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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

FDA OUTREACH MEETING

"Ensuring Compliance with the New FDA Rule for
Establishment and Maintenance of Records
Implementing Section 306 of the Bioterrorism Act"

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Center for Food Safety and Applied Nutrition

Question and Answer Session

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P R O C E E D I N G S

MR. CARSON: --others who might have the same question who can hopefully hear my eloquent response. I say hopefully, because I did receive one question and I will sort of start off with this, and--I guess we're out of the--

[Pause.]

MR. CARSON: Okay, the question I have is silo A contains grain from 10 farms; silo B contains grain from 10 other farms; and silo C contains grain from 10 further farms. I ship grain from silo A only. And the question is do I need to provide, if FDA asks for records, all 30 farms or only the farms that contributed to silo A?

And the answer is: You only need to contribute the names of the farms from silo A. Because we are asking you about a product that was produced from grain from that production and you say it was all produced from silo A.

So I don't know if we started with a simple one or what. Next question?

MR. : Bruce Myers. Since you

can keep records electronically, does part 11 apply to these records?

MR. CARSON: You have to translate what you mean by part--

MR. : 81 CFR part 11.

MR. CARSON: But how do you--

MR. : Electronic Records and Signatures Act. There's a guidance document about the signatory to--regarding necessary or required records, in that part 11 guidance.

MR. CARSON: Right. Thank you for the question.

The record rule that we have described today is in conformance with part 11. So in part 11 is generally where FDA would seek certain records and have a meeting with the firm. This is a bit different here, even though we do allow for electronic records, we do not require them in this establishment and maintenance of records under the Bioterrorism Act.

We are not conducting a part 11 hearing, and when we seek records here, but there will be an

appeals process and there will be, you know, other processes that if you feel that we have had too broad a scope or if the records access that we seek, you believe is inappropriate, there will be a process for you to seek redress or to seek a change in that.

But it will be consistent with part 11, but it will not be part 11.

Yes, sir.

MR. : Chris Lane, Proctor and Gamble. Hopefully two straightforward questions. The first one is in your requirements for nontransporter, we are required to keep date of record--records of--what it says in the regulation is date released.

The question is, is that--what is the record that FDA wants? Do you want when the QA releases product or when the product is actually released from the facility, i.e., shipped? Now there seems to be some confusion based on the use of that particular term.

MR. CARSON: FDA is seeking the

information on the date the product was released for shipment.

MR. : Okay. One other quick question, then. You mentioned again that from the standpoint of the person required to maintain the records, it's the owner. Now the question is, is that the owner of the product or the owner of the facility?

For example, if you have a broker who may technically own the product, but they are in New York, but the product is going from a place in California to a place in Chicago to a place in Lexington, and the broker never actually has it in his facility, but he has contractors, he's the actual owner of the facilities that the product goes to, does he need to keep the records or the owner of the product?

MR. CARSON: Again, I'll go--the answer is the requirement or the person who is required to maintain and establish records is the owner of the product. In the case that you bring up--and we have had this many times--we often have brokers who

never actually physically own the product, but someone else owns it, they are brokering it around. It is the owner of that product who is required to have the records.

Now there are many different ways you could have asked the question. A warehouse in some respects only allows--only has space, but they don't really own the products in that warehouse, it's other owners that own the products in that warehouse. Again, it's the owner of the product is required to establish and maintenance the records.

Now there may be agreements between brokers and the owners as to who will actually establish and maintenance the records, and so it could be either one. But whoever owns the product under FDA's rule is the one that we seek, we would look to first, and unless they have an agreement with someone else, they are the ones who should be able to produce those records upon request.

MR. : Gary Churchill. I have a couple of questions. One leading up to this last one right here. If we have a--we are a wholesaler

working with a retail grocery chain, and if we have a manufacturer drop ship straight to the retailer and all we handle is the paperwork, are we considered the owner yet?

MR. CARSON: I guess I'd have to get into your business practice. Did the transaction--do you own that product even though the manufacturer drop-shipped it to the retailer?

MR. : Not until it's delivered.

MR. CARSON: Until it's delivered. Well, then obviously it's the manufacturer who needs to have the records of immediate subsequent recipients, meaning the retailer, and the transportation to get there, whether it's the manufacturer's transportation or a contracted firm.

So it would be their responsibility. And then the retailer would be responsible for establishing and maintaining the records of the receipt of those goods, but not who they sold those goods to.

MR. : Okay. The second question comes back from products that are considered to be

sort of like a kit. For example, if you have a Hickory Farms retail unit, such as beef sticks that you see on the holidays and everything, they have multiple products inside that container. Do we track the one retail unit which is the Hickory Farm display, or do we track every product on that display, as far as recordkeeping for the nontransporter?

MR. CARSON: Well, let me see if I understand. You have a container that has cheese and meat and other products in it?

MR. : True.

MR. CARSON: Under this rule you are only required to establish and maintain records for FDA regulated products, so that would only be the cheese, not the beef sticks. And yes, you need to maintain records about those FDA regulated foods that are in that kit.

MR. : Okay. Thank you.

MR. : Will Dunsing from Dumilling. Lou, when you are describing the food, several times the term "a specific variety" was

used, and that was curious to me because that means one thing maybe to a wheat miller but it might mean something altogether different.

Could you explain what is meant by "a specific variety" in this context?

MR. CARSON: Sure. Again, remember, FDA is seeking as specific an information as possible. So we are looking for something that is more than-- we don't want you to just say it was grain. We want you to say it was oats, it was corn, it was-- but, again, specific variety is usually we are dealing with produce or we are dealing with other products. So we are covering a pretty broad range. It may not specifically apply to the grain industry, but we are trying to have as specific an information about that product as possible, so we don't want people to forget that if it was a cereal, we want to know that it was Cheerios versus it was Cap'n Crunch.

MR. : Okay.

MR. CARSON: So that's what we're trying to say about variety.

MR. : And I note on all the slides referencing the FDA Records Act as guidance, they still include the word "draft." Is there anything significant about that?

MR. CARSON: The only thing--well, the thing that is significant is we did receive quite a number of comments, and we are finalizing those, that access provision. The reason we put out a draft, in FDA, all of our guidance is open for comment at any time, but it tells you the general procedure upon which we would seek records and the process to approve that request.

We did receive comments, therefore we will be making some modifications based on those comments, mostly to make it clearer, both to industry as well as to our own employees, so that we do it right the first time.

We hope to issue those records access guidance this month or next, along with the Q&A document.

MR. : John DiGiorgio with the Schuyler Company. Your first example about the 10

producers' grain in silo A, silo B, silo C, and then getting to the reasonable records. If we don't currently track producers' deliveries into specific silos, do we have to start doing that?

MR. CARSON: The answer is yes.

MR. : Okay. Then your example of if you dump 10 producers' grain into a bin and then the next day you dump 25 more and the next day you dump 25 more, and if you have a bin that's 600,000 bushels, and you don't empty that bin completely for two years, you might have 2,000 or 3,000 transactions into that bin, and those are the records that you are wanting?

MR. CARSON: Unfortunately, the answer is yes.

MR. : Somebody said there were no stupid questions.

MR. CARSON: No, no, no.

[Laughter.]

MR. CARSON: But that's just an enormous number of leads we'd have to follow up, but if, as you say, you don't completely empty that bin for

two years and all 2,000 can be in there, then that's what's reasonably available. We would have diminishing returns on the first, you know, 500, I would think, but we would have to follow that up.

MR. : Okay. Then just a little bit ago here you said the owner of the grain needs to keep track of the records.

MR. CARSON: Yes.

MR. : Something to that effect.

MR. CARSON: Yes.

MR. : Okay, so in the case where let's say we have a grain handling facility that dumps 3 million bushels of grain, and at the time the grain is dumped, half of that grain is still the property of the farmer, because he hasn't sold it. Is it the farmer's responsibility to keep track of that?

