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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

PUBLIC MEETING:

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

Thursday, June 9, 2005

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Food and Drug Administration
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MILLER REPORTING CO., INC.
735 8th STREET, S.E.
WASHINGTON, D.C. 20003-2802
(202) 546-6666

PRESENT

LESLYE M. FRASER, J.D., Office of Regulations and Policy, Center for Food Safety and Applied Nutrition, FDA
DIANE KELLEY, Office of Regulatory Affairs
MARK HACKMAN, Center for Veterinary Medicine
LOUIS J. CARSON
JEFF BARACH, Food Products Association
DEBORAH WRIGHT, Food Marketing Institute
LORRIN TUXBURY, Hogan and Hartson
GALE PRINCE, Kroger Company
DAVID LaMOTTE, Benny and Smith
MARSHA ECHOLS, National Association for the Specialty Food Trade
KAMAL KARDOSH, Lever
JANE DeMARCHI, North American Millers Association
RICK COX, Coca Cola
MARK SALIMBENE, Safeway

P R O C E E D I N G S

MS. FRASER: Good morning. Thank you for your patience and thank you for coming out today. My name is Leslye Fraser and I will be giving the overview. I have some colleagues who will join me for the question and answer period, Mark Hackman, who's here in the front row with the Center for Veterinary Medicine, and Diane Kelley, who's hiding up there in the lovely coral jacket from our Office of Regulatory Affairs, and that's the Enforcement Branch I'm sure all of you know. And so these are some of my partners in crime here.

It has been a tremendous and collective effort throughout the Agency to develop all of the bioterrorism regulations. And then this is the -- the last of the four we were required to do by statute. The registration and prior notice rules, as many of you know, we issued as interim final rules, that was something the Agency did voluntarily, not required by statute.

When we did issue them as interim final rules, they were final rules that did fulfill our

statutory mandate. We did offer an additional opportunity to comment, and we are still in the process of developing the final rules and hope to get those out shortly. But in the meantime, the interim final rules do remain in effect. So today we will talk about establishment and maintenance of records final rule. We will have -- probably this will take about 45 minutes or so for the overview, we'll take a short break, and then we can return for questions and answers. So those of you who may need to get up and go can gracefully depart, and we will be here for a while just to respond to as many questions as we can.

We are in the process of developing a guidance document, a question and answer document, to respond to a number of the questions that we have received already. Those questions have to have the same level of rigorous review within the Agency, as all of the questions that we answered in the preamble to the final rule.

They are collaborated on within the various centers, they are cleared by our General

Council's office, they are cleared by the Commissioner's office, and then they are released as guidance documents, and so, yes, that is your government at work, but it is really to make sure that we are given the same clarity of thought, the same level of detail, the same analysis as if we had considered those and answered them in the preamble to the rule.

And please do recognize that there are many more of you than there are of us, and we are doing and moving as quickly as we can on getting those guidance documents out. The, let's see, page down is not -- it works there, okay. In terms of the history of the rule, Congress did give us a statutory deadline of December 12, 2003, unlike the prior notice and registration rules which had what we call hammer provisions, and that meant that the regulation, or the requirements I should say in the statute took effect whether or not we issued final regulations on time.

This one just said get the rule done by December 12. As you all know, we did not make that

deadline. We had focused most of our energies in terms of prioritizing which ones we needed to hurry up and get done on registration and prior notice because they did have the hammer provisions. And then this one we were working on at the same time, many of the same people, and this one, as a result, came a little bit later.

We did have the proposed rule out in May of 2003. We had about 200 or so individual submissions. So when we say timely submissions, these are different comment letters or memos, most of which raise multiple issues or areas for commenting, most of which were many pages in length. And so we did go through all of those 200 plus various issues raised in the comments and addressed them in the final rule.

The rule we did publish December, 2004, and the compliance dates are based on that publication date. We did have a short correction notice published this February that corrected typographical errors in the first notice, including some of the errors in compliance dates. I'm going

to start with an overview of some of the key definitions in the rule. One of the things, if you are subject to more than one of the bioterrorism act rules, you do need to look at each rule separately and carefully, because you may be subject to one rule and not another, you may be subject to all of them.

Some of the definitions, as much as we could, we did keep the definitions similar, but they are not always the same, and so you do need to look at the applicability and the requirements in each rule separately.

Farm, this definition is the same as in the registration rule. Congress did exempt farms from both registration and record keeping. And we basically define a farm as a facility in one general physical location that grows crops, raises animals, or does both. And we do give examples of what we include in farm, not just the traditional land based activities, but fish farms, some water based activities are included within that definition.

We do recognize that many farms perform activities that would otherwise fall within our packing or holding definition or our manufacturing definition. And within the definition of farm, we do allow certain of these activities with some limitations that a farm may perform and still retain their exemption from the rule. So farms may pack or hold food on the farm as long as it is food that is grown, raised, or consumed on that farm or another farm owned by the same entities. The exact ownership has to be identical if multiple farms are involved.

Farms also may manufacture and process food if that food is consumed on that farm or, again, another farm under the same ownership. So we do recognize that a number of farms, for example, may buy feed, buy vitamins, mix their own animal feed on the farm, that is a permissible activity for a farm to remain exempt as long as they are feeding that product to the animals on that farm or another farm owned by the same entity.

If they are selling the feed to another

farm or another part of commerce, then the manufacturing processing activity is subject to the rule with respect to the product that is sold off the farm or transferred to another owner. The other parts of the farming activity would remain exempt.

Food, this is the definition that is in our statute, the statute does say food is food, food is food or drink for man or other animals, chewing gum, and components of such food. And we do have examples, again, in this regulation of what is encompassed within FDA's jurisdiction. It includes not only food, food additives, food ingredients, dietary supplements, and dietary ingredients are food, infant formula, pet food, beverages, including alcoholic beverages are subject to this rule, fruits and vegetables, fish, seafood, dairy products, shell eggs as regulated by FDA, liquid egg products as regulated by USDA, liquid egg products are not subject to these requirements, can food, live food, animals, snack foods.

The last one, packaging and food contact substances, under our definition, they are food. Anything that touches food is considered food by law. But you will see that there are -- within the scope of this regulation, there are few requirements that generally apply to packing and food contact substances, unless you happen to be the person putting the packaging material in contact with the food product.

Foods that we don't regulate, these are the ones regulated by our colleagues at the U.S. Department of Agriculture, those under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act. If your food is under USDA's exclusive jurisdiction, you are not subject to these requirements. If your food product is subject to joint jurisdiction, such as fruits and vegetables, you are subject to these requirements. Manufacturing and processing, we define basically as doing anything to the food. So if you're manipulating the food in some way, that is

considered a manufacturing and processing activity, and we have numerous examples at the bottom of the slide and in the rule as to those things that we would consider a manufacturing, processing activity.

We define a non-profit food establishment because we do create an exemption within the rule for non-profit food establishments. These are charitable entities that prepare or serve food directly to the consumer or otherwise provide food or meals for consumptions by humans or animals in the United States.

