relate that to like a Class II recall?

DR. BERU: As I said, we will make those determinations on a case-by-case basis, but our internal deliberations of that would relate to a Class I recall, not a Class II recall. I might add that we have had records access authority the minute President Bush signed the Act on June, 2002 but we haven't had the need to use that authority, thankfully, because if we have to, then we will be in a public health emergency situation.

MR. HOLCOMB: Hi. Greg Holcomb, with Gay Gourmet and also representing Endpoint Service Association. I have several questions from different entities that are represented by IPSA and

I will try to go through them as quickly as possible but the implication of this to our industry is enormous.

We have one question from Continental Airlines regarding the service of food over international waters or countries that originates from a U.S. facility. Is that still considered under these requirements for traceability?

DR. BERU: Yes, the rules apply for all food in the U.S., not necessarily just for food and consumption. That confusion may have arisen because of the proposed rule. Because registration is for food consumed in the U.S., that sort of inadvertently snuck into the record-keeping proposed rule. But we have since corrected it. The rules apply to all food, whether it is for import, for export or for domestic consumption.

MR. HOLCOMB: And how about the reverse if it is, let's say, produced in Mexico City and is flown over the U.S. and consumed over the U.S., is that exempted or not?

DR. BERU: That is a good question. There

are situations like this which we have not specifically addressed in the preamble or codified. In those instances, I can give you an answer which may seem right to me at this point because, you know, it is off the top of my head, but what I would like to do for these types of questions is really get them in writing and handle them--

MR. HOLCOMB: I understand.

DR. BERU: That is a question we haven't addressed.

MR. HOLCOMB: Also from Continental, there was a question regarding their services. They own six catering facilities where they serve directly to the passenger. In other words, they own the airline catering facility and they own the airline and they own the trucks that transport all of this, and the question is even though those are interstate conveyances that is much more similar to a restaurant situation for them.

DR. BERU: Actually, that is more similar to the vertically integrated company situation we talked about in the preamble, whereby a

manufacturer who uses his own fleet of trucks to transport, say, to a retailer does not have to maintain records of when they put it on their transport vehicle and then another set of records. Essentially, they have to maintain records, even if they transport their own food, then they are only subject to non-transporter. In this case, it appears to me this is the same company. This is never released to any other outside entity so in that case the rules would not apply. That is analogous to the vertically integrated company.

MR. HOLCOMB: That was their question and that is helpful for them. The implications on potable water into the airplane, is the airline required to maintain records regarding all the watering points or the last time it was flushed? Because, I mean, that is food; it is water. It is in the airplane and it is added and mixed with water from other places.

DR. BERU: Yes, water is food and you have to maintain the source of the water.

MR. HOLCOMB: The facility or organization

size under the requirements, in other words, Gay Gourmet has 20,000 employees in the U.S. but we have facilities that have less than 500 employees. Is the implementation based on that plant or unit, or is it based on the company as a whole?

DR. BERU: No, it is based on the corporate size.

MR. HOLCOMB: Corporate size?

DR. BERU: Right. Our reasoning there is, you know, because compliance dates is in order to facilitate compliance. We feel that corporate size may have smaller units in places but the sum total of the resources is such that they can comply the same as a large business that has more than 500 at one location.

MR. HOLCOMB: On beverages that are recovered, this is an area that we have great concern over as an industry, and I think it probably would be an area that is better addressed as a direct question. Now that I started saying it, I think we will submit that one in writing.

Under the law there was a provision for

overly burdensome on any one particular industry exemption. Was that changed in the final Rule and/or what is the route of appeal, so to speak, for that?

DR. BERU: These rules are final and they will be effective when the compliance period kicks in for you. I think in looking at all the comments, we have tried to accommodate many of the comments we received without, at the same time, sacrificing our ability to do an effective trace-back or trace-forward. We have tried to make it as least burdensome as possible. We have tried to take the information pieces that you have to maintain records. We don't care how you keep them, whether it is electronic, paper or so on. So we have tried to reduce the burden in those terms but, you know, for a segment of the industry that is saying it is already burdensome I don't know what the remedy there is. We have considered all the arguments and we have tried to put in a final Rule that we hope relieves some of the burden but, at the same time, should a public emergency come it

will enable us to do a quick and efficient trace-back and trace-forward.

MR. HOLCOMB: So, I guess my question is was that eliminated from the final Rule, that statement of overly burdensome?

DR. BERU: Frankly, I don't--it is such a long time since we did the proposal; it took us one year and seven months to do the final Rule--I am not quite sure in what context that statement went in the proposed rule.

MR. HOLCOMB: It may be in the law that was signed. I am not sure. We will have to look into that. Thank you very much.

DR. BERU: You are welcome.

MR. MACINTIRE: I think it is time to take a break. I saw there is fresh coffee out there. So, we will make it until 10:30 and then we will take more questions. Thank you.

[Brief recess]

MR. MACINTIRE: Please take a seat. I understand there are some folks who are looking for a seat so, again, if you have a seat next to you

that is open maybe you could raise your hand and make the open chairs available to those who don't have a seat. There is a seat up front--well, nobody likes the front seat. It is the best seat in the house.

I am taking written questions, if you have them. I think there were a couple of people here who had their hands up, right in this general area, before the morning session. Did anybody right here have a question?

Q. I have one. We import spirits and wine and also have a distillery, and I am the importer of record and I am in Louisiana. Our distillery is in Kentucky. Our import license is in Louisiana but the goods are physically in Kentucky. Where would the data have to be? Where would you look for that information if you were going to come to us?

DR. BERU: At the facility. I mean, you don't actually take the physical--

Q. The physical goods are in Kentucky.

DR. BERU: That would be where we would be

interested. Because, remember, part of what we want to do is to be able to trace the food back and forward along the chain so in this sense it would be the facility that is in Kentucky, did you say?

Q. Right.

DR. BERU: And that is why we say the records have to be created not only when the transaction or the activity took place but also at the site where that took place.

Q. Thank you.

MR. MACINTIRE: I am going to go across now. While I am walking, Nega, could you clarify the requirements for a firm that receives food from other entities, but once they receive it they have control of it and they distribute it in-house to their own facilities using their own vehicles? I understand the trace-back. Those requirements would be needed for those companies who supplied that, but once it is received and held by the firm who is going to have control of it for their own business--

DR. BERU: Well, again, I think that is

what we refer to as intra-corporate transfer. I mean, the example we give in the preamble is if you are a manufacturer you obviously have to keep the immediate previous source of your ingredients. But once you have manufactured your product, you don't have to then maintain records of transfers within the corporation. If your own trucks take it to a retailer, then the retailer is your immediate subsequent recipient. You don't have to keep records of when you put it on your transporting vehicle and when it was off-loaded at the retailer. We refer to that as a vertically integrated company in the preamble.

MR. HURLEY: I am Pat Hurley, with Spangler Candy Company. I have three questions, of which the third one is a two-point question. On processing [not at microphone...] that is used on food contact surfaces, would that have to be included?

DR. BERU: I am sorry, I didn't quite get the full question.

MR. HURLEY: on processing aids, such as a

lubricant used on a food contact surface, would that have to be included?

DR. BERU: Yes, it would have to be included. Processing aids and food additives are food by definition so they are included, yes.