MR. CARSON: Well, again, as I said at the outset, farms are exempt. So farms need not establish and maintain records. So whatever records they are using today as their business transaction with the mill is satisfactory. It is

the manufacturer-processor-packer that needs to establish and maintain records. So you are receiving information from the farm, this is what you received, this is the kind of information you need to maintain at your mill.

So the answer is the farm is exempt. They have never been required to establish and maintain those records, so they don't have to keep that half, you know, whatever the half was.

MR. : Okay, but are we only required to--

MR. CARSON: You are only required to establish and maintain records of your incoming goods.

MR. : That we own?

MR. CARSON: Of whatever is coming in that you are using to produce your finished product, whatever product you release out of either your mill, your silo, your processor, your packer, your manufacturing facility.

MR. : Okay. Thanks.

MS. : Cynthia Mundy. We are an

herbal foods supplement manufacturer so I have a couple of questions that you didn't cover in here.

We sell bottles of finished product that we make to like health food stores and things like that. We assign lot numbers to those particular products. When we ship them to a health food store, do we need to keep a record of the lot number of the product that we actually sent to that store?

MR. CARSON: You need to--if you receive your ingredients with a lot code and you produce a lot code as a manufacturer on that product, then you need to track that lot code to, as part of its release, to its immediate subsequent recipient, yes.

MS. : Okay. The other thing is that we keep samples of everything we manufacture. How long do we have to keep it? I know the records are two years, but how long would we have to keep the sample of the actual product? Is that two years?

MR. CARSON: There's no requirement for

you to retain that sample; only a record.

MS. : We don't have to retain samples of what we make?

MR. CARSON: Under this rule--there may be other rules that you are retaining that sample for other purposes. This rule does not require you to retain a sample of anything.

MS. : Okay.

MR. CARSON: It requires you to retain records.

MS. : Okay. You talked about what is excluded from the records access which would be your recipes, formulas, you know, with the individual ingredients and how much you put in each one. Is that what you're talking about?

MR. CARSON: Yes.

MS. : And then when you go in here, when you say that they might be able to get the company's nonpublic confidential commercial or trade secret information, does that include that, too, then?

MR. CARSON: No. I mean again we are--

recipes are not information we can have access to. We can have access to ingredients. That's why we pointed that one out. There is other confidential business information that may help us track and trace a particular ingredient or product that you may have because of other purposes that we may access to help us in our investigation. But it will not be the recipe. The recipe is exempt from the records we can access.

MS. : Christy Galbraith, Cogan.
I represent a small company that manufactures bottled water, and we also deliver our bottled water. Currently we document our lot number per sale. Under this new rule, will we need to document what lot numbers are going on our trucks for delivery as well, or does our current business practice cover the rule?

MR. CARSON: Well, again it's for you to determine, but what we are asking for is if you manufacture and/or pack or process, using lot codes, then you are to upon release say which lots went to which immediate subsequent recipient, and

so to go from your facility to a recipient has to go via a transporter. So you are saying on release date of April 10th, again, you released 20 cases of bottled water on cartage company A to John's Food Mill down the street.

MS. : Well, we own our own trucks, so we are self-delivering.

MR. CARSON: I see. Well, then, if you own your own trucks, then it's part of your internal operation so you are keeping that record as part of where your trucks are going, anyway.

MS. : Correct.

MR. CARSON: So it's not another--so you are both the transporter and the nontransporter.

MS. : Yes.

MR. CARSON: What we are saying, when you are both the transporter and nontransporter, is the nontransporter requirements generally cover all the information that we would require, so you are keeping information on when you release it. It's your own truck that's taking it, so you don't need to keep duplicate records of that transportation,

because you are already tracking it as part of your internal documents.

MS. : Okay. Great.

MR. : Hi, Randy Gordon with National Grain and Feed Association.

Lou, first, thanks for having this meeting in Kansas City. I think the turnout is excellent, and we appreciate you having it in a midwestern location.

I think a number of the questions on both the grain elevator and the feed manufacturing side have to do with deliveries that are coming in from farms at this stage, and in a number of situations, if you are in a landlord-tenant type of relationship on a farm, the grain delivered to an elevator may be in the name of the landlord, it may be in the name of the tenant, sharecropper, each of which may have some ownership in the commodity.

The settlement sheets and others will have a multitude of this kind of information, and I wondered if you could provide a little more clarification on what kind of information that

elevators and feed mills might already be keeping in that regard, how they would comply with that kind of information.

MR. CARSON: All right. Let me see if I can go to that slide.

[Pause.]

MR. CARSON: Well, let me just say, again, as I mentioned earlier, we have exempted farms from the establishment and maintenance of records. So for a mill to be receiving product--grain or other products--from a farm, whatever the current business practice on a sale or whatever is the incoming information, the mill needs to know the name of the producers, their location, and when they received that ingredient, and specify what that product is.

As you mentioned, the owner of the farm may be different than the producer of that grain, and as we have tried to say that the information that we are seeking here is the owner of that product.

However, as you had mentioned earlier to

me, that the bill of sale may generally have not the tenant or sharecropper name but have the actual owner of that property. If that is what is reasonably available to that mill, they need not seek further information. That is what is reasonably available.

We will need to go back to the owner of that property and find out who was doing the farming if that's where the investigation leads.

MR. : One follow-up, Lou. In terms of the transporters that are used by farmers to deliver commodities to an elevator or feed mill, a lot of those will be contracted for by the producer, maybe a custom harvesting situation. Is there any obligation if the elevator or feed mill is already keeping track of the farm from which it's coming or the owner and so forth, as you have just explained, to also keep track of the transporter that's bringing that commodity into the elevator?

MR. CARSON: The answer is yes. You need to keep records not only of all immediate

subsequent--immediate previous sources--that includes transporter and nontransporter. So you would need to have the farm, bill of sale, as well as whoever transported that product to the mill, that information. Sometimes it's the same person and it's truck; sometimes it is a second party. But whoever it is that shipped that product to you.

Again, we are trying to determine why the contamination occurred. It may have occurred in the transportation; it may have occurred at the farm; it may have occurred in the processing. We are trying to determine where the contamination may have occurred by investigating each part of that process or that chain of events.

Yes.

MS. : My name is Julie Krueger, and I work with a small company. We make vending sandwiches, and I have a question about the lot numbers. Here's an example. We get deli meats that has a lot number. Do I have to keep track of that lot number, what lot number went into what sandwich? Or just from when I receive it?

MR. CARSON: Okay. Again, meats are excluded from--

MS. : Well, that's just an example.

MR. CARSON: But if you got lot numbers for cheese, for example, then we can follow through on that question. The answer is if you are a manufacturer, processor, or packer, and it sounds like you are, then you must maintain the incoming lot information for the ingredient to its finished product and its release. The answer is yes.

MS. : Thank you.

MR. CARSON: Any other questions? Yes, sir.

MR. : Gary Larcher. You have used the phrase "adverse condition" a couple of times. What constitutes adverse conditions? Or, rather, can an adverse condition be the result of a customer complaint or an employee complaint?

MR. CARSON: Okay, the term I have been trying to use is "serious adverse health consequence or death." That term has not been

specifically defined in our rule, so it is a term of art, but I tried to give you some tangibility to say it would be something on the order of a class one contamination in food where we would seek a recall down to the consumer level.

As far as a consumer complaint, sometimes consumer complaints can lead to class one recalls, but a consumer complaint in and of itself is not a class one recall. Class one or serious adverse health consequence means we have information of either a threat, an actual contamination where the contaminant can lead to serious injury, illness, or death, and we have to assess that, and through the process I already mentioned, determine that it does meet that standard, and once we do believe it meets the standard, then seek records from you to try and locate the product or the ingredient that contained the contaminant and remove it from the marketplace.