You'll note that we say that to be within this definition, you must meet the terms of Section 501C3. Those words are critical. You do not have to have applied for an exemption under 501C3, you just have to meet the terms, you have to be able to qualify for such an exemption should you choose to apply for one.

Packaging, when used here as a noun, is the outer packaging of the food that bears the label. The example we tend to use is the cereal

box. Most cereal boxes have the outside cardboard that has the label on it and an inside plastic liner that actually contains the cereal. The outside cardboard box would be the one we would consider the packaging material, it is not touching the food. The cereal liner we would consider a food contact substance.

A recipe we define as having three components. So to be a recipe, you must have all three. It is the ingredients, the quantities, and the instructions for making the product. When you see later when we talk about access to records, we will be able to access the list of ingredients in a proper access. We will not be able to access the full recipe, which is not only the ingredients, but the quantities and the instructions.

So to the extent that you do not -- that you want just the list of ingredients as part of your records and you choose to separate those out, that separation needs to be done in a manner that you still can meet the access time frames.

A restaurant we define as a facility that

prepares and sells food directly to consumers for immediate consumption. Directly to consumers is a key feature of this definition, so that if you are a central kitchen or an interstate caterer, for example, those conveyances that provide or those entities that provide food to airplanes or to trains to serve in their -- on board, then those are not restaurants because they are not providing the food directly to consumers. Immediate consumption does not mean that the food has to be eaten on site, it just means that no further preparation is necessary. So you can go in and buy a pie at Cheesecake Factory, take it home, that still is a restaurant because it is available for immediate consumption without further preparation being necessary.

A retail food establishment we also define as one that sells food products directly to consumers as its primary function. Again, directly to consumers is key. Consumers do not include businesses. And primary function we measure by monetary sales. So the monetary sales of consumers

has to be greater than the monetary sales to non-consumers to meet the retail definition.

You can start your measure of annual sales at any point in time that you choose. So if you're on a calendar basis, that's fine, if you're on a fiscal year basis, that's fine, if you happen to use your birthday or your anniversary as your starting point, that's fine, but just have to be consistent with your measure of annual sales.

Transporter, there are two requirements in the rules in terms of what type of entity you may be. You are either a transporter or a non-transporter, you are not both. So we start with a transporter, and that is a person who has possession, custody, or control of the food within the U.S. for the sole purpose of transporting the food. So if you are a foreign manufacturer in Canada or Mexico and you drive the product across the border in your own company trucks, at that point you are a transporter because your activity in the U.S. is limited to transporting. You are not doing any of the other activities.

A non-transporter obviously is one who does not have possession just for transportation, and it includes most of those entities subject to the rule, those who manufacture, process, pack, hold, distribute, receive, or import food.

So who is subject to this rule? Within the record keeping provision in the bioterrorism act are generally two types of requirements; there is a records access requirement, and that requirement did take effect when the act was passed in 2002; and the records access requirement said under certain conditions, FDA can access records that a company may retain or keep as a matter of business practice, as well as any other records we require by regulation. And so there is the records access part of Section 306 of the bioterrorism act. And the second part of Section 306 was the one that authorized FDA to issue a regulation that would require the establishment and maintenance of records for those who manufacture, process, pack, hold, transport, distribute, receive, or import food, and those are the requirements that we will

mostly be talking about today. And so only if you are specified in the rule as having to establish and maintain records and you don't have an exemption that applies to you, then you are subject to that second piece.

But generally, when you look at the whole provision, you could be subject just to the access provisions, and we'll talk about those folks, you could be subject to the establishment and maintenance and access provisions, and so there's a mixture here.

And so this is going to say who is subject to the sub-part, that means who's subject not only to the requirement to establish and maintain records, as we specify in the regulation, but also to the access provisions, and as I noted earlier, it is a broad regulation.

This goes beyond registration. Registration is only limited to those who manufacture, process, pack, or hold food that will be consumed in the U.S. This picks up not only the manufacture, process, pack, and hold, it picks up,

transports, distributes, receives, or imports. It also is not limited to consumption in the U.S. It is an activity occurring in the U.S., whether the food will be consumed here or not. So again, this is one of the places where, although the manufacture, process, pack, and hold looks similar from registration, the scope is different because here it is not limited to food consumed in the U.S.

And note, we talk about a person as not just individuals, persons are partnerships, corporations, and associations. And this becomes important when we start looking at the trace back and the trace forward, the immediate previous source and the immediate subsequent recipient. We will be looking at transfers from one person to another person. We are not looking at intra corporate transfers.

So if you are a vertically integrated company, we will be looking at what comes into your personhood, what comes into your corporation, and what leaves your corporation. We're not looking at the various transfers within as part of the record

keeping obligation.

Who is excluded from everything, not subject to establishment and maintenance, not subject to records access? Farms and restaurants, those are the two that Congress specified in the statute. Congress did not give an exemption for retail facilities like they did in registration. So people say why don't retailers have an exemption, in the first instance the answer is, Congress did not give them one from the record keeping rule. In the second instance, you will see we have created a partial exemption for retailers from the establishment and maintenance of records, transfers to consumers, and then we've also created one based on the size of an entity, but those are ones we created by rule. Congress did not create one by statute.

We also exclude all foreign persons unless they are transporting food within the United States. In part, this is because foreign persons are subject, bringing food into the United States, are subject to the prior notice requirements. And

we do get quite a bit of information of the food product coming in before that food arrives under the prior notice rule.

Also who is excluded? This is one that we created in the rule, a restaurant/retail facility combination, provided sales of the food that is prepared and sold to consumers exceeds 90 percent of total food sales.

The folks we were interested in looking at here are places such as Cracker Barrel that, for those of you who like visiting that place up and down the highways, they have a retail store outside of the restaurant area, and then you go into the restaurant. Inside the retail store, they actually sell very few food products, they sell candy and maybe some other things, they sell a lot of clothing and other products, we would consider that a restaurant/retail facility. They would, in all practicality, be exempt under this provision because we are only measuring food sales to food sales.

We're not interested in the clothing sales

or anything else they sell in there, toys, we're only looking at the sale of food, what's the revenue derived from that on the retail side, what's the revenue derived from the restaurant side, and as long as the restaurant side exceeds 90 percent of the total food sales, then that facility would fall under the restaurant/retail exemption and be exempt. And as I noted earlier, if you are subject to the exclusive jurisdiction of USDA for your food product, then you are not subject to any of these requirements.

We also have created within the regulation anyone who manufactures, processes, packs, holds, transports, distributes, receives, or imports food for your own personal consumption. Personal consumption includes our family and friends plan. So if you're having a party of family, picnic, a wedding party of 200 people in your back yard, whatever, that you're cooking for, it's still within personal consumption. And then we've created, in response to some of the comments, people who are basically like the concierge, the

doormen, if you live in an apartment building and you get a monthly delivery of bottled water and you're at work and the bottled water is held by the person at the desk or the door man, we don't count the door man as receiving the food, we count the transaction as the bottled water company to you, and that person is essentially just your agent or their agent, and so that's what this limitation is to capture.