MR. HURLEY: When we rework our candy we melt it and put it through a processing system using diatomaceous earth and carbon. All that processing aid is gone, then we end up with a clear syrup. Would we have to label, or would we have to watch the processing aids in that process, such as the carbon and diatomaceous earth that is used to clean the syrup?

DR. BERU: Yes, processing aids, when you think about it, there is potential for contamination of foods through that route so, yes, if it is being used as a food additive or as a processing aid. Remember, the definition of a food additive is not food that is really usable. It becomes a component of that food but also alters its characteristics. In this case, you are clarifying/purifying and, yes, the Rule would apply

to that case.

MR. HURLEY: Okay. I have a corn syrup tank which I put the corn syrup into and we draw the tank and we put lot numbers into the tank so there is a big co-mingling going on there. How do I handle that?

DR. BERU: Again, describe that to me in some detail. You are putting syrup into the tank?

MR. HURLEY: I have a large storage tank--

DR. BERU: Right.

MR. HURLEY: --which is three tanks in a row. I purchase a load of corn syrup and it goes into the tank, and we usually have about three loads in there at a time.

DR. BERU: As I said, this is actually very analogous to the cooking example we gave. You have one container and several lots are going into it, and the only visible thing that you can be expected to provide is that when you do ship material from that tank you have to say, you know, that that syrup could have come from company A, B and C. That may be the only thing you can do. You

cannot specifically link the outgoing--especially for liquids. I mean, there is a lot of co-mingling that takes place. So, you will only be required to have in your records the number of companies that could have contributed to that lot that you are shipping out.

MR. HURLEY: The second part of that third question is we use molding starch for depositing a product into. We continue to add new starch to the molding starch as we lose some of the starch. So, how would that be handled? We could have starch in the system for a year and you add more starch to it.

DR. BERU: I am not quite familiar with that process. What would be useful really, as I was explaining to folks who had questions here during the intermission, is that for real-life situations like that of conditions we would appreciate getting the questions in written form so we can address them in questions and answers. But I am not quite familiar with this process so I can't answer that.

MR. HURLEY: I can write that down and give it to you and you can get me an answer.

DR. BERU: Well, as soon as we can.

MR. HURLEY: Okay.

Q. Just with that reclaim process that he was talking about where we take our hard candy and reclaim it, we have like three different departments so they are all going to have different lot numbers of ingredients in them. Then we co-mingle them, all those ingredients together, and run it through that reclaim process and them pump it back into the departments. I don't see how there is any way possible that you could ever decipher what lot numbers are in that reclaim.

DR. BERU: And the Rule does not require you to do that. We have said that, you know, the Rule does not mandate that you change your long-standing process. In that situation you are co-mingling a lot of products into one big batch, and the only thing you can say is that in making that product, that rework, you know, products from lot A to F were used in making that. That is all

you can say and we would expect that. If you are able to have different processes going where you take one lot and make product out of it, it is an easy matter to relate the incoming from the outgoing. But in this instance, you are saying you are putting all those different lots into one big co-mingled product and the only thing you can say then is that the finished product that comes out of that process came from these lots. Your records would have to indicate that, the sum total of what the lots are, not specifically--

Q. But there are six or seven different lots--

DR. BERU: Then it would have to contain the six or seven lots.

Q. I represent the distilled spirits industry as far as manufacturer and an importer. I have two questions. As a manufacturer, when the first phase of FDA came out for barrels, caps and bottles for your finished product, those were not required to be FDA-registered as manufacturing facilities. Under the record-keeping, when you

talk about your finished container, when you are speaking of items that will touch the finished product, does the glass and the cap now follow through this record-keeping where we have to know who we received our glass from, what trucking company delivered it and then manufacturing records from there?

DR. BERU: Yes. Like I said, any finished food contact material that comes in contact with food--if you are actually the one putting the food in that container, then you have to keep records of the immediate previous source of the food contact material. Now, others who make it, manufacture the bottles or the caps, if they, themselves, are not putting food--in this case alcoholic beverages into the bottle, then they would be subject to the records access requirement of the Rule but they don't have to establish the immediate previous source and immediate subsequent recipient.

Q. That is why I get a little bit confused when you talk about the record access. Tell me specifically what it is that they would

have to keep.

DR. BERU: Records access is records access for records you happen to keep. I mean, it doesn't mandate--

Q. General manufacturing records?

DR. BERU: Right, exactly, whatever records you happen to keep, you know, just as a matter of your own business practice or as part of complying with some other regulation for example.

Q. But as the manufacturer who is going to be filling that bottle, we would have to keep the records?

DR. BERU: Yes.

Q. Okay. The second part of my question is as an importer. When you spoke about foreign facilities, you spoke specifically of Mexico and Canada being our bordering countries. Does this not apply to foreign--for example, we import from Sweden. We have foreign manufacture over there and we import product over here. As the importer, the immediate preceding would have been just the rail line that brings it in to us. Am I correct, does

it go back to all foreign manufacturers, or is it specifically limited to Mexico and Canada?

DR. BERU: No, I used Mexico and Canada because primarily those are most of the comments we received because there are a lot of truckers and rail cars that cross those borders. We had a number of comments on that. I suspect most foreign entities that cross borders to the United States either come from Canada or Mexico but, as you say, it could come from other places.

But with respect to you, you have to have a record of the importer that you got your material from as the immediate previous source. Then you are responsible for maintaining records of the immediate previous transporter source and whoever brings it to your facility, not anything beyond that.

Q. Not anything beyond that? So, just who delivers it to our plant--

DR. BERU: Right, and who you ordered it from and who delivers it.

Q. Okay.

Q. In line with that question, you might contract with an ocean carrier to bring it to your door, but XYZ truckers are actually subcontracted by the ocean carrier to bring it to your door. Who should you record, the XYZ carrier or the ocean carrier?

DR. BERU: I don't know if everyone heard that but the question was you might contract with an ocean carrier who then subcontracts with truckers who bring it to your door. In this instance the truckers will also be maintaining where they got that from. So, in your case, you only have to maintain who delivers it to you because we are able to get back to the vessels, the records that the transportation company would hold.

Q. You are basically trying to create a trail.

DR. BERU: Yes, you hit it on the head. We want to create a trail and be able to follow through. Essentially, heaven forbid, if there is deliberate tampering we want to be able to get to where the tampering took place and, you know, from

there the tampered food might have wound up elsewhere so we also want to be able to follow the trail and trace forward and remove it from the market. So, you have to keep that in mind as you ask these questions because really that is what the intent of the Rule is.

Q. More clarification on the vertically integrated company example. I am a food manufacturer that is owned by a grocery company with distribution warehouses and retail stores with over ten full-time employees at each location. We have to keep track of our goods coming in, but for the goods that we manufacture, the food that we manufacture and distribute to our own company we will not have to keep records on the transport of that material?

DR. BERU: No, if it is intra-corporate transport, yes, we specifically said in the preamble that you do not have to keep those. That is, food moving within your own corporate structure, you don't have to keep records of that. The minute that it leaves you though and you sell

it to a retailer that is not your company, then you have to have the immediate subsequent recipient record of the retailer.