We do find this information not only from analyses we may conduct, we may get it from complaints, from other countries who have had a problem. There have been illnesses associated with

a particular product, or there may be intelligence information received where there is suspicion that someone has targeted a specific product to try and contaminate. Any of those may lead us to that determination.

MR. : How much weight is there because FDA is a public entity and therefore complaints to FDA would cause FDA to go ahead and investigate without scientific evidence of any real problems?

MR. CARSON: Well, I mean today, notwithstanding this rule, but FDA receives hundreds of thousands of consumer complaints each year, and we, to the extent that the complaint is something we can follow up on, we do today. And we seek--we first go and try and find that product. Sometimes we find that people are actually manufacturing--the complaint really doesn't exist, and they are contaminating or tampering with the product and trying to get some economic benefit from it.

But in other words, we will investigate,

we have had a number of off smells in products where petroleum distillates got in some way and the company didn't take it off the shelves. But it all depends on what the contaminant is, but we will investigate, and if it is a serious public health concern, we will take appropriate action.

Obviously if it turns out to be something that we cannot identify or it's sporadic, it doesn't occur everywhere, or we can't locate what the agent or what the problem was, then obviously that's how it ends.

But consumer complaints are one of the many ways that we follow up on unintentional contaminations of products that occur on a daily basis.

MR. : Thank you.

MR. : Mark Warren, International Ingredient Corporation. I've got about three questions, right quick.

Concerning transporters, we are a manufacturer and we use a multitude of trucking companies to transport to our customers. Is there

any liability on the part of our company to make sure that that transporter is in compliance with this rule?

MR. CARSON: I won't use the word "liable." You are only required to maintain the records for your company. The transporter is required to maintain their records. Unless there is an agreement between the two of you that one of the other will maintain those records. So you are not required to maintain or establish their records.

MR. : Okay. Good. Thanks.

I participated I guess last week on an AFA Web cast, and there was a rule or a comment made that I may have misinterpreted there, as related to locations within your company that only do processing or storage, if you will, of your product but don't--overtime never reaches an outside customer from that location. The records were not required to be kept at those locations.

It sounds to me like if that location does preprocessing, as an example, of an ingredient that

then goes to another location of yours before it is made into a finished product, those records have still got to be maintained. Am I correct in this thinking or is that--

MR. CARSON: Yes. I'm trying to understand the question and the comments. Let me try and answer it this way.

We are asking for all incoming ingredients at your facility for you to have records not only of who is the nontransporter but the transporter, and whatever processing or manufacturing you conduct, whether--within your company, and I don't mean it has to be that facility. It may go off to another facility and do some preprocessing and bring it back and then incorporate it into your finished product. You are going to have a record that, you know, X number of pounds went this way and the preprocessed end product came back and we formulated it back into the finished product. That is an internal record that you will have and that should be part and parcel because that will tell us if a contamination occurred at the preprocessing.

That would be a place we'd have to go and look and see if there was a possibility that occurred.

So certainly the records need to be maintained. It doesn't have to be maintained at that second facility. You can collate all those records at the primary facility, if you wish. I think that's what they meant. You don't have to store just the records of the preprocessor that did the preprocessing. If you want to combine all those records together for that particular finished product at your primary facility, you may do that.

MR. : Okay. Lastly, concerning packaging, we bag products, a lot of people in this room, I'm sure, bag products. We put products in super sacks. There's no lot coding, of course, on a bag. What type of records? Those products obviously come in contact with the finished good. Anything but just manufacturer of the bag?

MR. CARSON: Manufacturer, when you received it, and what finished product that bag went out, on what date. That's the information that we're looking for.

MR. : Okay. Thank you.

MS. : Jane Campbell of Wakes.

As a food manufacturer, we take an order. We will be putting in if this is a customer pickup. If the customer changes and does not pick up, that customer arranges to have someone pick up that feed, what responsibility is that of ours? Because we have already noted in our records that it was a customer pickup.

MR. CARSON: Is this the question you sent me?

MS. : Yes.

MR. CARSON: That I haven't responded to?

MS. : Yes.

MR. CARSON: Well--

[Laughter.]

MS. : That's good.

MR. CARSON: Well, it's part of the Q&A that's coming out, so--but I'm trying to understand--I think you said that you actually then retrieve that product and put it back into production, or you just left it there? I'm trying

to understand.

MS. : No, what I'm trying to say is that when the order was placed, we are going to ask, you know, are we going to deliver it or are they going to pick it up? The customer is going to come and pick it up themselves. But if they change and they arrange to have someone else pick it up, we will already have in our file that that customer, with their name, address, was going to pick that product up.

MR. CARSON: Oh, I see.

MS. : But in the meantime they have changed.

MR. CARSON: Well, not knowing how you--I mean if you know that it's changed, then you can change your record. I guess it's not clear to me--see, I didn't have to answer it.

[Laughter.]

MR. CARSON: If you--if it's reasonably available information that you know that a different transportation company came to pick it up, then it is information that you should

maintain. But if it is not, then obviously the record will hold and we will have to go back to the transporter and get their records, and if they chose to get a third party to come and get it, then it's their responsibility.

MS. : Okay. But I needed some clarification. If we perform a direct ship function--in other words, we buy commodities from a supplier, we don't take any physical ownership, it goes directly to the customer--

MR. CARSON: You don't have to establish and maintain records.

MS. : Okay. Thank you.

MR. CARSON: There was a similar question. Any more questions?

MR. : Bruce Myers. I have a couple here.

In determining the place of contamination, to what extent is accessibility to laboratory, passive records, that sort of thing?

MR. CARSON: Thanks for bringing that up. That certainly is part and parcel of the other

information that we may seek if it does exist over and above what we have required in this particular rule. Not all products are under a HASIP rule, but in FDA there are a number of seafood and juice, to name two, are under HASIP, so we may seek records there to see if contamination was noted or what was done or if there was any lags.

So certainly those kinds of records and any other records of testing of a product, QA that were done may help us in the investigation.

MR. : . Since quite a number of documents might have to be gathered, can the appropriate summaries be created by the manufacturer, let's say, in spreadsheets or whatever, or the actual--can that be a first wave of information or do all actual records have to be recreated and if they are electronic then they have to be printed out? Is that correct?

MR. CARSON: FDA is going to seek records for a specific product or ingredient in your facility. You need to produce them in whatever system you determine. If a summary satisfies all

the information we require, then a summary is sufficient. But you are under no requirement to summarize existing records. We ask for the records, you can give them to us, we will reproduce them. So that means we will make a copy of them either through some copying that we would have to get those records.

Obviously if you are electronic, you're going to have to print them out or give them to us on a disk. Some way to reproduce those records so that we have that information. So I assume it could be either way, a disk or printed copy from electronic.

So when you ask for the actual document versus a summary, what we are trying to do is get the information, and again the information may be on existing documents, for those that keep paper records, and we are not asking for you to go and do a summary of all the paper records to bring to us. We will copy those paper records and sort of put the puzzle together.

Obviously if you have the puzzle put

together for us, that will help us enormously. But that is not a requirement upon you.

MR. : Lot accountability, there's damage in warehouses and distribution sent from the manufacturer, and do those types that cause natural damage and that sort of thing, do those records for what I call mass balance or lot accountability, are those applicable to the 24-hour time period as well when doing lot accountability?

MR. CARSON: We are asking--again, I'm not sure--I guess you're saying that we are coming to a warehouse in this case, perhaps, where there has been water damage and product has been destroyed or thrown away because it was water damaged, and it was part of the product that we're seeking. Those are records that you should be maintaining, so it should be, you know, don't go looking for this because we put it in the landfill two years ago, or we burned it in the incinerator or whatever you did to it. But that is part of the records of what you did with that product, how it left your facility.

Yes, sir.