Here are the folks that are only subject to the records access and prohibited act provisions. Prohibited act, we'll talk about a little bit, but it basically says it's against the law to fail to comply with these regulations if you're subject to them.

And so who is subject only to the records access provision? Again, going back to records access, this is those we may be able to access any existing records these entities may keep, but they are not required to keep the records that we are talking about today in this regulation.

Fishing vessels that are not factory

shipped are exempt. We kind of consider them similar to farms, they're just harvesting the fish from the sea. This is a new one we've created, retail food establishments that have ten or fewer full-time equivalent employees. We do have a calculation on how you figure out how many FTE's you have in the rule. But basically, this is one where we are counting it facility by facility. So if you happen to own let's say ten 7-11 stores, we would look at each of those stores separately, and any of the stores or all of the stores that had ten or fewer FTE's, they would be exempt from the establishment and maintenance requirements. That will be a different calculation when we get to compliance dates. But for the purposes of this provision, we are looking at the exemption store by store, not the whole corporation.

We've also exempted those non-profit food establishments as we discussed as the definition earlier. And generally, anyone who is manufacturing, processing, packing, holding, transporting, distributing, receiving, or importing

food contact substances are exempt from establishment and maintenance. They are subject to the records access provisions for any existing records other than the finished container that directly contacts the food.

Only subject again to records access and prohibited acts are those with respect to packaging. And again, the packaging we defined as the outer container that bears the label, and anyone else with packaging is exempt. So generally, what the next two charts show is, since packaging and food contact substances seemed a little complicated, we tried to make it a little clearer in the charts that you generally, if you look at the far right corner, you're generally only subject to records access provisions unless you happen to be the entity which typically is the manufacturer, perhaps it's the repacker, but it's typically that entity that is placing the food product in the container that the consumer is going to receive the product in.

And then you are subject to the

establishment and maintenance requirements, to let us know from who was your immediate previous source of that food packaging container, of that finished container, and who was the transporter that brought it to you. It looks like all the rest of the food regulations.

Partial exclusions, these are, again, ones that we created in the rule. If you are distributing food directly to a consumer, whether you're doing it from a store, whether you happen to be over the internet, you're doing a direct buying business, if you're distributing it directly to a consumer, you do not have to keep records of those transactions. You do have to keep records of your immediate previous source. So we need to know from whom you acquired the food, but you do not have to keep records of your immediate subsequent recipients who happen to be consumers. If you happen to be an entity that distributes both to consumers and to non-consumers, then you do need to keep track of the transactions and the distribution to non-consumers to the extent that is reasonably

available information. An example of reasonably available information may be a business account, cash and carry stores, a number of the business that come in have business accounts, they charge it to their business accounts, that is reasonably available information, you would be required to keep records of those distribution.

Conversely, if you happen to be the Giant Grocery Store and a person walks in from the 7-11 down the street and they purchase a bunch of ham because they happen to have run out of ham to make sandwiches, you don't have to inquire are they purchasing it because they own the 7-11 store or are they taking it home to the family, that is not reasonably available information, we do not require you to ask those kind of information.

Cosco, which sells both to consumers and non-consumers, we do expect to keep track of that information. They do issue different cards for access, they issue the business cards, and they issue individual membership cards, so that is, again, reasonably available information. We now

will turn to what are the requirements that do apply to non-transporters for the establishment and maintenance of records. The next several slides after this will actually specify what the records must contain. But in this graphic, what I wanted to show you is that here, the manufacturer is sending the food to a retail store, and it's going by truck in one city to the airplane, which is taking it to the other city, which is picked up by the truck and delivered to the retail store.

The records are immediate previous source and immediate subsequent recipient only. People often refer this as the one up, one back provision. There is no obligation to send the records forward, you have an obligation to keep your own records, they don't move with the food.

You also have no obligation, if you look at this example at the manufacturer, to have records from the company A to company B transaction because you are not a party to that transaction. You only have an obligation to say I gave it to company A and I gave it to the retail store.

The distinction between the non-manufacturer, I'm sorry, the non-transporter and the transporter, there are several, but one of the key ones is, the non-transporter has to record the immediate previous source who is a non-transporter, so if I focus for a minute on the retail store, they have to tell me that is the manufacturer, they also have to tell me the immediate previous transporter, who is the transporter that brought the food to them, so the retail store would have to tell me company C. You'll see when we get to the transporters, they don't have to keep both non-transporter and transporter, they literally just have to do one up, one back, regardless of who was at the end of the chain, and we'll come back to that in a minute.

So if you are a non-transporter, you have to retain records to identify the immediate previous source. This is the one back provision. Your records have to tell us for all food you receive, and this is as of the date of your compliance, so you do not have to start keeping

track or retain records for anything that happens before your compliance date.

But once your compliance date arrives, as of that date and moving forward, for any food you receive, and remember again, food includes food ingredients, as well as the finished product, the finished container that contacts the food, we need to know the firm name and the contact information of the non-transporter immediate previous source, whether that was domestic or foreign. A description of the type of food received, this is pretty specific. We don't want it to just say cheese, we need it to say sharp cheese or colby cheese or swiss cheese, because if we have an outbreak related to swiss cheese, to have an effective trace-back, we want to focus on swiss cheese, not every cheese product you happen to receive. The records also need to say what date you received the food so we can limit the scope of our investigation accordingly, the quantity, and how the food is packaged, how much did you receive, and was it six ounce containers, 12 ounce

containers.

Sometimes we may be doing a trace-back with canned vegetables, and perhaps the vacuum didn't pull on the six ounce canning line, but it worked just fine on the 12 ounce canning line, that is the reason for wanting to know how the food is packaged, so that we can focus just on the six ounce canning lines and those products in a trace-back and not effect every canned vegetable that may have gone out from that same manufacturer. And here's where we pick up the firm name and the contact information of the transporter who brought the food to you.

In addition, if you happen to be the manufacturer, processor, or packer of food, you have to record the lot or code number or any other identifier to the extent the information exists. Two points about this bullet, it only applies to those who are the manufacturers, processors, or packers of food. If you are not one of those, you don't have to record this information; you do have to record the information I had on the previous two

slides. The other piece to note about this is, if it does apply to you, it only applies to the extent the information exists. This does not require you to create lot numbers of identifiers if they are not currently existing on the product or not going to be on the product as they come in.

But if it is a product that comes in with a lot number, or if you have your own unique identifier within your company, then you do have to record that information if you are a manufacturer, a processor, or a packer.

So those were the requirements to identify the one back, the immediate previous source. The information for non-transporters to record the one down or immediate subsequent recipient is essentially the same with one addition.