Q. What about the responsibilities of the retailer with over ten full-time employees?

DR. BERU: The retailer with over ten full-time equivalent employees is not exempt from the establishment and maintenance part of the regulation. They have to establish and maintain the immediate previous source, in other words, where they got their food from. They don't have to maintain records of the individual consumers they sell to but, if they are ten and above, they have to maintain records of who they get their food from.

Q. So, in our example we would maintain records of the goods we receive to manufacture our products, the transporter that we got them from, and the retailer and not the distributor would have to maintain the records of where they came from, from the warehouse. Is that correct?

DR. BERU: Well, now I am a little

confused. You say you are a manufacturer--

Q. Correct.

DR. BERU: You have several companies and food moves within your company--

Q. Right.

DR. BERU: --you eventually sell to a retailer, which is not part of your company.

Q. We are owned by the retailer.

DR. BERU: You are owned by the retailer?

Q. They have stores; they have distribution; they have trucks; they have manufacturing.

DR. BERU: Again, this may be one good example I think for a written submission of questions so we can address that.

Q. All right. Thank you.

Q. That is why I was asking that question earlier because I know there is a lot of confusion out there on this issue.

Q. Just to clarify then, if I am buying ingredients from a broker or distributor, then my responsibility is to know the identification of the

carrier and that broker or distributor. I do not need to know the identification of the actual manufacturer of the product?

DR. BERU: Whoever you are buying from you have to keep records of. Presumably, once we get to the person who sold it to you, we will be able to identify the manufacturer from that record. So, basically, you have to keep in mind that the rules require you to keep records of the transactions that you are a party to, not further upstream or further downstream. Remember, one up and one down. You don't know what happened previous to the place you got the food from or subsequent to where you sell food. So, we expect you to keep records of the immediate previous source and immediate subsequent recipient. The tracing is step-wise here.

Q. Okay. My second question is this, in the registration phase individual warehouses and individual manufacturing facilities each had to register separately. So, if I am purchasing ingredients from a manufacturer that has multiple

warehouses or multiple manufacturing sites, do I need to know which precise warehouse or manufacturing site manufactured or provided or shipped that product?

DR. BERU: Yes. Presumably, your records would include which plant it was shipped from. We are not interested in the address and contact information of the corporate headquarters but who sold you that food. Isn't that normal industry practice? You would have that information, would you not?

Q. Not necessarily, no. For example, if a manufacturer is using five separate outside warehouses, I place an order with that manufacturer, the shipment comes to my door. In the past, have I cared which of those five outside warehouses it came from? Not in particular. Do I know the manufacturer? Certainly.

DR. BERU: Well, in that case the manufacturer who delivers it to you would have records as to which warehouse that came from.

Q. So, then it is their responsibility--

DR. BERU: Yes.

Q. --to identify which warehouse or which specific site provided that product as long as I know the main manufacturing company?

DR. BERU: Yes.

MS. GOMBAS: Kathy Gombas, Dean Foods Northeast. Nega, first I would like to compliment you and Leslye Fraser for the information that you provided. It certainly does help answer some of the questions.

I have a question on the enforcement side. You had indicated or explained how FDA will make requests for records through the notice of inspection process. Will the investigator, the FDA personnel--will they also provide in writing the list of the specific records that they are requesting, or is that just a verbal request?

DR. BERU: Well, first of all, it is a written request. Maybe I should let Scott answer that question since he is one of the authors of the guidance document.

MR. MACINTIRE: The written request, It

is the notice of inspection. If you look at the Food, Drug and Cosmetic Act, Section 704, which is our authority to inspect, it basically says there that we will present written notice and show our credentials to the party that we are inspecting at a reasonable time.

The question did come up that we received from many parties, will the request be a specific request for records, similar to low acid canned foods where we have a demand for records that is issued and there is a specific item detailing what record exactly it might be that we want, product record or transportation record, etc. We discussed that internally and we didn't want the burden for the investigators to become greater than it already is for our normal course of doing business, which is to issue the 42.

So, they are to explain in the draft guidance what we are proposing on record access. The investigator wants authority by the district director to go out and request the record. The scope of the record will be identified verbally,

not in writing, after they have issued the 42. That is the written notice. That is the "in writing" part. We narrowed it down to that because, again, we didn't want to burden our investigators with more paperwork than we already have been burdened with for other rules. It doesn't put an adverse burden on the industry. The request will be given and, hopefully, be granted. If not and if it is a required record, if we have a refusal, then we will deal with it as we do with other refusals, and sometimes that means get an inspection warrant. Then there might be a court case because someone didn't obey the law.

DR. BERU: There is a question, from Mr. Jack Webster. My company produces a food contact substance. A few of our products transfer color to the food products covered by the Rule. Is the only material of concern to us the colorant?

I know the food contact/food packaging part of this is a little complicated, but if you are a food contact substance maker, even if you make the finished packaging material that contacts

the food, so long as you are not the one putting the food in the packaging, you know, we have access to the records you happen to keep but you are not required to keep the immediate previous source, immediate subsequent recipient of the food contact substances or the finished packaging.

If, on the other hand, you obtain the finished packaging material and you package food, then you have to keep track of where you got the finished packaging material. I hope that is clear.

Q. Yes, my question is in a farm operation if you belong to a co-op and if you transport that product from your farm to the co-op, is that considered transporting it within the corporation? And at that point when I deliver it to the co-op, is my responsibility as far as tracing the product over with, or do I have to try to get those records from the co-op? They distribute it once I deliver it to them.

DR. BERU: Well, first, you don't have to get records from anyone but what you are required to do is to establish records of the one up/one

down. So, you would maintain records of delivering to the co-op but there is nothing that you have to get from the co-op. You don't have to get any records from the co-op but your records would have to indicate that you delivered it to the co-op.

Q. And would that be considered a movement within a company from my farm to the coop?

DR. BERU: I don't know that co-ops fit the corporate picture that we talked about in the preamble. This is, I presume, an association of farms?

Q. Right.

DR. BERU: Individually owned farms?

Q. Individually owned farms that belong to the co-op.

DR. BERU: Then that doesn't get you out of the farm exemption. You have to maintain records of foods that are delivered to the co-op.

Q. Thank you.

Q. We generate scrap in our building and it is generated like Spangler, a combination through many days maybe, but it goes to a pig

farmer who uses it to make pig feed. Is that covered? Yes? No?

DR. BERU: What kind of operation is it?

Q. Chocolate manufacturing, bulk chocolate. So, food scraps for feed.

DR. BERU: Yes, feed is food. You have to keep track.

Q. Even though it is not for a pet animal?

DR. BERU: No, no, whether it is human food, animal feed or pet food, it is all covered.

Q. So, what would be acceptable? Let's say that a truck load is generated in a one month period, we don't know specifically the lot codes but we would know the days. That would be acceptable? Our lot codes are tied into days.

DR. BERU: Basically, from the days you can get the lot numbers, is that what you are saying?

Q. Yes.

DR. BERU: In that instance, similar to a question that was asked earlier, when you are

putting it into one large container there is no reasonable way--in other words, you are delivering from that. You are taking some from the bin, so to speak, to deliver it to the pig farm.

Q. Yes. So, we would just put on the bill of lading the lot code period that that would be?

DR. BERU: Right.