MR. : Jim Manley with Hanson Miller Grain Company. I have a question about transporter information. We handle grain and it comes through elevator situations, and at harvest time we're dumping anywhere from 100 to 300 trucks a day, and the grain can come in semi-load farm trucks, pickups, wagons, tractor and wagons, and when they're coming in, you can imagine the congestion and traffic we have to maintain throughout the day. We don't--typically we don't know who the driver of the truck is or the vehicle. We don't have a record of the truck. What do you expect from information on these vehicles?

MR. CARSON: Well, again, we are asking for you to establish records of both the transporter and the nontransporter of those goods that you receive. So to the extent that you can establish that information is what we are asking you to do. We recognize that it is not always easy, but we are asking you to know if we want to come back to that silo and find out who, you know, gave you product, and I think it's in your best

interest. If you find that some contaminated product got into your silo and it's going to contaminate all of it or only some of it, it's in your best interest to know who actually produced that, and so that we can go back and find out why that happened.

MR. : How do I identify what the farmer owns for a tractor?

MR. CARSON: Well, again, we're not asking you to tell me that it's a John Deere model whatever, but we are asking did you--who was the person that brought you--if it's the farmer that brought it to you, then that's sufficient. If it is the same farmer that produced the grain and brought it to you, fine. But if it is a third party who is conveying that for him, then you need to say who brought this grain and it's from these 27 farms. That person who is the transporter is going to be required to do that. He's going to have to give you some bill of sale or some transactional document, I would think, that will have that information.

MR. : He's not.

MR. CARSON: He's not? Well--

MR. : They just pull onto the scale, they have the grain examined for quality, and they are directed to a dump pit. They don't come in. I mean they tell you whose it is and that's about it.

MR. CARSON: Well, I guess we're going to have to work with your industry then to educate people as to what is required.

MR. : Okay.

MR. : Steve Rosanic, Dome Pitcairn. I was trying to make sure I understood the responsibility of a transporter, and I guess I go back to whoever owns the products or if we're shipping to a customer, we own the product and we keep the records of who we ship it through, and that--I guess the question is where does the transporter come in as far as his recordkeeping?

The reason I'm asking this question is I'm just curious, are there any transporters in this room? Are these mostly--there are some

transporters? Okay, thank you. Because I was just concerned if the word was getting out to them on their responsibility in recordkeeping because most of all I see is the feed and the grain and the food producers. And so that was my question--

MR. CARSON: Sure.

MR. : --is the involvement with the transporters.

MR. CARSON: Okay. Again, here's the requirement for transporters to establish and maintain records. They have five options to comply.

They need to establish and maintain the following records themselves:

The name of the transporter's immediate previous source. Where did they pick up the product that they are transporting, and the immediate subsequent recipient, where are they taking it to. And those are the origin and destination points.

They need to know the date of shipment received and released. In other words, the date

they received it and the date they released it to the recipient, the number or quantity of goods, the description of the freight--I picked up corn--route of movement during the time food transported. I basically went from Wanexa, Kansas to Kansas City, Missouri.

Transfer points through which shipment may have moved, if there were any transfer points. Again, we have shown a number of situations where it went from one conveyance to another.

And or if they have the DOT bill of lading for interstate transporters, that will satisfy the requirement. Or if rail and water, that bill of lading, that will satisfy. Likewise, an airway bill or entering into an agreement with a nontransporter to hold that information on their behalf.

So that's what the transporter is required to establish and maintain.

Yes, sir.

MR. : Tom DiGiorgio. Somewhere in here it mentioned bill of loadings as a document.

If we are shipping grain out of these various silos, each one of which has these two or three thousand transactions and we are blending this grain to ship, so now we've got 12 or 14,000 of these transactions that are going in the shipment, is it the bill of lading that controls the detail of the recordkeeping that we need to have on the outbound shipment for the upstream transaction?

MR. CARSON: No. Again, what is governing the information is what is explicitly stated in this rule. If the bill of lading has all of this information, then it can serve as the record. If it does not, then you need to supplement it or you need to create a new record that will have all the information.

So on the immediate subsequent recipient, you need to know the name, so on the previous source, on the immediate subsequent recipient, you need to know the firm name and contact information of the immediate subsequent recipient, who you are sending that product to, the description of the type of product you're sending.

MR. : I'm sorry, I didn't ask the question very well. The bill of lading could be for one car or it can be 110 cars of grain. Do we--as we track this information about whose grain is going into the shipment, is it the bill of lading that covers the entire shipment, or is it each vessel that we are loading the grain into?

MR. CARSON: Are you talking as the nontransporter or the transporter?

MR. : Nontransporter.

MR. CARSON: Okay.

MR. : I'm shipping grain now out of these bins, these silos.

MR. CARSON: Okay. Your requirement then is to have information on immediate subsequent recipient, transporter and nontransporter. So you need to know--if you have information on your release of your product to 27 gondolas is going to be picked up on train or 27 vessels are going to be coming to pick this up and ship down river, but the transporter is one company, that's--you need to know it was delivered to this company, they had,

you know, it was 27 vehicles, but it was this company, that's immediate subsequent recipient transporter, and 10 of those went to this immediate subsequent recipient and five of them went to somebody else, and the balance went to another person. You need to keep that information as to where all of those went.

MR. : I understand that part. It's the recordkeeping of whose grain went into those --

TAPE CHANGE.

MR. CARSON: --27 need to be linked to that, the finished product. If there is 2,000, as you had mentioned earlier, then it is 2,000. Immediate previous sources came in, you did your grinding, your milling, or whatever, you produced this product and it went out into 27 gondolas. That is the information that is reasonably available.

MR. : Thanks.

MR. CARSON: Randy, did I trip myself up?

MR. : I just want to ask a quick

clarification on that point, Lou. Randy Gordon, National Grain and Feed.

So if in this kind of a situation, if the shipper were keeping track of the bins from which that commodity was drawn from for those shipments and had the record that would establish what producer's grain was delivered into those bins, that would suffice in that kind of a situation. Is that what you are saying?

MR. CARSON: Yes, that would suffice. If I misunderstood that, I'm sorry.

MR. : Mike Ridge. Continuing on with the contact information just a little, we manufacture feed for obviously a number of customers. What is the contact information that is required and where is it required? I read when this rule first came out that we had to have the name, address, phone number, fax and e-mail address if available. Is that required on the bill of lading, the shipping documents, the invoice, or is simply having that in the main office in the customer's information sufficient?

MR. CARSON: You can establish that in any document you wish. It is part of the information we will seek when we seek records. We are not telling you how to format that information. Whatever is the most convenient or whatever way you have it existing now, you do not need to apply it to an existing record, but you need to be able to retrieve that information upon request.

MR. : Okay. How about for ingredients coming in from obviously a multitude of suppliers?

MR. CARSON: Same.

MR. : Are we required to keep that information or are they required to provide that information?

MR. CARSON: Well, both.

MR. : Both. Okay.

MR. CARSON: You are required both one step back and one step forward. So whatever you receive as incoming, you need to keep the same information, and then tie it to the outgoing from your facility to whomever is receiving it be it the

transporter as well as the nontransporter receiving it.

MR. : Okay. Thank you.

MR. : Will Dunsing. Lou, this authority granted to the FDA to access records is of course under the Bioterrorism Act, and you have given some idea as to what determination and assessment would take place on adulteration with serious adverse health consequence. And you gave as an example a category one or class one recall. That could, however, be as accidental, if I can use that term, as not adding eggs in a brown mix that a small company made, or it could be as potentially criminal as finding arsenic in a bunch of wheat flour.

Does the rule of the FDA pull this trigger in both cases, or because this was granted under the Bioterrorism Act, will there be a focus on those that appear to have a criminal intent?

MR. CARSON: The authority given to FDA covers both intentional and unintentional contamination of products. Therefore, it may be

from a terrorist threat or actual event, or it may be from environmental contamination that occurs in a normal--in a traditional food safety or foodborne illness situation.

We receive this information to have a better tool for us to conduct an investigation. Yes, you are correct, it was done under the umbrella of the Bioterrorism Act, but the authority vested in us covers both food safety and food defense or food security.