So again, we have the firm name of to whom you sent the food, the description of how the food was when you released it, the date you released it, the quantity, and how it was packaged, the transporter who took the food from you, and again, the lot number, if you happen to be the

manufacturer, processor, and packer, to the extent the information exists. The additional piece is, your records must also include a linkage of incoming ingredients to outgoing product, again, as of your compliance date, to the extent this information is reasonably available, and again, that will be decided on a case by case basis. We've had a number of inquiries of people asking us to clarify reasonably available, and it's a difficult one to do without appearing on one hand too prescriptive, because not everything that we could say would apply to every fact pattern, or on the other hand, too permissive, where we would inadvertently create a loop hole because we've specified three things or five things and someone says I only have four out of the five.

So it is something that we will help discuss with you. We can provide examples, is probably the best way we know how to answer this question. And I have an example in here to show you what we mean by that. But one of the things we have seen in the numerous, numerous questions we

receive is very, very specific fact patterns that are peculiar to a particular entity.

There are probably close to a million entities subject to this rule, and we cannot answer a million plus fact patterns that apply with that degree of specificity. And I will also say, within our guidance documents, we will most likely continue to focus in the first instance on those questions that have the broadest applicability just so we can reach as many people as possible. But turning back to this reasonably available, in this example, I have a cookie manufacturer, and they are receiving flour that they source from three different entities, so they get flour from source A, source B, source C, they dump it all in a common silo, and then they make their cookies.

Here, what is reasonably available to them, to tell me for each batch of cookies that they ship out the door, and when they're linking incoming ingredients with outgoing food product, they can say for these cookies manufactured on this date, the flour came from source A, source B, or

source C, because it was all combined in the silo, the silo does not drop as a plug, it mingles, it swirls, and that is reasonably available, it is one of three sources, and that's the best they can do.

In this example, though, we have a different cookie manufacturer that has dedicated silos for suppliers. And they may do this as a matter of business practice, they can figure out whether they get better yield from one supplier or another, they may do it so they can isolate production runs, for whatever reason, this is how the plant is configured.

And when they decide to run a batch of cookies, they flip a valve, they open up source A, and they run flour from that, or they open up the valve for B, or they open it up for C. In this case, they're manufacturing records, and if they don't contain it now, they will need to start retaining and recording that information, they can tell us with specificity that for a particular batch of cookies produced on a production run, which source it came from, this is reasonably

available to them.

The same with ingredients that you may dump in or add that come in in gallon containers, they may come in in burlap bags, as you're emptying a different bag, and if it has a lot number on it, or if it doesn't, there should be some specificity to know for a production run which ingredients are going into which batch of a product that is being made, and that is reasonably available information.

We do not require reconfiguration and new equipment as part of this rule, but we do require you to capture information that is reasonably available and within your control.

Transporters, so turning to the transporters, there are five options for transporters to comply with this regulation. Three of the options are consistent, and the same as existing Department of Transportation requirements. So if you are in compliance with the DOT regulations, you will be in compliance with the establishment and maintenance provisions here, you will just have to do and take steps to make sure

you can meet the time frames for records access as a transporter. So the first option is basically, we have specified the information that you can keep. This looks similar to the information we had for non-transporters, except we've added origin and destination points, which is basically from whom did you pick up the food and to whom did you deliver the food.

And the route of movement during the time the food is transported is something that I will discuss on this one. Here is the route of movement, which doesn't apply in this case, per se, because it's manufacturer to company A, to company B, to company C, to the retail store. A, B, and C are three distinct persons, they're three different corporations.

So if I focus on company A, their records would be their immediate previous source is the manufacturer, their immediate subsequent recipient is company B. Their route of movement is really, I took it from the manufacturer to the airport, unless they happen to go through a truck terminal

facility that was owned by company A, and maybe they reallocated the load, let's say it was a central hub, they moved the freight from one truck to the other truck, we would want to know that. The reason we would want to know that is if a terrorist decided to attack the central hub, then we also need to know what other products might have been at that hub at that time frame, or if the terrorist attacked the first truck and the product on this one ended up on a second truck and we start seeing people sick in city where company C is, but we also find out people are getting sick in other parts of the country, that's a way of maybe tracing back and finding out that we need to figure out what was on that first truck because other products may have been similarly tainted.

So when we say route of movement, we really are looking to see where the food may have moved within that company A's possession, if it was not just on the truck. We don't need to know they went on I-40 before transferring to a different interstate. We really are looking for transfer

points.

In this example, though, we have the purple transportation company, and they own everything. This might be DHL, UPS, Fed Ex, they have their own trucks and planes. So here the manufacturer is shipping to the same retail store, they're in two different cities, the first purple truck picks it up, takes it to the purple plane, takes it to the second purple truck, who delivers it to the retail store. Here we do need and we do require this transportation company to tell us its part of route of movement, it went from its truck, to its plane, to its other truck for the very same reasons. If the contamination occurred on the airplane, the only way we're going to find out what was on that plane and what other places it may have gone is from this trucking company, the manufacturer, and the retailer will have no indication how the food moved from -- between one to the other. So that is the first way a transporter can comply.

The second way is, if you're a trucker,

you can comply with the DOT regulations that apply to Motor Carrier Safety Administration for interstate transporters. These are basically the bill of ladings. I will note that the DOT requirements here only apply to interstate transporters, are put conversely only interstate transporters are required to comply with this DOT regulation.

If you happen to be an intrastate transporter and you would still prefer to comply with the DOT regulation as opposed to any of the other options, you may choose to do that. So even if you are not subject to the DOT regulation, you can choose this option if this one is more familiar to you as a transporter.

If you happen to be a rail or water carrier, then DOT has regulations that apply there, you could use those. If you happen to be an air carrier, you can use the Warsaw Convention that applies. And then the last one is, if you happen to be a fortunate transporter who can arrange with a non-transporter immediate previous source or

immediate subsequent recipient, and my example on the other slide, that would either be the manufacturer or the retail store to keep records on your behalf, you may do so.

This is probably one of the few times you will ever see in a federal regulation the ability to transfer liability from one person to another. Here you can by agreement transfer the liability only if you're a transporter and only if your immediate previous source non-transporter or your immediate subsequent recipient non-transporter enters into a contract with you to do so. We do not need a copy of that contract, but you do need to have it on hand if FDA shows up with the request to access records.

We do specify what the agreement must contain at minimum, it's the effective date, printed names and signatures, a description of which records are going to be established and/or maintained. You can enter an agreement just to establish the records for you, you can enter into an agreement to have someone maintain the records,

which basically is store the records for you, or you can enter into an agreement to have someone do both. You also have to say the records will be maintained in compliance with this regulation, they will be made available as required to FDS upon a proper request, and an acknowledgement that the non-transporter is assuming legal responsibility for this activity, as well as a provision that says if the agreement is terminated in writing by either party, the legal liability reverts to the transporter.

Record retention period, so if you are subject to the establishment and maintenance requirements, this is the maintenance half of the regulation. How long do you have to keep the records? The length of keeping the records depends on what kind of food you have and whether you are a transporter or a non-transporter.

In the first instance, what type of food, we looked at typically how long does food remain in commerce, and that's how we established, at least as the initial matter, our retention periods. For

packaged foods, although we know that many of them may remain in commerce longer than two years, the bioterrorism act limited our authority to require retention to a maximum of two years.