Q. Then keep track of where it was shipped to?

DR. BERU: Yes.

Q. Okay.

Q. Thanks for being here today. We are a manufacturer of pharmaceutical products. A couple of our products are purchased by food manufacturers as components in food. My understanding from what you said today is that we are not subject to this particular Rule because we do not manufacture, hold, process the food, etc. Am I correct?

DR. BERU: I don't think I said that. You are a pharmaceutical company but you make food ingredients?

Q. We are a pharmaceutical company. Our major products are active pharmaceutical ingredients--

DR. BERU: But you do make food ingredients?

Q. These APIs, one of them in particular, can be used as a food ingredient. It is pancreatin. So, some of our customers, a very small percentage of our customers, purchase that particular API to be used for food.

DR. BERU: Well, anything that is intended for food is covered here.

Q. It is just a component though.

DR. BERU: Yes, it doesn't matter.

Q. I am glad we are here today!

[Laughter]

MR. MACINTIRE: Sugar is food that makes a cake. Right? So pancreas--whatever--as as food ingredient is food.

Q. Yes, if you make something like a sandwich bag that food goes into or water filtration systems that are advertised all over, do

they come under this requirement? You know, people put food into it. By law, except for the Bioterrorism Act as I understand it, it is a food. Given that, do we have to have the same kind of records?

DR. BERU: Let's deal with the sandwich bag first. If you are manufacturing sandwiches and putting them in sandwich bags and selling them directly to consumers for consumption, then that is. But if you are selling it to other firms, let's say to retail outlets to sell to consumers, then yes, the Rule would require you to keep track where you get the sandwich bags from.

Q. For something like a Glad sandwich bag, we would have to keep these requirements.

DR. BERU: Well, it depends. Like I said, if you are making the sandwiches and giving them directly to consumers, then you may fall into the restaurant exemption if you are selling directly to consumers for consumption. If you are selling to another outlet for further sale to consumers, then, yes, you would be covered.

Q. I think I am still lost. If you manufacture the sandwich bag and it is sold in the food store to the consumers as a sandwich bag--

DR. BERU: Oh, no, no, no. We are talking with respect to finished packaging material that contacts food. You are required to keep those records only if you, yourself, are putting food into the container.

Q. Thank you.

Q. We donate product to donation locations. Where does our tracking need to end at that point?

DR. BERU: These are the non-profit?

Q. Correct.

DR. BERU: No, you have to have records of having delivered to the non-profit organization. They, on the other hand, have exemptions similar to grocery stores.

Q. So, when they hand it out they don't have to track it?

DR. BERU: No.

Q. We just need to track it to them?

DR. BERU: Yes. They would have to maintain records that they got it from you, but they don't have to maintain records of who they give it to.

Q. Back on the 482 a little bit, I still need clarification. In the oral discussion with the inspector, are they going to share anything as to the reason they are asking for these records, or are they just going to tell us they want to inspect?

MR. MACINTIRE: Luckily, we haven't had that situation, not in the sense of meeting the threshold. I mean, in our course of business to inspect under the authority of the Act in other parts of regulations, if required by the Rule for the firm for the manufacturer person to have the record, then we would, in a sense, request the record and expect to see it. Prior to the BT Act, foods that weren't low acid canned food, seafood, etc. that the presentation presented, we would request records verbally and we are not going to change that practice. It is just that now we have

the authority to say we are going to request the record and you are required to maintain it, provide us access, copying of the record, inspection of the record. If not, then you are in violation of the Food, Drug and Cosmetic Act and you can be prosecuted as a person who violates a law.

Like I said, we aren't trying to change what we have basically done prior to the BT Act, except that now we have the authority to get that record from a manufacturer, which we never really had the authority--we could always request the record and voluntarily that firm could give us the record but they could also refuse to give us the record and we wouldn't really pursue it unless--I am not going to say we were not going to always pursue it but if we didn't have people that were sick and maybe have died from, let's say, a food-borne illness--an example would be a food-borne illness outbreak and we were investigating that and trying to do trace-back and trace-forward, most firms voluntarily gave that information to us because they wanted to assist the

agency in finding out what was the cause for that illness.

In the sense of the BT, we are talking about the illnesses that I talked about. We are also talking about possibly some terrorist act. And, when we get around to discussing records access and finalizing it, I think that is a good question that you brought up--what information is FDA going to supply to the party that they are requesting the record from? You know, now that you have stated that to me I am thinking we may not want to get too specific because it could be a terrorist act, and there are certain things we have to be careful in disclosing that this is a terrorist act and we need this record now. Let's say that was an example. Gosh, you know, it could be anthrax. Do we want to disclose all information that you I am sure would want to know out of curiosity, for one thing? But is it really beneficial to our protecting all of the public health?

Q. Do we not have the right to [not at

microphone...] whether or not you have met the opportunity that the law requires you to meet? Do we not have the right to assume--

MR. MACINTIRE: You have the right to assume or to expect. I think you have the right to expect. If we follow this process that was laid out here we have gone through our general counsel.

DR. BERU: Again, let me say that we have not finalized those records access procedures--

MR. MACINTIRE: Right.

DR. BERU: --and here is your chance--

MR. MACINTIRE: Right, you still can comment.

DR. BERU: Like I said, this is not final.

MR. MACINTIRE: That is a good comment.

DR. BERU: With respect to your other question though, I think we may handle it similar to the way we handle administrative detention. Some of this information that relates to records access may be classified information that is received from the intelligence agency. In that case, you may be given sort of the general, overall

reason without going into specifics.

Q. [Not at microphone].

MR. MACINTIRE: I agree with you but I have secret clearance and I can't tell anybody--if I have been given secret information by my authority under that secret classification, I cannot talk to anybody else unless they have secret or top secret classification. Do you have top secret classification? Then maybe I would be able to assist in providing more information. But, you understand, there is a little bit of a dilemma there security-wise overall that we are going to have to deal with. That is an excellent question because I haven't thought of that before but, now that you have asked it, I am thinking, you know, I am probably not going to tell you everything because there is certain information there that could jeopardize the case. You could be the one who actually did the terrorist act or it could be someone who works for you.

Q. I went to a seminar a few weeks ago with a few other people that I see in this room on

supply chain security. This is relating to Scott's comment. Prior to 9/11 we all operated our businesses--I happen to be a customs broker but we all operated our businesses doing commerce. Since 9/11 we all have to understand that we operate our businesses with one word in mind, security. If your businesses do not understand that the word security is the top priority, then you need to do some retraining because that is exactly how all of our industry in the United States is going. There is not a person in this room that doesn't embrace the idea of the Bioterrorism Act. Its mechanics sometimes can be a little cumbersome but it is global supply chain security.

DR. BERU: Thank you.

Q. One question regards the follow-up on the records. A company can always voluntarily share records, but in terms of when FDA can actually require to access those records it still has to meet the recall definition, otherwise you cannot require access. Is that true?