MR. : John Kramer. I have a question on customer pickups. Is there anything that requires a customer to let the manufacturer know what carrier they are going to use? You know, they might change carriers in the middle, they just show up and just say I have a pickup for X whatever.

MR. CARSON: Okay. You are sort of the second or third person calling it a customer. So this is a business-to-business transaction. To the extent that you have conducted a transaction with your customer and they are the ones who are paying

for the transportation, not you--sometimes it's you that pays for the transportation, sometimes it's them--then obviously the metronome is a little bit on this side. They are the ones contracting with the transporter, they are going to need to provide you that information, and if it's changed, it's really their responsibility to capture those changes. This goes back to Jan's comment earlier.

Obviously to the extent it is reasonably available to you to know who the transporter was, we ask you to establish and maintain that. Obviously if things change, you know, the dog ate the homework, somebody else showed up, it's really for them, because they are the ones that contracted them, to have that specific information.

So when we do an investigation and we come back and we ask this transporter who you have a record of, and it doesn't coincide with the recipient's transporter, we need to connect those dots. We're going to have to find out, well, why did you transport it and not this. Well, we understand they changed.

It's not incumbent upon you. To the best of your ability, you have as accurate information as you know is reasonably available.

MR. : Okay.

MR. CARSON: It doesn't seem like it satisfies you. What answer were you looking for?

MR. : I guess I have an issue with customers, that they should be required to notify us, because what if somebody would come in that is not supposed to pick--

MR. CARSON: Well, I think that is a security issue that you should pursue. I don't know that we have authority to tell you to do that. But that's certainly something you should pursue as a business transaction. Who you let onto your premises and who you let take away product, you know, and Joe told me to pick this up. If that's sufficient for you, then there's not much we can tell you.

MR. : Okay.

MS. : Can you provide some clarification on the foreign person that transports

food into the U.S.? If it's just like a Canadian manufacturer that's selling into the U.S., but then has no--

MR. CARSON: No. The only foreign persons that are covered are transporters who may transport into the U.S., such as trucks or trains, and probably only those from Mexico or Canada. So no manufacturers in Canada are required to establish and maintain records here. The transporters that pick up grain in Canada and Canadian rail will bring it in, they bring it all the way into the United States, not just stop at the border, would be required to keep those records of who they picked it up from and who they are bringing it to.

MS. : So only if one person owned the transportation can they--

MR. CARSON: Only the transporter is required.

MS. : Okay.

MS. : Hi, Jan McKay, Public Supermarkets, and I'm going to beat the transporter one more time. How do we handle a situation where

the trailer belongs to the company that we contracted with, but the driver of the truck cab belongs to an independent that they subcontracted with? Would that be the contracting entity that we record?

MR. CARSON: Yes.

MS. : Okay. I would like to talk a little bit about byproduct. We buy product for produce, bakery, and milk plant byproducts. We have those going to local farms for animal feed.

MR. CARSON: Yes.

MS. : Do we need to record a lot number on those corn husks or--

MR. CARSON: No, I mean if you are a manufacturer, processor or packer and lot codes exist, then you need to maintain a lot. But as a retailer, I think--this is a retail?

MS. : This is a retail--we are a retail super market chain, but we have manufacturing and we have distribution and we have stores.

MR. CARSON: But only as a manufacturer if

you produce products with lot codes, then you need to maintain that information. If you do not produce products--corn husks--I can't imagine you have a lot code on it, but then you need not. But that information of where you sent that product to animal feed, that information needs to be established and maintained.

MS. : Okay. We'll get a truckload of corn in, and then we'll husk it and we'll put it in prepackaged containers, the corn, for customers, but that husk is a byproduct.

MR. CARSON: I understand. So you are selling that to a business?

MS. : We're giving it to a business.

MR. CARSON: Same difference, but, yes, you need to maintain--in other words, you don't have to keep any records of the consumers that ate the corn, but you do have to keep records about--or access information that you have on who you gave or sold those husks to as another business.

MS. : Okay. Let me ask one more

question on this. We also have a deli plant where we have USDA authority. However, we have a renderer pick up scraps that those scraps could end up in an FDA-regulated product.

MR. CARSON: Well, rendering usually is under FDA regulations, so that rendering--the products you send to rendering would fall under this rule.

MS. : What requirements do we have as far as lot identification for the renderer?

MR. CARSON: Are there lot codes on the product? Well, there is no lot requirement. Only if there is a lot--if you are producing a product with a lot, then that's the only time you need to have a lot identifier. You do not need to have a lot identifier.

MS. : Thank you.

MR. : Jerry Churchill again.
Just one question on clarifying foods that are not regulated. Any product that is federally inspected through the meat, poultry, and egg production do not fall underneath this rule; is that correct,

from the time it's a kill house all the way to the retail store?

MR. CARSON: That is correct. From the slaughterhouse to the consumer, correct.

MR. : Okay, it's not regulated underneath this rule?

MR. CARSON: Correct.

MR. : Okay. Thank you.

MR. : Tom Stout. We are a feed manufacturer. All our plants are FOB so our customers supply the trucking. We have to keep track of our customers, but then we also have to keep track of the independent hauler that they contract to as well?

MR. CARSON: Again, you're saying your immediate subsequent recipient, whoever you are selling your product to, also is the contractor for the transporter? Then, you know, to the extent--if they are the same person, if they subcontract, it is their responsibility to know who the subcontractor is. You simply put down their name and location as a transporter as well as the

recipient.

MR. : Okay.

MR. CARSON: That is your requirement. As a manufacturer, we create lot codes that go to dealers that are nonmanufacturers or retail stores. If we provide them the lot code, then they have to also keep the lot code and show the lot code going on to the customer?

MR. CARSON: No. Retailers need to keep the --

MR. : Dealers. Dealers, not--

MR. CARSON: Dealers. Okay. I'm not sure what a dealer--

MR. : Feed dealers.

MR. CARSON: Okay. As a feed dealer, let's call a feed dealer simply another--I don't know if it's a holder of food, let's say. If you are producing a product and you give it to a dealer, they need to keep a lot code, and then if they are selling it to another business, another farm, they need to maintain they sold this lot to this number of farms. It's only when a retailer

sells it to a consumer that they need not keep those records. So this is not a retailer.

MR. : Okay, a feedlot is considered a farm.

MR. CARSON: Correct.

MR. : If a feedlot does manufacturing on site, does that manufacturing plant have to maintain the records?

MR. CARSON: Yes.

MR. : Okay.

MR. CARSON: Again, farms, where they conduct their traditional farming practices, are exempt. When you move into manufacturing or processing, then you come under this rule and need to comply.

MR. : I know you don't know the term trucker corn, but--or brokers. What happens sometimes is that we would purchase from a manufacturer and he would then purchase from another manufacturer so the plant of original might not be the original purchaser, so we keep records of the original purchaser that we bought it from.

MR. CARSON: Exactly. One step back. Your requirement is to know who you purchased the product from. Then we would go back to that person, and in turn they would tell us who they purchased it from. It is your responsibility only to keep one step back or one step forward.

MR. : And the term for that is who owns--who we bought it from or who we paid for that service?

MR. CARSON: Correct. It's what is reasonably available. Again, we understand there are people who are paper owners and people don't actually own it, but they all have to maintain those records of who actually produced it.

MR. : Hi. I'm Bruce Chapin of Louis Dreyfuss Corporation. I want to ask a little bit more in depth about when you have a grain bin that's a large bin, half a million bushels, and you are loading that out onto rail cars as has previously been mentioned. That bin does not get emptied for numerous years. You are then requiring us to keep thousands and thousands and thousands of

tickets to trace back?

MR. CARSON: All we can do is do what is reasonably available. If you--I mean if you are saying that the first bin doesn't get out of there for two to three years, which is amazing to me--I guess--

MR. : Well, say you start with a bin that's completely empty.