For transporters, we balanced the -- and this really showed up in the distinction on the products that have a shelf life of longer than six months basically, we balanced our desire to have those records for two years with a desire to make sure that we weren't imposing unnecessarily duplicative requirements. Since the DOT regulations limit retention to one year maximum, and since we had made a decision to allow DOT regulations to be sufficient to comply here, we adopted the one year retention period for transporters, again, recognizing that we still could access any existing records they may have longer than that, and they may be likely to keep them longer than that for other reasons such as auditing purposes by the IRS. And if you have animal feed or pet food, then it's one year.

In terms of record retention, generally

records have to be created when the food is received or released, except to the extent it's an existing record. So you do not have to copy over new information that may already exist. An example of this might be a bill of lading, where you get a copy of the bill of lading.

You generally have to retain the records at the establishment where the activity occurred or at a reasonably accessible location, and you can keep records electronically. We do have an exemption if you do keep electronic records. When we issued this final rule, we also created an exemption from Part 11 of our regulations, which specifies what electronic records must look like. Part 11 does not apply to these regulations here. Prohibited act, it is a new prohibited act which is basically a nice way of saying it's against the law not to obey this regulation if it applies to you. It's against the law to prohibit us from accessing records if we've made a proper request. And it's against the law to not make records available as required. And for that, we can bring a civil or

enforcement action against you. It is also against the law to prohibit us from refusing to permit us copying privileges of those records.

In terms of compliance dates, it is based on the total size of your business. So here is where we are looking at the total personhood of your entity. We are not looking at it store by store. If you go back to my exemption for retail facilities, here the person that owned the ten 7-11 stores, we would look at how many total FTE's were in all stores combined. If you are a large business with 500 or more full-time equivalent employees, you must be in compliance by this December.

If you are a small business with 499 down to 11 FTE's, you have 18 months to come into compliance, or next June, and if you are a very small business with ten or fewer full-time equivalent employees, we gave you two years to come into compliance.

Just as an FYI, more than 80 percent of those who are subject to this regulation fall

within the small or very small category. So they will be learning from the experiences and the opportunities gained by the large entities as part of their learning curve. And here's how you count an FTE for compliance date purposes. Do other record keeping requirements apply? Yes. This does not replace anything. If you're subject to any other record keeping provision, either an FDA one or someone else's, those still apply, this does not supplant that. But you can use those records to satisfy these to the extent all of the information is contained therein; and if it's not, you can just supplement those records with the missing pieces for this.

So you don't have to recopy the records, you don't have to duplicate them, they all don't have to be in one place, you just have to be able to provide access to all of the information in an access request within the time frames required.

So what is the standard for access? We can access the records basically in a serious public health emergency. We must have a reasonable

belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. This is our SAHCODHA threat, it's the same standard for administratively detaining food under Section 303 of the bioterrorism act, for those of you who are familiar with that regulation. In the regulation that we issued, it says if you are subject to the access provisions, then you must make those records available to us as soon as possible, not to exceed 24 hours. A lot of people like to focus on the 24 hours, yes, that is the point at which you will not be in compliance. We like to focus on the as soon as possible, recognizing that we will only be coming to you to demand mandatory access to records in a public health emergency. And so we ask you to think about how to make them available as quickly as possible, recognizing that your liability or your prohibited act kicks in at the 24 hour mark.

Records excluded from access, these are specified in the statute. We cannot access the recipe itself. Again, remember, that's the

ingredients and the quantities and the instructions. We can access the list of ingredients, including the secret herbs and spices. We can access all of that under the access provisions if we have made a proper request.

We cannot access financial data, pricing data, personnel data, research data, sales data here, and as used, here means we can't access, you know, what's your profit margin, how much did you make on that product, we can access immediate previous source and immediate subsequent recipient. So we can figure out who are your suppliers, immediate suppliers, and who are your buyers. We did issue guidance document that specified how we would access those records, we put it out for public comment. We have receive comment, we're working through it, to issue a final guidance. I put final here in quotes because agency guidance is truly never final, it is the one thing, any of our guidance comments you can comment upon at any time you feel like it, unlike regulations, where you do need to wait for an open comment period, a guidance

document you can access and comment upon any time you'd like.

And basically the procedure apply to us. It says there will be great coordination within the agency, not only with our Emergency Operations Center, because we need to make sure we are truly met the public health emergency, SAHCODHA standard.

We will be working with our Office of Regulatory Affairs, on the Office of Enforcement, we'll be working with our Chief Counsel's office to make sure we have met the legal standard for reasonable belief, and we will be working with the appropriate centers to figure out just exactly what is the scope of the requests that we need to see. And so all of this is who gets to consult with whom. And I think one of the recommendations someone has commented upon that we're thinking about, as well, is, this might be nice for -- to include in a future training exercise, not only for the companies, but also for the agency to see how this would actually work in practice, maybe one of our top off exercises that we do. But once we've

made all the determinations, the director and the district in which the food is located would be the one that would actually authorize or send out the investigator. The investigator would present the request in writing, present their credentials, and that is the point at which the 24 hour clock would start, for your purposes.

We do recognize that some of the information we may request may be trade secret or confidential business information. There are laws that do govern that that apply to us as individuals. They do not apply -- this is not one where you could stand behind the federal government and the federal government will provide an attorney to defend you.

This is personal liability, you see it unfortunately from time to time in the newspaper, usually in the defense industry, somebody has taken classified documents home in their briefcase or something other, this is personal liability.

The same investigators who would be coming for you regularly see confidential business

information, maybe not the food industry as much, but they do see it on the drug device regularly. We get confidential business information all the time. They are well familiar with what is required of them in terms of keeping that information confidential. And we are continuing with our ongoing training to make sure we have reminded people of that.

So with that, it is 10:03, I suggest we take a stretch break until 10:15, and then we can come back and do Q and A's, those in the back, okay. And feel free to pop up at a microphone. We do ask you to go to a microphone just because we're recording this to transcribe into the Q and A's, and I think we have posted transcripts of the other public meetings in various places, so this is helpful.

A couple of introductory comments. The web site does have a copy of this presentation on it, or a little older one, I need to update it. This is -- it's in your packet, but the easy way to get here is www.FDA.gov, and then click on

bioterrorism.

At the bottom of this home page, the bioterrorism home page, in the bottom right hand corner, is a place where you can sign up to be on our list serve, if you're not on there already, and that way any time we issue something new, we issue a new guidance document, we issue a new regulation, you will get an email alert, and you don't have to kind of remember to check it on your own. These are booklets that are available on our web site. Most, if not all, are in English, French, and Spanish. They are the cliff notes versions of these rules. You can also get hard copies from Lou, if you'd like. They're really pretty glossy ones. But you can download them, as well. You can email them. But this is what they look -- they're really nice little versions of the rules. So with that, we'll start with the gentleman at the microphone and do our best to stay out of the dunking booth with the question and answer period.

SPEAKER: I just want to make sure that, in my own mind, I understand what you were saying.