MR. MACINTIRE: When we were developing

the guidance, drafting the guidance that issue came up. What we already have within FDA that exists is a policy or guidance that industry is aware of and is familiar with that they can relate to. One example was of a Class I recall. I think we had some language--I have to go look at the draft as it currently exists--it is on the web;I don't know if it is still in there. They used that at one point--I don't know if they left it in there or not--that helps you and myself understand what is the seriousness. It is more like the threshold, the threshold that we define as a serious adverse health consequence that may result in serious death or injury to humans or animals. We used the Class I recall definition to help us define what that means and then, from there work on why, for one, do we want the records, because we have a serious event and information is available that we need to probably protect thousands of consumers versus one or two that had a complaint, and that is why there is a recall now, because there was an illness, let's say.

DR. BERU: To add to what Scott said, we were actually in the process of issuing a regulation to delineate what we meant by serious adverse health consequence to humans or animals. We are not going that route now because we feel that is something that should be decided on a case-by-case basis. But you are right that in considering whether or not we met the threshold we are sort of thinking along the lines of is a Class I type situation but we haven't fully defined it.

MR. MACINTIRE: Right, we didn't come out with an actual rule on the definition but that was one of the things we were thinking about doing back when we started in 2002.

Q. Just real quick, we are a manufacturer that does a lot of private labeling. Almost everything is private labeled. Other manufacturers use the same label. So, when it comes to an inspection, if it gets too tight lipped, we may be able to provide information. We have had this in recall situations where it wasn't even our product. That happens. So, just a suggestion.

MR. MACINTIRE: Thank you. Whatever you can do though to help us face it, that is what we ask.

Q. [Not at microphone].

MR. MACINTIRE: Well, we will try; we will try. I understand; I hear you.

Q. Hi. I am Greg. I am from Bronx Confections. One question I did want to ask because we have a lot of imports is how does the regulation address items or goods in transit, and if it is not received in our warehouse or manufacturing facility yet are those purchase orders for goods in transit subject to record-keeping requirements?

DR. BERU: Let me understand this. They will eventually make it to your warehouse but they have intermittent stops?

Q. Yes. Well, they are in route from the supplier.

DR. BERU: Well, the Rule applies to when they do get to you because, remember, the records have to be created at the time the covered activity

takes place. So, when you take possession, custody of the product, your records have to show that you got it from whoever the exporting firm is. You have to have the name and contact information for that firm, as well as the transporters that brought it to you and the date it was received. So, when it is in transit and hasn't arrived to you, you are not really technically subject to the Rule. The minute you do get possession of the food though you have to establish those records.

Q. Actually, just as a follow-up, some of our ocean shipments are where the terms are CIF to the port so we are actually owners of the goods once they reach the port, let's say, in New York but the goods haven't arrived in our warehouse yet.

DR. BERU: That is why I said you may be the owner but you really don't have custody or possession of it. When you have it is when you establish the records.

Q. Just a little bit of confusion, a farm is exempt in what you had presented, yet, the gentleman talked about delivering a load of corn or

going to the co-op. Where does a farm then step into the FDA regulation? Once delivery is made of the product?

DR. BERU: Well, remember, I said that if a farm is transporting within its own farm or between its farm for packing and so on, it stays within the farm exemption. But in this case the farm is transporting food to a co-op. So, while the farming activity is exempt, the minute it is transported, the food then falls subject to the transporter regulation and you have to keep track of who you deliver the food to.

Q. So, is it safe to assume then that once it departs the farm it falls under the regulation?

DR. BERU: Right. Remember, an entity can be carrying on two different activities, one of which may be exempt and the other one may be covered. I mean, an orange orchard may be processing oranges into juice on the farm for entering into commerce. They will still be exempt with respect to the farming activity but they will

be subject to the regulation with respect to the processing activity.

Q. Thank you.

Q. If the same company ships milk from California to Hawaii and that product is picked up at the port in Hawaii by that same company and delivered to that port in California by the same company, what documentation is required?

DR. BERU: A good question. Again, this is one we covered within the Continental U.S. but not crossing the ocean, but it seems to me it falls within the intra-corporate movement of goods for which you wouldn't be required to keep records.

Q. Let me follow-up with this gentleman's question because I think I am a little confused. The form 42 is the written notice. That is a written notice for any inspection, not something special like this. So, the form 42 is the written notice and that gives you authority to get access to records with or without some type of a clearance where you go through general counsel and with and without notifying us why. Because I think you are

going to get a lot of push-back from this.

DR. BERU: There is going to be clearance by the Office of the General Counsel. Remember, when the district FDA official thinks the threshold has been met, they notify the Office of Emergency Operations--

Q. [Not at microphone...] In this case the form 42 is also a notice of bioterrorism threat [not at microphone].

MR. MACINTIRE: Well, that is being worked out as far as the question the first gentleman had regarding what is going to be disclosed to the firm that is inspected, or the person or party that is inspected. The 42 actually is a required document by the Food, Drug and Cosmetic Act. It states we have to issue that and we have amended the notice itself to include the new Bioterrorism Act language. It already had language under 704 and 704 was amended back in June of 2002 when the President signed the BT Act. We included the new language on the 42 which states and also to have access to copy, etc., etc., records under the BT

Act when there has been established the serious adverse health consequence.

Q. [Not at microphone].

MR. MACINTIRE: We have discussed that and it is in discussion still. If we do disclose to the party that we are now requesting records under the authority of the BT Act, there has been discussion that we would do that but then, you know, we have this issue with how much information should the investigator be disclosing when making the request so that at least you know what it is or why it is basically. I think you will know what it is we want; it is the why part that is the question here. I would appreciate it if you would submit comments to the public notice on the draft guidance for record access because it is going to be helpful. Now that I am in the district, I haven't been privy to a lot of that has been going on for, like, six months so I am going back on my memory prior to June of last year when I came to Chicago.

DR. BERU: By the way, the comment period, as pointed out by the lady sitting in the front, is

45 days past publication, which was December 9. So, technically the date for submitting comments has passed, however, we always consider comments.

MR. MACINTIRE: Right.

DR. BERU: We will consider comments.

MR. MACINTIRE: Even on rules that are final. You can comment on any rule that is final. It doesn't have to be a draft rule or draft guidance. You can comment at any time through the Federal Register notice.

DR. BERU: Yes, even when a guidance is final you can submit comments.

MR. MACINTIRE: Right, you can still submit comments and the agency will review the comments, no matter what stage we are at in the process because what you are saying here is very important.

Q. I guess I wanted some more clarification on that gentleman's question. If we are a company--I fall under the low acid canned food regulations. So, you come in and issue a 482. You are not going to tell me now that it is for a

regular inspection or if it is for the BT Act? You are just going to issue that plain and generic? I mean, I understand we have to assume that the records are available but, you know, it doesn't give us the knowledge to help you I guess at that point where we need to know what type of inspection it is.