MR. CARSON: Yeah. I mean gravity has to work --

MR. : No, the bin is flat. You are talking these half million bushel bins that are perfectly flat on the bottom. Okay? And there's corn or beans that are put in it to start off, they might be at the edges. You will never get to those goods until you clean the bin out. If I don't clean the bin out for three years, that means there could be some grain that has sat there for three years. And that bin, just to add more to it, it has been unloaded and filled to various stages thousands of different times.

MR. CARSON: Well, I think you have

answered your own question. I mean obviously if we are going to come back and ask you, a product has been suspected of having a contaminant--and I used this example before; I don't know if it applies to you, but where we had docks and feed, and we have had other environmental contaminants entering into feed products, and we are going back to find where these things were made. If you are telling me that this one bin is where it came from, but there were thousands and thousands of producers that put things in there, then I guess that's the best we can do to go back and look at all those 3,000, where it came from.

I don't know if I'm telling you to change your business practice so you don't have the burden of keeping thousands of tickets, or it's easier for you to clean the bin. I don't know which is easier for you. But, you know, you choose your poison here.

The point here is that we need to be able to locate the grain when we need to locate the grain, or who the source was.

MR. : I mean I just think that industrywide, this particular topic is huge, because there's lots of bins that don't get cleaned out every three months, every four months. It's years. We have thousands and thousands and thousands of tickets in there.

MR. CARSON: I understand what you're saying, and it's unfortunate that--I mean but again I don't know--do you know of a fix on how to make this work? I don't quite see where to--you know, how to draw the line here. But again, if we don't know what contributed to this suspected lot, it's all of these possible contributors, then we have to follow up every one of those possible leads.

MR. : Mark Warner again. Most of the ingredients we receive into our company came from food plants that already are regulated by FDA. Where does our recordkeeping need to begin? We take those products, transform them into feed ingredients. But they came from a regulated facility to begin with.

MR. CARSON: Well, again, yours is no

different than the food manufacturer. You need to maintain records from both the nontransporter and the transporter of all of those incoming goods. And then the process that you conduct on those products to make your finished product, you need to tie the incoming ingredients to your finished product, and then tell us when it's been released and who it's going to, and what is the transporter of those goods to the recipient. So it's no different.

MR. : Okay.

MR. CARSON: Obviously, if that food manufacturer is under FDA authority and is already complying with those rule, the information that they can give you is the same as what you need to capture. So it should be easier in that regard. But it's still that you will have to establish and maintain records of the receipt of those goods, what you have done to it, and what finished products and when you shipped them out.

MR. : Thank you. One question on transportation. Again, our company has a

division that is a transportation broker; don't own the trucks, but broker all of the transportation. Does the broker have to keep all of these records as well, or just the transporters themselves?

MR. CARSON: Again, the rule says if you are the transporter and only serve to transport the goods, then you need to satisfy the rule as far as transporters is concerned.

So, again, if the broker is subcontracting to another, the broker or the transporter need to work this out. I can't answer it because oftentimes these agreements are different between different brokers and different transporters. It could either be the broker or it could be the transporter. But one of them needs to establish and maintain the records.

MR. : Okay. Thank you.

MR. : I'm with New York Coop. Did I understand you correctly that a lot number needs to go on each invoice? For example, if I have--I'm delivering a truckload of 960 bags of 16 different products on it. The loader that is

loading that, the warehouseman that is loading that truck needs to write down each unit, 16 products, 38 different lot codes?

MR. CARSON: Okay. Are you a manufacturer, processor, or packer?

MR. : I'm a manufacturer.

MR. CARSON: And you produce products with lot codes?

MR. : Correct.

MR. CARSON: Then you need to--

MR. : Well, we do both. We produce it--it has a lot code on it, but it's also--we can track it by item number or product ID.

MR. CARSON: Okay. If you have a tracking number, whatever tracking number works for you to show the link between the incoming ingredients, what you produced and what you released, and that is reasonably available and it's something that you can do, then that's information that we would like you to establish and maintain.

MR. : Okay. What that does, it just broadens the spectrum--I mean it would be nice

to show each lot code, it would be nice to show exactly the tree that it came from, but what you are saying is it's okay because it broadens the spectrum, because we are tracking all inbound and I track all outbound.

MR. CARSON: We are using lot code as an identifier. If you have multiple identifiers and one can serve the same purpose, then we're saying use that as the identifier. But if you don't use an identifier, then we are not asking you to create one. But if you do, then please do, and that helps us track that product through the process.

MR. : Okay. So we are going to do the best we can to track things because the second question I have for you, we are a cooperative. We have a grain division and we also have a feed division. Our grain division will pull in grains like the last few comments have been talking about, having 10,000 different records for the grain. It might be blended for moisture or protein, and then it comes directly over to the feedmill. We are going to have many thousands of

different suppliers or places that it probably could have come from. The FDA needs to recognize that we will do our very best to track this, but some of this, realistically speaking, we may not-- I'm a black-and-white guy--we may not be able to tell you exactly that this is exactly where it came from.

MR. CARSON: No, I understand, and that goes back to the bins that aren't emptied out for over three years. I mean the best you do is it's one of these, but I can't go beyond that.

MR. : Okay.

MR. CARSON: And that's what is reasonably available.

MR. : Okay.

MR. : Bill Harter. I manufacturer dairy products, and I have a question about samples. Our sales force drops off a lot of samples at restaurants and retailers. Do we have to track which lots go to which restaurants and which retailers?

MR. CARSON: Okay, I think you asked two

different questions.

MR. : Yes, there are two different questions, yes.

MR. CARSON: Okay. One was about samples.

MR. : Yeah.

MR. CARSON: And the Proctor & Gamble guy in the front seat already asked that question, I think, what, three, four months ago. That's part of the Q&A. So I can't quite answer you on samples that you give a sample to someone you're trying to sell a product to, they can taste or look at. We will be coming out with that answer shortly, so let me sidestep that and preempt that.

But the second part of your question, if you have lot codes as part of the information that you retain, then you need to track that lot code and to which retailer you gave each lot code to.

MR. : Okay.

MR. CARSON: On the date of release.

MR. : Okay. And the samples, the answer to that will come out later?

MR. CARSON: Yes, that will be part of the

Q&A.

MR. : Okay. Thank you.

MR. : Tony Glaxton, Missouri Department of Agriculture. You mentioned, citing the example of the feedlot, that manufacturers' feed for their own livestock, and if I understood you correctly, they are required to track?

MR. CARSON: They are required to establish and maintain records as a manufacturer or processor.

MR. : Okay. Now--

MR. CARSON: Now when you say for their own animals, if that farm, you know, feeds their own animals and that food is only food to their family, then you are exempt. But if you are feeding it to other animals as a business, for--you know, and those animals go to slaughter and go to other than--yes, you are covered by this rule. So I just want to make that clear.

MR. : So this then also would apply to the many farmers across the state that manufactures their own feed for their livestock

that they also sell?

MR. CARSON: That is correct. If you are a manufacturer or processor and we know a number of farms do--they mix their own feed, and if you are--you know, that's part of the manufacturing, then that part of your operation--not the farm part, but that manufacturing part is what you need to establish and maintain records for.

MR. : Tom DiGiorgio. Lou, I'm going to be kind of bold here and kind of speak on behalf of the grain industry. Okay? And it gets to not providing you--we don't mind providing you with information, but it gets to the quality of the information that you end up with if you have a problem, and okay, so there's a--as I understand it--a two-year record retention requirement for grain?

MR. CARSON: Well, animal feed is one year and pet food.

MR. : I'm talking about grain.

MR. CARSON: Okay, grain. Now when you say grain, is that grain for--yes. Okay.

MR. : Grain.

MR. CARSON: Yeah, grain.

MR. : Okay. That's grain, two years?

MR. CARSON: Got it, two years.

MR. : Okay.