I just want to make sure I understand in my own mind what you're saying. Your presentation was very good and pretty clear, but I need a lot of visual aids.

I represent a steamship company, essentially a third party logistics company. We have container freight stations overseas, steamship company, also do cross docking facilities and warehousing here in the U.S. Effectively, what we need to maintain in terms of records is just our bills of lading from point A to point B. That would be the records we would normally keep in the normal course of business and the bill of lading itself for both the steamship bill of lading, any truck bills of lading, subsequently are sufficient?

MS. FRASER: If I understand you correctly, for anything overseas, you don't have to do anything. You're only subject for activities you do within the United States. With respect to your activity once you enter the United States, then it's whatever would apply as, if you fall into the transporter category, it's whatever

transportation activity you're doing, and I'm assuming at that point if you're doing anything, it's by truck, and then you would -- then the DOT requirements, if that's the option you choose, which is a bill of lading requirement, that is what you're doing, and it is compliant with the DOT regulations, then that is all you need to do for the establish and maintenance part of the regulation.

You just will have to have whatever procedures in place to make sure you can meet the access time frames, if that's something that would become necessary in the future.

SPEAKER: So the steamship part of the business is excluded from this then?

MS. FRASER: Correct, because all foreign persons are excluded except for those transporting food within the United States.

SPEAKER: So it's only in the -- that's the key, in the United States --

MS. FRASER: In the United States.

SPEAKER: -- is the key, okay.

MS. FRASER: Exactly.

SPEAKER: I thought that was kind of ambiguous and I wasn't -- that's why I was trying to get that clear in my mind.

MS. FRASER: Right; this only applies to activity within the United States, which counts our territories in 50 states, the territories in the Commonwealth, or Puerto Rico.

SPEAKER: I'm sorry, and our container freight stations overseas are required to register?

MS. FRASER: Yes.

SPEAKER: They're required to register, but record keeping, they're not subject to the record keeping?

MS. FRASER: They're not subject to the record keeping, correct. That's what I say, each of these rules, you have to look at --

SPEAKER: Okay, all right.

MS. FRASER: -- uniquely.

SPEAKER: Again, that was -- okay, so it wasn't me, I did understand that, okay. And then finally, for our customers, which we represent some

grocery store chains and some consumer big box type stores, they just need to maintain records of the manufacturer and the fact that they got it from our company, is that --

MS. FRASER: Well, they are separate persons, so they have their own obligation to maintain records.

SPEAKER: Right.

MS. FRASER: And they would fall under the non-transporter set of requirements, which would be the three slides that had the different, you know, description of the food, who was the non-transporter, immediate previous source, who was the transporter they received it from, so that's where they would pick you up.

SPEAKER: They need to keep records of both.

MS. FRASER: Right.

SPEAKER: Because part of my job is to explain this to our customers.

MS. FRASER: Right; they would have to do both. But you would be under the transporter set

of requirements, they would be under the non-transporter set of requirements.

SPEAKER: Right, which would mean who they bought it from --

MS. FRASER: As well as the transporter.

SPEAKER: -- transporter, okay.

MS. FRASER: Exactly, and then also on the other side, if they're retail stores, they don't have to do the consumer transaction, but if they're releasing to other businesses, then they do have to keep track of that if it's reasonably available.

SPEAKER: Okay, very good. Thank you.

MR. BARACH: Hi, Jeff Barach with Food Products Association. Many of our members process fruits and vegetables. During the processing say of tomatoes, there are several steps. One of the first steps may be to gather well water and add a sanitizer like chlorine, and another step may be to add a processing aid like lye for peeling the tomatoes.

Those types of compounds and processing aids, chlorine and lye, or peel aid as they call

it, how are those covered, and if they are, how would one expect to be covered, because that would be like on a batch basis, not an individual ingredient basis?

MS. FRASER: They are food contact substances in one place. The processing aid, and there is a description in the preamble. One of the things I should note, that if you go on our web site and pull up the rule from our web site, it is linked by topic, so that like, for example, food, if you click on food, it will jump to that part in the rule where we discuss it, if you don't want to read through the whole federal register.

But there is a discussion in the preamble, I'm pretty sure it's in records. I apologize because when you do all four rules, they start running together in your head of what you said where. If it's not there, it's in registration. But there is a discussion on food contact substances and food processing aids and what's covered under one and what's covered under the other. In yours, though, I would think, in your

description, they're both food contact substances, they're coming into contact with the food for an effect.

You are subject to the record keeping requirement on the linking. The question I think you're getting to is linking the ingredient with the outgoing finished product. Even if it's done on a batch basis, you can -- I mean you're linking however many tomatoes you process that are shipped, whether it's the first 600 cases or the next, and then you change over your batch water, those first 600 cases are whatever ingredients you had coming in from whatever sources of your tomatoes to the extent you can segregate it or not to the extent you had the batch water or not, but there is as much information as possible, but that linkage is required.

MR. BARACH: So it sounds like they are covered under the processing aid?

MS. FRASER: They are covered, yes. The distinction is, and because I'm not a food contact expert versus a processing aid expert is why it

would be better to direct you to where we do discuss it in the preamble, because the experts have opined on that with a little more specificity.

MR. HACKMAN: I think, Leslye, in the -- it was in the registration portion of it, because we talked about chlorine that's added to municipal water supplies being exempt.

MS. FRASER: Right.

MR. HACKMAN: But then if you add additional chlorine, and I forgot what the part per million level was, then you went from something that's a municipal water supply to something that's having an effect on the processing.

MS. FRASER: Okay.

MR. HACKMAN: So one would be an exempt from registration, but if you start adding chlorine, for example, to like a bath for washing the fruit in, and if it goes above a certain part per million level, then you fall out of the exemption and you fall into the requirements for registration.

MS. FRASER: Yeah, and I think it's in the

registration Q and A document actually.

MR. HACKMAN: Yes.

MS. FRASER: That's where it is.

MR. BARACH: Okay. I'll look there. Thank you.

MS. FRASER: Yeah.

MS. WHITE: Hi, Deborah Wright with the Food Marketing Institute. We represent the retailers you talked about. And we appreciate your doing this really. I was talking to Lou, I've been working through this for a while, but it's helpful to go back to the basics again and talk about them.

I went out to our membership before I came and came back with a whole slew of different questions. I won't go through them here now because I'm sure lots of people have questions, but there are a couple I guess that I'd like to talk about.

On the very simple side of things, when you're identifying the immediate previous source, are you looking just for the corporate address? If a retailer receives, I don't know, Twinkies from

Hostess, do they need to know which plant it came from or just that Hostess' headquarters is X?

MS. FRASER: We've gotten that one in our Q and A's that we're looking at answering in the document. I think our thinking is that we don't really want corporate headquarters, and if you look at the rule as a whole and the provision that says records need to be kept at the site where the activity occurs, and they're receiving the -- and I'm looking at say the manufacturer side, so they are shipping out the Hostess Twinkies from plant one of the 20, then that's where the records for plant one are going to be, then it would be from the retailer side. I think for us it would be -- we would like to know that the immediate previous source is not the corporate headquarters, the immediate previous source is the manufacturing plant one.