Q. [Not at microphone].

DR. BERU: Use the microphone.

mr. macintire: [Not at microphone...] low acid canned food inspection, but we saw something during the inspection that led us to believe that there is a serious threat. Okay? We get this information to our top-notch individuals and our attorneys and, let's say, we get clearance. Now we want to request a specific record that is a little bit outside what we normally would collect or demand because you would get a 482-A which is a demand for records. The discussion would be we would get clearance; we would go back and, even though we have issued that 482 when we walked in the door a week ago and we are still there the

second week, we are not sure what we would do--issue a second 482 and point out we are issuing this now because we need records that are under the authority of the BT Act, or just leave it as we have issued a 482 and we haven't closed out the inspection so we don't have to issue a second one. That would be the scenario if we had to issue a second one because we have left and closed an inspection. But if we haven't closed the inspection we normally don't issue another 482. But we may provide information why we want these records, outside the low acid canned food record, or the seafood HACCP record or that juice HACCP record, but there also could be a scenario where those records that we demand or require to have based on seafood HACCP, low acid canned food or juice HACCP is a record that shows us information about that threat. It gives us the information we need to protect the public health based on the threat. So, I can see it getting complicated but I think we tried to keep it simple because if it gets too complicated we will never get the record. I

won't get clearance, for one thing, to go and get the record, and then whom are we protecting?

Q. [Not at microphone].

MR. MACINTIRE: When an investigator is in-house doing an inspection and they see something they think is a serious threat to the public health, then once they get the information up to headquarters and get clearance--when the district director provides the investigator the authority to go in and ask for a specific record, the clock starts ticking then. "Reasonable" is within a 24-hour period.

DR. BERU: Well, it says "as soon as possible but not to exceed 24 hours." Again, there seem to be a lot of questions on records access and I am glad Scott is here. But it is draft and please do send in your comments because we will take them into consideration as we finalize it.

Q. What you are saying then is that an inspector can't request it without having the clearance first?

MR. MACINTIRE: That is right.

Q. So, we are assuming then that this is all going to be bioterrorist-related and not just a public health issue?

MR. MACINTIRE: When we come to you during inspection or the first time come to your door and say I am [not at microphone...] Let's say we were already doing a trace-back or a trace-forward, we would know from the records we got from the previous sources that your company or whatever is part of that entity that has responsibility over the food and held it, had repacked it, had stored it and transported it and we need now your records, the records you would have to help us get to the source or get to the problem and protect public health. In a normal GMP inspection we are there, yes, to protect public health and that is our main mission but now, because of 9/11, we have been given another mission and that is, again, when we have that threat that has been established and been cleared and we met the threshold then we will go to the second step, into protecting by security means the public versus public health by means of safe

food, nutritious food, or safe drugs, effective drugs--you know, the old way of doing business as far as FDA is concerned. We have a new way now.

Q. So, when the second request comes in we had better call in our lawyers.

MR. MACINTIRE: That happens now anyway without the BT Act--you know, "wait, let me get back to you, I'm going to call my lawyer" or "if you give it to me in writing." So, we are not changing the way--we never gave a written request for records unless it was low acid canned food and there is a form for that.

DR. BERU: Any other questions?

MR. MACINTIRE: I don't know if I am helping or explaining the FDA properly.

Q. One question I want to ask is for transporters of food, when it says description of freight, do they have to have the specific SKU information and the quantities?

DR. BERU: For transporters, actually, we have tried to simplify it in that we have tried to give them many options, which they already have

under other regulations anyway. So, they do have to have a general description of food, certainly not to the level of SKU, lot numbers and so on but they do have to have the amount and the general description of the food. That is what is required.

Q. See, for example, the bills of lading that our system generates, it just combines all the SKU numbers. Like, if there are ten SKU numbers it will just say, like, a thousand cases and this is the total weight. Would that be sufficient for the FDA record-keeping requirements?

DR. BERU: Your records don't have to have the actual name of the food. You can have it in code, provided at the time that Scott comes and asks for it you can translate the SKU number to what the actual food is.

MR. MACINTIRE: [Not at microphone]...the requirement would be you have to delineate or identify [not at microphone]...We have a 100 cases of this; we have another 100 of this or 500 of this.

DR. BERU: But the SKU does identify the

food.

MR. MACINTIRE: That is something else and, yes, we can use another record to help us identify what is in this record.

Q. [Not at microphone].

MR. MACINTIRE: That is right, put two together to make one. It causes a lot more work for us but not any more work for you guys.

Q. [Not at microphone].

MR. MACINTIRE: That is what we train our people to do.

DR. BERU: But I think that is one that we have addressed in the preamble. We were asked in some instances, some practices, to keep records using codes for foods and can we continue to do that or would we have to identify the exact food and brand, and so on? We said no. So long as when we ask for the records you can interpret for the FDA inspector that this code means this food, then you don't have to.

Q. Can you expand on the definition of intra-company transactions? So, if it is an

ultimate parent and you have a foreign subsidiary transporting into a subsidiary but not the same entity but they have the same ultimate parent, would that be considered as intra-company transfer?

DR. BERU: Not in that instance. If you operate in the U.S. for all intents and purposes you are a domestic facility, not a foreign entity. So, if you operate within the 50 states and Commonwealth of Puerto Rico and the others, then you are subject to the requirements of the regulation.

Q. What if you have the same parent company and your foreign subsidiary transfers to another subsidiary of the same parent company?

DR. BERU: But where is the transfer taking place? From the foreign to the United States firm?

Q. Yes. Then the foreign is not required, remember, except for those who transport within the United States. So, there is no requirement on the part of the foreign subsidiary. But the domestic subsidiary will have to have

records indicating that it came from the foreign subsidiary.

MR. MACINTIRE: I want to save some time for the written questions and I think we can do that.

Q. A question regards the 24-hour response time, that is a reasonable 24-hour response time. So, if it is on Christmas day it is business hours?

DR. BERU: No, it is 24 hours from the time the written request comes to you. We have considered that. We have considered time zones. We have considered that you don't necessarily keep records on site, that a contractor may actually keep your records. So, we have considered all that and we feel that between what we were told were very onerous requirements of four hours if we ask during normal business hours and eight outside of business hours, we feel that "as soon as possible, not to exceed 24 hours" is a reasonable compromise.

Q. But if your corporate headquarter centralizes record-keeping and can respond to the

request within 24 hours, that is acceptable?

DR. BERU: Again, you know that is a standard. So long as you can do it within 24 hours, you can store it where you find it convenient but you have to make it available to the FDA inspector.

Q. And one last question, we are a manufacturer who retails and wholesales water treatment systems, and just a follow-up to a previous question, a water treatment system, does that fall under these guidelines?

DR. BERU: I think that is a question we need to get back to you on and I would appreciate you submitting it.

MR. MACINTIRE: I think that is the zip-lock back question again. Do they actually use the filter to filter the water they are putting in the container? You are not bottling water?

Q. No, we are just selling the equipment that Polar Water uses.

DR. BERU: Then I think, by way of the food contact analogy, you would be subject to

record access for whatever records you happen to keep, but you would not have to establish the one up and one down.

Q. In terms of packaging, if you put candy in a plastic bag and then put the plastic bag in a corrugated carton, does the corrugated carton then fall under the requirements, or is it just specifically the food contact packaging?

DR. BERU: It does. Since you are putting food in the packaging--remember, we defined packaging as the outer box, in this case corrugated--then you are not required to keep track of where you got that from but you would be subject to records access for whatever records you may have for the outer box.

Q. So, as a manufacturer, we put the candy into the plastic bag and I am responsible to maintain records on that plastic bag, but then the corrugated carton, since it doesn't come in contact with the food--

DR. BERU: You don't have to. But whatever records you have with respect to that, if

the situation arises we can exercise our access requirements for whatever records you may happen to keep on that.