MR. CARSON: Thank you.

MR. : Now I've got my friend back here who's got this big bin with--he doesn't empty it out for three or four years. After two years I can throw away the records that pertain to that bin?

MR. CARSON: Right. So I mean it's a self-fulfilling prophecy. We're only going to see the most recent ones, so we're not going to see the three-year-old grain.

MR. : So the quality of the information that you get in that case is really bad.

MR. CARSON: Well, I mean if the gentleman is correct that the three-year-old grain is now what's coming out as opposed to it was coming out

earlier, then you're right, it's not producing the information that we want. But if that three-year-old grain is largely gone and it's only what's around the edges--

MR. : I'll guarantee you when he empties out that bin, it's the stuff that was put in there first three or four years ago that is coming out, and if that's the stuff where the problem is, there are no records because he's going to throw them away.

MR. CARSON: Right. So--right. And if there is a problem with that grain, then we're going to follow it back. Obviously we won't have those records to use as a tool, but we're still going to follow back.

MR. : Okay. The other issue, again, getting back to this whole issue of the quality of the information that you will get, if I have got a dozen of these 500,000 bushel bins, all of which have these multiple records of producers that have dumped the grain in them, and I have a quality problem in one of them, or I have to move

that grain from one to the other, and I may take some of that grain from one of those bins and distribute it to 10 of them, and I have to do that multiple times, now this mountain of records for each of those individual storage silos is huge. And again, the quality of the information that you will be looking at six or eight or 10 months down the road not only is going to be voluminous, but it's not going to tell you anything.

MR. CARSON: Well, you don't paint a very rosy picture, and I do appreciate that that is a possibility, maybe even a probability. We only have the requirements that we can establish. We can't tell you how to do your business, but we can tell you what kind of information we need. Obviously in this case the two are not coinciding as best as they can.

So you're right, the quality of information that we are going to receive when we need it is not going to be the best that we can get. I don't know of a solution other than changing your business practice, which we are not

asking you to do.

But again, we are trying to tell you our intent. If you know of a solution to this problem, we would be happy to hear about it. But off the top of my head, I don't have a solution.

So again, if we have to go back and do an investigation, as we do today, we do it with the best information that is available. I mean we're getting this same information today. If we did an inspection, you're telling me today this is the best that you can get, you're going to have three-year-old grain in this 5,000 bin, and that is the best you're going to have, then we're not changing anything by this rule. We haven't changed anything. It's the best that you can offer. It's what's reasonably available.

MR. : Well, but what I'm telling you is that earlier, you know, you said it's not just the information that's available today, that you want us to change our business practices and the way we keep track of our records, and I'm telling you that we will do that and we will go

through and the economic ramifications of doing that will be significant, and at the end of the day the information that you will receive, if you have a problem and if you have to come back to one of these facilities, will not be any better than what it might be if I don't do anything different today. That's what I'm telling you.

MR. CARSON: Then I would ask you to please submit that or ask Randy to submit that in a formal comment to FDA.

MR. : We will. We will. Thank you.

MR. CARSON: Okay.

MR. : I'm Jeff Dillon. We buy grain from all these good gentlemen, and we also buy grain directly from the farm, and to me, you are really mandating that we change our business practices because all this comes down to an issue of liability. Because if I buy grain from him and it comes out of a 500,000 bushel bin that hasn't been cleaned for three years, but in my bin I have also bought from these other 250 farmers, and one--

and we'll go back to the intentional one farmer upset with agriculture puts some deleterious ingredient in there, and it comes back to this pool of liability because, okay, he may have 25 percent of the liability because that was 25 percent of my grain because I brought trucks in from him, but you could have a recall and just completely stop, or at least significantly hamper, agriculture as it is today, because it is a homogenous product.

When you have feed or corn, it becomes homogenous, and so to me, you are saying you are saying don't put it in a 500,000 bushel bin, you need to put it in a 1,000 bushel bin and have a thousand small bins so you can keep track, or you are going to be liable for this massive recall. To me, we are really opening up a significant can of worms here.

MR. CARSON: Well, again, I appreciate your comment. Again, I don't know that this rule changed anything. If we found a contaminant that led back to a 500,000 bushel bin, then that whole bin would be suspect if the contaminant was indeed

found in there.

This rule doesn't change that. What this rule does--I mean it's either pointing out the problem to you now and perhaps it wasn't pointed out before, but what it is asking is on the one hand, here's the information we're asking for, so we can do a better inspection, investigation. But we are also recognizing what is reasonably available. And I realize that you see that as two contradictory things as opposed to being--trying to at best allow for existing business practices.

The two perhaps in this instance clash and don't mesh, but to the best that you can do, that's all we are asking. We are not asking you to find the last grain in that bin. We are not asking you to know absolutely to the nth degree, but to the best of your ability, to tell us who contributed to that bin during this period. And that's--I would think that's the best I can do for right now.

Again, I would ask Randy or others to submit a written question. If that isn't satisfactory and you want something that is

clearer, we would be happy to do so in writing.

Now there had been a number of other questions that have come to us in writing, and I believe you will see in writing a similar answer to what I have been giving to you verbally. It is this balance of what's reasonably available and the information that we are requesting. And for us to make it any more finer is to go one way or the other here and say, well, don't keep any records, or keep exacting records. So it's going to be a balance.

Yes, sir.

MR. : I feel like this is "stump the director" day.

MR. CARSON: Well, you've stumped me several times, so I feel humble already.

MR. : My question is if I play the commodities market and I buy 100,000 bushels of grain, it's my understanding if I don't see it fast enough, I am actually the owner and they will deliver it to me. Do any of these rules apply to me if I own 100,000 bushels of grain in the

commodities market?

MR. CARSON: If you are the owner of food, if you are the manufacturer, processor, packer or holder of food, then you are required to comply with these rules.

MR. : Well, then, my question would be how would I possibly get the information on where my grain is?

MR. CARSON: But again--well, if you are a commodity person, then someone is holding your commodity and that person is already complying because they're the ones that's holding it, and you, by purchasing it, have purchased that information. So if you're a big poohbah, you're a big poohbah with the information. I mean--

MR. : Okay. From the broker?

MR. CARSON: Right.

MR. : Okay. Thank you.

MR. : Bob Jorkey in processing.

Just further clarification. If a grain elevator is not currently tracking the bins from which it's pulling grain to fill an order, must it start?

MR. CARSON: Okay.

MR. : I didn't think it would be that difficult.

MR. CARSON: I'm trying to--okay. If you--I'm trying to--if the information that we have requested as you as a manufacturer, processor, packer, a miller, is--if you are already capturing that information so that your incoming ingredients can be tied to the outgoing finished product, then you are satisfying the rule.

If you are saying that during your processing, you are not tracking the incoming to what goes to the outgoing, then you do need to establish, whether that's simply telling me you're taking it from this incoming ingredient where I put in this bin, mixing it with this other stuff, coming up with this finished product. You do need to track all of those that go into your finished product. The answer is yes.

But if you are--you know, you're saying you've got this incoming ingredient, and you know it came on, you know, week two of April and the

finished products went out on week one of May, and all of those ingredients went into those products, then, you know, you basically have tied the incoming to the outgoing.

I don't know if you need to know it came from this bin or not, that's part of your internal operation. I can't answer that specifically, but you need to tie the two together. That's what I can tell you.

MR. : Okay. So it wouldn't be acceptable to consider an elevator or a bin, even though you might have 100 bins, or is it possible, I guess?

MR. CARSON: Well, I think we have used examples where we have used a silo is equal to an elevator. If it's not, then we sort of meant it that way, so if you have product coming from silo or elevator A, it's going to make a finished product, then all of the sources, immediate previous sources going into elevator A, are what went into that finished product or potentially went into that finished product. And if we asked you

where did you get your incoming ingredients, it would be every one that came out of that.