But that is something we are looking to address in our Q and A document, because people have interpreted that in different ways, and we just still need to work through that and figure

out. But that is how we intended it to be was the manufacturing facility, because that is the source that it came from.

MS. WHITE: Okay. Well, I mean if that's the case, then we'll need to start asking our suppliers to provide that information, because that clearly isn't done, retention of it may be challenging, as well. And very similarly, also a very simple, if Hostess sends the Twinkies to a retailer in their own trucks, they're both then the transporter and the non-transporter immediate previous source; is that correct?

MS. FRASER: Right; the place I just want to clarify, if Hostess sends the Twinkies in their own truck, they're a non-transporter, because you're either one or the other. With respect to their records, they would say I released it to the retail store, and the transporter that took the product from me to the retail store was me. On the retail side, what they would record is, I received the Twinkies from Hostess plant, and the transporter that brought the food to me was

Hostess.

MS. WRIGHT: Right.

MS. FRASER: So, yes, they would be captured. I just want to make people understand that you're still only a non-transporter or a transporter.

MS. WRIGHT: Right, but the identity is the same? I mean --

MS. FRASER: The identity would be the same. And vertically -- in a number of vertically integrated companies, that would be the case.

MS. WRIGHT: Right. Also then, talking about, well, vertical integration actually, and Lou and I talked about this a little bit, as well, we appreciate the concept in the regulation recognizing that, you know, if you are all part of the same corporate entity, there is no immediate previous source or immediate subsequent recipient legally, I mean it's a person, as you say, for distributions within that corporate entity bubble, and there's specific recognition in the documents that are out there about that, with respect to

distribution center, trucks and retail store that are all owned by the same entity. It gets more complicated for us because some of our guys are starting to now also have say a manufacturing plant where they might make ice cream, and so that's still all within the same corporate bubble, or they might also not only have a manufacturing plant, but they may now also own a milk production facility, a dairy, so still all within the same corporate bubble.

And I would like some clarification from you or at least the opportunity to talk to you about how the record keeping in those types of -- in that type of a situation would apply.

MS. FRASER: Yeah, we could talk about it. I think generally, though, there is an immediate previous source, it just is where it's entering into your bubble. So for your milk processing plant that eventually is going to feed ice cream, the milk processing plant, their immediate previous source is going to be wherever they receive the milk from the farm, that's their immediate previous

source, as well as what other ingredients they happen to be using, the containers they're putting the milk into, whether it's bottles or, you know, assuming it's going to consumers, but whatever, you know.

So to the extent -- so there is an immediate previous source coming into your bubble, just like for your manufacturing plant, not the milk, because that's already in your bubble --

MS. WRIGHT: Right.

MS. FRASER: -- but whatever other ingredients for the ice cream --

MS. WRIGHT: Okay.

MS. FRASER: -- are coming in are coming into your bubble. I think your challenge is going to be when you ever decide to ship off the ice cream to the retail store, now your internal records need to be pretty clear about for that -- those gallons of ice cream that just got shipped to Giant or Safeway, you know, linking incoming ingredients without going sources, you're going to have to have a pretty good system of tracking,

well, the milk came into the bubble over here, the vanilla flavoring came in at the manufacturing plant, the whatever else you put in came in here, and then it all -- there is an immediate subsequent recipient, which is your retail store.

So, yes, we don't worry about how you transferred it internally, that's your issue, but we do expect the incoming into your bubble and the out going out of your bubble to still be retained.

MS. WRIGHT: But to the extent that it's going to consumers --

MS. FRASER: Then you don't have --

MS. WRIGHT: -- we're not required to do recipients, so we can still --

MS. FRASER: Exactly, so you would only have the incoming. And it still is okay for us because if your outgoing as a consumer, if you're selling it directly, you own the retail store, let's say --

MS. WRIGHT: Right.

MS. FRASER: -- and you're selling it to the consumer --

MS. WRIGHT: Right.

MS. FRASER: -- then when those, not that this would happen to you, but if and when those consumers, you know, we ever had an outbreak and the consumers ended up sick, then we would say, okay, what's the retail store you purchased it from, then we're back to you, and we're saying, okay, now we need to do the trace back to figure out, you know, where that could have occurred, where, you know, let's see the records for incoming ingredients, whatever, so it doesn't -- it hasn't changed how effective the system is, in some ways your vertical integration means that we don't have to do a step at a time --

MS. WRIGHT: Right.

MS. FRASER: -- we're at the one source that is the manufacturing, the distributor, the transporter, the -- everybody, and so it's fine.

MS. WRIGHT: Okay. I'll yield the floor.

MS. FRASER: Okay. And then I also have some here, so that would be -- we'll get to -- we have quite a bit of time, so we're okay.

SPEAKER: Okay. Question about -- you didn't use the term track and trace, but relative lot numbers, we're in the feed business, and in many cases the incoming material is co-mingled, as you described in one of your slides, and I understand, correct me if I have the right understanding, correct me if I'm wrong, that we're required to record any lot numbers that may be available, but as far as being able to track and trace, those are limited by the co-mingling that happened, so we can identify lot numbers relative to a particular window of time, but because of the co-mingling, I can't tell you exactly where they went; now, is that okay, you know, per your understanding?

MS. FRASER: You can't tell me for perhaps a bag of feed going out the door that it was limited to lot number 1, 2, 3, 4, 5, but for that bag of feed going out the door, I should be able to see maybe 20 lot numbers, if that's how many were co-mingled, or 40 lot numbers, if that's how many were co-mingled.

There still is a requirement to trace incoming ingredient to outgoing product, it's just that the level of your specificity might be broader than someone who has a dedicated silo and can tell me for that bag of feed going out the door, it only is this lot or these four lots. But there's still -- the requirement is still there, it's just that the scope -- the list of your lot numbers is likely to be much longer.

SPEAKER: Correct, okay. Second question, on pet food, if there is a retail outlet that is a, what we would call a cash and carry business, there's normally not a record of the purchaser, it's simply a cash transaction, how is that handled?

MS. FRASER: Is this -- and this is a purchaser that you know is a business, so this is a purchaser you're not sure whether it's a business or not a business?

SPEAKER: Off the street, a person off the street.

MS. FRASER: That's not -- that's the same

as any other retail store where we would not count that as reasonably available to you to be able to -- we would assume that's a consumer.

SPEAKER: So a Walmart or a Big Lots retailer would not be required to do it unless they had a process in place to -- where they could attach it to some sort of identification?

MS. FRASER: Correct, or if they had a business account with, you know, a supplier, a retailer, and the supplier came in and said this is, you know, I'm ordering 20 cases and charge it to my business account, then Walmart does know that it's a business transaction, it's reasonably available.

MS. TUXBURY: Hi, Lorrin Tuxbury from Hogan and Hartson. We've got numerous questions from different manufacturers and retailers, but I'm just going to give you two today. Our first question is about compliance with the December 9 deadline. A lot of large companies will have product in stock for six months or so.