Q. We are a company that has many USDA-inspected facilities but we also have one within the company that produces FDA products to ship out to these USDA facilities for further processing. In that case, are those FDA items, being that they are going to go on for USDA processing--would we be required to meet these requirements for those items?

DR. BERU: The FDA products would, yes, but not the USDA products.

Q. In that case, to throw out an example, if we are doing spice bags and we are shipping them out to the USDA facilities to be used in USDA items, we would have to track those spice bags following these requirements?

DR. BERU: Right. You know, there are some products with joint FDA and USDA jurisdiction, for those the Act exempts USDA products but does not exempt FDA products. So, you would have to

keep records with respect to the FDA-regulated products.

MR. MACINTIRE: In your scenario the finished product is exempt because that is a USDA establishment but anything you are making that is an ingredient in that that is food--you know, it doesn't really matter who was using it or what they were using it for but if you produce food, FDA-regulated food, then you have a requirement to meet the regulation.

Q. I have a question regarding that. There are no specific requirements for record-keeping tracking product within a warehouse per se. Correct?

DR. BERU: Correct.

Q. So, from a practical standpoint, we are a beverage wholesaler, if a SAHCODHA incident was declared we could give you records of the product that we receive from our suppliers and where that product went to, various retailers, but we might not know exactly which case or pallet, which trucking company brought that in if it was

over a two-year period. Would we just turn the records over to you and then you would do a fishing expedition from there? I am not necessarily asking you to give us more requirements but from a practical standpoint I don't know how you would be able to necessarily track where that product came from and which company shipped it into us if we don't keep track of it in the warehouse.

DR. BERU: Well, I know we lose some ability there but, remember, in the proposed rule we did require that a warehouse be able to link incoming with outgoing down to lot code numbers.

Q. Right.

DR. BERU: However, in fact we went on some field trips and saw actual practices and at least at the warehouse level it was pointed out how impossible it is for a warehouse that is breaking up one lot of product and filling orders, and so on, to be able to keep track of the lot code numbers. It is basically relatively impossible. That is why we removed that requirement for warehouses essentially for distribution centers and

downstream. So, yes, I think all you can do is tell us that you received the product from what firm and what transporter brought it to you, and also give us the information about where you send product. But the Rule does not force you to identify the breakdown by lot code number.

Q. Then a follow-up question on the time requirement, it is two years both ways, inbound and outbound? Correct? So, if we receive a product and we have it for a year and a half or we have it for three years and then we sell it to a retailer three years later, we need to keep those records as long as we have possession of that product until we sell it to a retailer? Is that correct?

DR. BERU: Well, the records have to be created, like I said, when you receive the product. That is one set of records with the identity, time received, date and so on. And then you are shipping product. If it is happening three years down the line, this set of records, according to our record retention requirements, would not be available.

Again, I think this is one where we probably have to clarify, for product that you hold onto longer than three years, what the record retention is. The way it is written now, the literal interpretation is that the record you create for incoming you have to keep for shelf-stable products for two years. Records you establish for outgoing products you have to keep for two years. But inasmuch as you want to connect incoming with outgoing product if it is in the warehouse for longer than three years, we haven't addressed that but I think that is one we should address in the questions and answers.

Q. Just a quick one, can you give me a definition of a firm with, like, a broker or agent

DR. BERU: Can you say that again, please?

Q. Definition for a firm. You mentioned a couple of things, that you have to track the name of the firm that is shipping you something as well as the transporter. Can you give us a definition of a firm? Would that include an agent or a broker?

DR. BERU: No, by firm I just mean a company or corporation. But the Rule says persons who manufacture, process, pack--for ease of language I am using firm but it could very well be an individual; it could be a corporation; it could be an association. It could even be a government entity. Person is broadly defined.

Q. Would your presentation be available on the FDA website or anywhere?

DR. BERU: It is already on the FDA website. I don't know if the French and Spanish versions are on but we intend to put both Spanish and French versions on as well.

Q. Thank you.

MR. MACINTIRE: This is going to be the last question this way and then I have the written ones to do next.

Q. Good morning. I want to go back to your definitions and to your slide that records must include all information reasonably available to you to identify the specific source of each ingredient. That is as a manufacturer of food when

we ship out. The question here is the definition of food contact surface. You explained very well the packaging piece, but what about things like gaskets and other food contact surfaces that we have in our plant and are those considered food?

DR. BERU: Right, legally they are.

Q. So, when we ship out a shipment of food do we need to know the lot numbers, because we have those in the plant, but how do we tie them to the specific lot?

DR. BERU: That is a very good question. We had another similar question in the DC presentation where a person asked what about bottle caps; what about every little piece that comes in contact with the food? Are you supposed to track the lot code numbers? We said we would address it. That is a very good question.

Q. Just another thing to consider, besides the caps, liners, those types of things, but gases, for example, flushing containers with either nitrogen, carbon dioxide and nitrous oxide.

DR. BERU: And these are the types of

questions we really want to have real live situations for so that we can address them in questions and answers. We issued a regulation that we think can be applicable broadly but, as I said, there are many covered entities and many different situations. We think we walk on water but we can't possibly address every situation and, to the extent you can help us do that, please do submit these types of questions and we will address them. We will vet them through our Office of General Counsel. These are, you know, interpretations of the regulations so they are likely going to be sort of level one guidance which, again, gives you an opportunity to comment if we haven't got it right. So, please, do submit those questions.

I was told that our web folks are supposed to have put up on the bioterrorism web link a place to submit written questions. It is not up. Actually, during the break I gave out most of my cards and I am willing to give them via email. If it is not up soon, you can either wait for it to be up or you can send me email directly. My email

address is nega.beru@cfsan.fda.gov. I may have a few other cards in my bag as well.

MR. MACINTIRE: I have some written questions that we received, and this goes in line with the last question and comment by Kathy on closures.

I think this one is a supplier of closures, actual manufacturer of closures who understands that they are not required to keep a record because they are not making a bottled drink.

DR. BERU: That is correct. But you would be subject to the access requirements.

MR. MACINTIRE: Exactly. So, if you have records that you keep under just your normal course of good business practice, you may be requested at some point by FDA in an investigation, most likely a trace-back investigation--you know, how did you make those caps? Or, who did you get them from? You may have got them from somebody else.

Here is a question, we manufacture finished human food and in the process of manufacturing we also generate animal feed

byproducts. So, they have waste products. This might be very similar to the candy waste question. Then they sell those to a firm that makes cattle feed.

What I heard is that there are no exemptions. There is a requirement for both. The food manufacturer provides the tailings to the feed firm and then the feed firm is going to have to keep records too because they are producing a food that is under this particular rule.

DR. BERU: That is correct, yes.

MR. MACINTIRE: It is a double whammy! Hopefully not the same company!

At our manufacturing sites we contract out the restocking of vending machines which are kept on site for employees' food purchase. Is there any record-keeping requirement on the manufacturer? I am trying to think who is the manufacturer, the machine or the food in the machine? What do we do with vending food?

DR. BERU: As someone else pointed out to me, vending has the restaurant exemption. That

food is, you know, directly to consumers, although it wasn't on my slide. So, they do have that exemption.