Now all you need to know as the miller is who the source, who is the elevator A. Who owns elevator A. Then we go to elevator A and ask them who produced--who did you have in your elevator on this particular day. And it may be 200, 300 different producers. That's their responsibility to give us that information. Yours is only one step back. You go back to the elevator, that elevator is where you got those ingredients.

MR. : And if we don't keep track of the grain, into which bin--where we put the grain, in which bins we put the grain into, then if you asked for the information, it would be every source, every producer that went into the whole elevator?

MR. CARSON: And then it's in your best interest to track going into which bin, and then those bins going to different immediate subsequent recipients. Those, you know, customers that you're selling the product to.

So internally you should track from your elevator to your bin to your finished product that's going out the door.

MR. : It appears that it would be in the best interest to the FDA, not us, because it's going to take us additional work to track into which bin we go. But if we do that, it will reduce the records that the FDA will have to review.

MR. CARSON: That's true, it would be in our best interest, yes, it would.

MR. : But yet so you would like us to do--track it into which bin it's going, the grain, but earlier you said if we are not tracking it, we should start or must start. So I'm just looking for clarification as to what are we required to do as a grain elevator.

MR. CARSON: Okay. You are definitely required--to use the word "track"--to connect the incoming with the outgoing. I thought what I was trying to say about tracking had to do with identifiers, lot codes, and the like. If you have those, then you need to retain those throughout the

process.

If you don't have those, then we are not asking you to create those. But you do need to link the incoming ingredients, and if you put them in different bins and track them that way, and then outgoing to your finished product to your ultimate customer, whoever that may be.

MR. : Okay. Thank you.

MR. : Thomas Vall. In reference to lot codes--and I'm a manufacturer, and we manufacture finished products and use in-house records to generate what could be considered a lot on a specific day. You can use the date as a lot code, you can use anything to determine that manufacturing.

Now when we ship the product out, we also know all the dealers that we ship them to. Would we have to specifically know where that lot went, or that this lot either went to four different dealers, and that we would have the lot numbers to recall them if we needed to, but we didn't know it when we shipped it to them? Do we have to know it

when we ship it to them, or can we say it is at one of these four sites, and bring it back?

I don't know if I--

MR. CARSON: Well, again, you're saying that you currently create an identifier, either a lot code or a date code.

MR. : Right.

MR. CARSON: And you know when you are releasing that date code to your dealers or your customers, and you know that a specific--you are saying that a lot code could have gone--you have records to show that that lot code went to four different dealers.

MR. : No, we have records to show that that lot code was manufactured on a certain date and then the last--and four dealers came in and picked up that feed.

MR. CARSON: Okay, you need to establish and maintain records of those lot codes going to specific customers.

MR. : Okay.

MR. CARSON: Because that's what you are

creating. You are creating an identifier for that production lot and we need to know where you--who your customers were for that particular lot. That's how you connect incoming with the outgoing.

MR. : Specifically?

MR. CARSON: Specifically.

MR. : Not generally. It has to be specific.

MR. CARSON: Well, it's specifically because you said you can specifically do it.

MR. : I feel like I'm in my statistics course. How much corn is in the wheat. But I certainly appreciate the dilemma. I just want to make a comment. It's a matter of how big of a chunk you want to have defined as maybe liable for, whether you define lot codes or not. I'm not asking him to comment, or he can bob his head, because some things he can't, but we have a plant that receives over a hundred 5,000 gallon milk tankers a day. Okay? We are lucky because it is perishable so we have to empty silos, and if we decide to commingle tankers and we can't exactly

figure out what went into which cream lots we shipped out or whatever, we have to commingle those results for potential distribution. Okay?

The tighter we can control that, then the easier it is for us to manage potential liability on a recall.

There are a lot of other things tied to recall besides just lot traceability. There has to be a lot of other factors, epidemiological or dilution factors, can it really cause illness. If one farmer had arsenic-contaminated grain, the dilution affects the go-on. Those are not going to be considered by the FDA or any other health authority, I used to be a public health person, that those are not going to be investigated. But there are a lot of other factors involved, and I think that's important.

One thing specifically, though, I came up about was someone mentioned that if they had a silo of grain, but it wouldn't matter if it was a pallet of salt, and it was an ingredient or they kept it for three years, that they wouldn't need the

paperwork on that.

I think you defined earlier that once I use that and I put that product into distribution, I need to be able to trace that lot code or item, once I decide to use it and I put it in distribution three years later, I should still have those records available for that ingredient. Yes?

MR. CARSON: Well, again, our rule on the establishment and maintenance of records, we can only --

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-- the current. You may not--if you have kept the records of the ingredients, then, fine, that is stuff we can access. But we cannot require you to retain records more than two years for nonperishable products, and one year--pardon?

[Off microphone.]

MR. CARSON: Obviously it--yeah, again, the gentleman was asking about he's a manufacturer, he produced a product but it's three years old. But now he's selling that product. Well, the record of the sale of the product will create a

current record. The manufacture of that product is three years old, and therefore those records under our rule can only be--we can only require you to retain them for two years. If you retain them for longer, then that information will still be there, but we can't require that.

Obviously for the person who purchased the product, their record is just starting now with the purchase of the product. They are receiving those goods from he as a manufacturer. You would then need to have the information, his name, contact information, the variety of food you received, the quantity, all of that information. You're just starting now with establishing and maintaining a record of that purchase of that product.

Did that answer your question?

So I mean the time starts upon your actions as a manufacturer, processor, holder of the food, retail or restaurant, whatever. That is the time start for recordkeeping. So if you just received a product, that's day one. Depending on the perishability of that product, animal or pet

food, then the record retention time is specified, either six months, one year, or two years, depending on its perishability.

Now we have a few stalwarts who are still here.

MR. : Randy Gordon, National Grain and Feed. Just a couple of real quick questions that tie into this last one.

So in terms of the enforcement date or the date, December 9th being when the largest companies are required to comply with this, that would be for activity that occurs on or after that date, then, for receipt of commodities for manufacturing activity or outbound shipments; is that correct?

MR. CARSON: That is correct.

MR. : So not for any grain that might have been delivered prior to that date?

MR. CARSON: No, but let me just further expand on that. Obviously if FDA finds that grain before December 9th is implicated in a foodborne illness or terrorist event, then we are going to investigate that. But we are not requiring you to

have these records available, but whatever records or information that you already hold, we would seek that information to help us in that investigation.

But, again, December 9th, 2005, is when you need to have a system available to provide this information to FDA for the large companies, if and when we come seeking that information.

MR. : And one question related to intracompany records. There is an exemption basically for, as I understand it, for commodities that might be moved from one facility to another facility that's owned under the same corporate umbrella, if you will. What about joint ventures that might have multiple ownerships?

MR. CARSON: Well, a joint venture is still one company entity for this purpose. It is wholly under the control of that joint venture, so therefore it's not a business transaction between two different parties. So the records that you have internally will satisfy.

I hope I have clarified more than I have confused, but I fear that I might have done some of

the latter. I understand that these are quite difficult and complex issues with grain and how things are both brought in and brought out. And again, I think we will try and clarify to the extent that we can. I don't know that we will give you ultimate satisfaction because of the manner in which business seems to be conducted with grain.

But suffice it to say the purpose for FDA is to have the best information available so we do as effective and efficient an investigation as possible. Also to try and limit the number of potential food products that have to be investigated so that we can release and say to the public that these are other food products are safe and secure, and concentrate our investigation on what we feel is the potential hazard.

So to the extent that you can comply as best as you comply, you will help us in that regard. Beyond that, I cannot solve the Rubik's Cube, so to speak, of what is the best information that you can provide. I think you are the best judge of what is the best information you can

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provide. And as the gentleman said, perhaps as time goes on, the quality of that information may degrade, but that is the best information that is possible at that time.

So if there are no other questions, I thank you very much for attending and thank you for your interest.

[Applause.]

[End of meeting.]