MR. MACINTIRE: And I don't think the manufacturer of the vending machine is required to keep any records either.

DR. BERU: No.

MR. MACINTIRE: It is not direct food contact service. I guess it could be--coffee--but then it is retail food. I don't know, it is a retail food without an operator. Think of it that way. It is exempt.

Our manufacturing sites purchase bottled water for employees to drink. Do records need to be kept regarding the water, previous source and transporter?

DR. BERU: Can you repeat that?

MR. MACINTIRE: This is a firm that purchases bottled water for their employees to drink and they want to know if they have to keep a record who they bought those bottles of water from. You know, they are basically a consumer. Right?

DR. BERU: This is for consumption by employees.

MR. MACINTIRE: By employees so they are a consumer. We don't require consumers to keep records of who they bought their food from.

DR. BERU: No.

MR. MACINTIRE: It would be nice when we are doing a food-borne investigation. I can tell you when we go to the home we want to know where did you buy it; who did you purchase this product from but it is not a requirement.

DR. BERU: But, in fact, consumers will in most cases be able to tell us where they bought the food that made them sick. In this case the employee may be buying the bottle, but they will know where they got the bottled water from.

MR. MACINTIRE: During the manufacturing process several items potentially come in contact with the final finished product, including chemically treated water, anti-foam agents, etc., etc. I think we are talking again about food ingredients or processes and components, process

components.

DR. BERU: Yes, that may reasonably expected to be a component of the food and they fall within the food additive definition. Some of this we dealt with in past questions.

MR. MACINTIRE: Before a truckload of food leaves the food processor, the food processor records the lot codes. Some pallets are delivered to customer A; some pallets go to customer B. The food processor does not have access to which pallet went to which customer. How would FDA view the lot codes? Well, we don't view lot codes.

DR. BERU: In this case the manufacturer is delivering, and what we have been told is that they do have lot code number information for those that deliver.

MR. MACINTIRE: But we are not requiring a lot code unless they have it.

DR. BERU: For the manufacturers we are.

MR. MACINTIRE: Sorry.

DR. BERU: Manufacturers and processors who pack food are required to keep lot codes.

Everybody else doesn't have to keep records of lot number but manufacturers and processors who pack do have to keep records.

MR. MACINTIRE: Because we were working hard to try to keep codes for food manufacturers a requirement because it has always been a problem for us to do trace-backs and trace-forwards without those codes.

Let's see, we have two facilities within half a mile of each other. The main plant receives all ingredients and ships all finished product. Does the transportation of ingredients to the second facility require the transportation documentation?

DR. BERU: No, again, this is within the same company transport that we said is exempt.

Q. I have a question on that. Are you exempt if you hire another transportation agent [not at microphone...] to one of your locations?

MR. MACINTIRE: The question was is there an exemption if you hire another company to transport the food between your two different

facilities?

DR. BERU: That is actually a very good question. That also came up at our headquarters briefing where you subcontract to somebody else. Does he become then really part of your company or is he a separate entity and, because he is taking possession of the food, does he keep records? We have to work that out with our legal department.

Q. [Not at microphone...] we don't have a fleet and we hire a transporter.

DR. BERU: Right. Actually, you don't have to submit that question. It has already been submitted and we will address that.

MR. MACINTIRE: And one last question--some of them I am not reading because we have already addressed them so I have skipped a few. But this one is interesting. Will a request under the BT Act be triggered for man-made events, for example, arsenic in corn, or also for already occurring natural events, like ethyl toxin in corn?

DR. BERU: Is that records access again?

MR. MACINTIRE: Well, in a way it is. It

is kind of both. We addressed this question that came in when we had some comments regarding terrorist act versus naturally occurring. You know, there is no exception. We may need to access records under the authority of the BT Act for a naturally occurring event of a food-borne outbreak. We never had a law that allowed us to get access to records in, like I said, a bakery before. Those processing records and transportation records weren't specifically required by a company to provide to FDA. We never had that for a bakery or possibly a dairy and a lot of the other food industries out here.

So, when we normally do business now under what we may have to do under the BT Act because of a threat, we felt that they are very similar. We need those records for a reason. How we are going to explain that to you when we request them, that still has to be worked out. But we will be issuing a 42 as a notice and then further clarification comments when we get that guidance out. But there is not going to be really any difference between

why we are going to request that. If it meets that threshold, then that is what is met and if we determine it meets that we are going to request a record.

DR. BERU: One last question here, ingredient storage bins at our feed mill are never empty, completely out. We co-mingle truck loads and rail cars of some ingredients in these bins. Number one, for products that are shipped do our records need to show some type of documentation for lots that may have been included in that outgoing product?

The answer is yes. We are saying that you have to tell us at least what is the universe of product because once we get there, if the contamination has been at the farm that supplies you, we want to at least limit the number of farms we need to go to in order to get to where there is a problem.

The second question, since the storage bins do not empty out, if we bring in ingredients over a year's time we may have several hundred lots

pass through the storage bin. How many of those lots have to be shown as potentially in the outgoing product?

A very good question. This very same question was asked in a different guise in College Park. This has to do with grain elevators that receive from potentially dozens, if not hundreds, of farms and they transfer between silos, and so on. Realistically, the only thing that you can provide is the sum total of everything that could be there, which isn't terribly helpful to us. I mean, we want to narrow it down as much as possible. But, again, you know, we are not looking to re-engineer your process but, keep in mind, we are giving adequate time for compliance with these rules and, to the extent that you can modify your operation to make it easier to trace back and trace forward, that would be a plus but that is not a requirement of the Rule.

So, in this instance you may tell us it could have come from a hundred farms, which won't help us very much unless it was narrowed down so we

could conduct a proper investigation. But if that is all you can do, that is all you can do. The Rule doesn't tell you to re-engineer your process. But, again, keep in mind that for large businesses you have 12 months to come into compliance; small, 18; and very small, 24 months. To the extent you can modify your operation to make it easier to trace--the nature of the times is such that a potential problem in the food supply could be devastating for everybody, not only from the number of casualties that could result but what it does to the confidence of folks in the food supply, to the economy and so on. So, to the extent that you can help us cope with this, it will be great.

MR. MACINTIRE: One last question.

Q. What you were saying about you can't trace it all the way to the ultimate consumer, do you think the advent of the RFID tags could some day be beneficial in helping you all the way through the entire chain?

DR. BERU: Yes. We have had presentations about RFID and we have been told by industry that

right now it is very expensive to implement, but with time the cost may come down enough for everyone to use it. We are hoping, you know, five years, ten years from now such a system will be able to be developed to help trace-back.

One more question?

Q. [Not at microphone].

DR. BERU: No. Well, I can't speak about five years from now. If we find that it is cost effective for everyone to do it, we may reopen the regulation and consider it but right now what the Rule says is keep these sets of information and your records, do it however you can, whether it is electronic, paper or other means. This is up to you. But down the line, you know, I can't speak to that.

MR. MACINTIRE: Thank you very much.

DR. BERU: Thank you very much.

MR. MACINTIRE: Please comment to both final and anything in draft regarding the BT Act. It is available on the website. As Nega stated, they are working on a link so you can submit

questions.

[END OF TAPED RECORDING.]

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