Say if they receive a product in September

of this year or October, or some ingredient that's not used until February or March or April of next year, after the compliance deadline, actually to be incorporated into a product or something like that, and then their records request comes out, how do they deal with the immediate previous source if they received that product before December 9 and aren't required to have records at that time?

MS. FRASER: I think we recognize that initially there's going to be holes in the records just because of that very fact, that people aren't receiving everything on December 9, or the products they're shipping out on December 9, 10, 11, January, February are with ingredients received after that date. So there will be some period of time that there won't be a complete set of records, but at some point all of the incoming ingredients are going to have been received after the compliance date, and then that linkage will need to be there.

MS. TUXBURY: Okay, great. Our second question is just sort of how we can help you guys

in terms of receiving data, are companies giving you data, if there's a large nation-wide company that has multiple distribution centers and multiple retail operations throughout the company, and they receive a request for, you know, say a swiss cheese product, in certain cases they're going to have boxes and boxes and boxes and boxes of data on that product, so how can they best provide that to you, in electronic form, or paper form, or how?

MS. FRASER: I'll answer what the rule has in it, and then maybe Diane has some thoughts on the -- on, you know, from an investigator standpoint, what has been helpful in investigations in terms of ease of turning over records. From a rule standpoint, I think the first place to start is the access request itself, and you know, one of the things our guidance looks at is being as specific as possible as to the scope of the request, and so, again, if I'm going back to the way we usually find out we have a problem is, a number of people get sick, and then we, you know, sometimes you hear about it through a threat or

sometimes you hear about it after product is shipped, that the manufacturing line either was tampered with intentionally or it fell apart and there's problems with the shipment coming in, so you may know some specific information.

But, you know, if we were able to know it's, well, let's take Hepatitis A, green onions, we had an outbreak, green onions from a certain distributor over a certain period of time, then that's one set of records that it's -- it's not just all green onions, it's probably limited to a distributor, and then we're looking at where did the distributor send those products, or it's swiss cheese coming out of a certain manufacturing plant, limited to that, so with some specificity, it's not just such a scatter shotgun approach, the article of food is adulterated, it's pretty specific as to what article are we talking, about as much as we can be, and presents a threat, you know, there's again some specificity.

We don't require records to be kept in any particular form, so you can keep them

electronically, paper, you can keep them in a shoe box, I mean there really is -- the requirement is to make them available within -- as soon as possible within the 24 hours.

You know, clearly, things that are searchable make it easier for everybody, but there is no mandatory requirement to keep them electronically. At the same token, you can't throw everything in a shoe box and say, well, they're in there somewhere, go find them, because if we are able to say we want the records from the green onion distributor for these dates in question, we don't expect to get boxes that span two months period of time and say, you know, as the old kids game used to be, go fish.

So, you know, I think those are sort of, from a legal perspective, some of the legal limitations in there, I don't know from an investigator who's not done that side of the house, if there are other things that you just would request, suggest, or common practice.

MS. KELLEY: I think what you've mentioned

covers it. We're going to try to limit the scope of our request to the extent possible. We're going to rely on you to be able to educate us about how you keep your records and maybe the best way that we might get access to the records we're looking for. So it's going to be a communication back and forth, too. We're not just going to go in and say give us all these records, we're going to expect that you're going to be able to help us to narrow the focus of our request.

MS. TUXBURY: Okay, great. Thanks.

MS. KELLEY: Sure.

MR. PRINCE: Sounds like a good question to pick up on. My name is Gale Prince with the Kroger Company, and I want to go further with this particular scenario of when you come asking for records. Where do we anticipate that that request may come, we, being the retailer, or does it go directly to the manufacturer if it's a national brand product?

MS. KELLEY: I don't know that we can answer that question because I think it's going to

be on a specific case-by-case basis. We're going to go to the place that we have the most recent information that the product came from and expect that we're going to be able to trace it back from there.

MR. PRINCE: So a national brand cereal sold in one of our particular stores, we will be asked to provide the trace back or where the store received it? That would take us back to one of our distribution centers, and at that particular point, we would have a bill of lading probably covering a shipment, but that may be from some warehouse where the particular products have been co-mingled from various plants that that company may have had, and so what would be the responsibility of the store manager in that case in producing the records? How far back would you expect that store manager to provide you with the records?

MS. FRASER: I think a couple of things, and I think this is what Diane was hitting on. If we see, you know, there's numerous types of examples. If we see consumers getting sick just in

the Maryland area, then -- and we talk to consumers and we find out that, you know, they all seem to have eaten cereal X, and maybe they all purchased it at the same store or they purchased it at different stores, those are two different scenarios.

Purchased at the same store, you know, we're at that store asking for records, maybe the tampering occurred in the store, maybe there was no tampering and there's a problem with the product and we're finding consumers in other cities are getting sick.

But you're only responsible for the records of what you have. You're not responsible for up the chain, you're responsible for telling us and showing us records that I received, here's my records that deal with cereal, from those records, we go back a step.

I mean it's literally -- it's a trace back one step at a time. So we go back a step and we figure out, okay, you purchased your cereal from the distributor. The distributor now has the

obligation of saying where did you get your cereal from, all of the many sources, whether you co-mingled it or not, and to whom did you distribute it in addition to you. So we're going to want to trace down to say, okay, he sent some to you, but he also sent some to four other retail stores. And so your responsibility is just for your records, and where we enter the system, it may be that the scope of the access, the nature of the toxin, the nature of the outbreak, that it is a national brand, and it's a deadly toxin, and we don't have -- necessarily, maybe the scope of the request is at the same time we go to you, we do go to the manufacturer. But it's case specific. There is no general we'll only come to the retailer, we'll only go to the manufacturer, it's going to be based on what we know.

MR. PRINCE: Thank you, that's helpful. I have a second question. As you talk about records and recording the activity at the time it happens, if you record the information in Excel spread sheet that has formula and bat size and all of this

information, at the time of the request that FDA makes, can we cut and paste the list of ingredients, the -- of that code date through cutting and pasting in the Excel program?

MS. FRASER: Yes, you could do that, as long as you can still meet the -- as soon as possible, not to exceed 24 hours. Some of the comments that people said was, well, if you come in with a request, we would want time to redact it or do something else, and our response in the rule is, that's fine, as long as you maintain the access time frames, you're not going to get additional time beyond the legal requirements to do that redacting or the cutting and pasting or whatever else. So whatever your mechanism is for providing access, if that's what you want to factor into your time frames, you just need to make sure you can comply with as soon as possible, not to exceed 24 hours.

MR. PRINCE: Is a list of ingredients that you would have on the ingredient statement of the package adequate?

MS. FRASER: No, because it doesn't include the secret herbs and spices.

MR. PRINCE: Thank you.

SPEAKER: Yes, I work for a third party logistics company and I have two questions. If we pick, pack, and ship, and we are responsible for tracking and tracing lot numbers, are we considered a non-transporter for that process, or are we still a transporter?

MS. FRASER: You have to explain what you mean by pre-package ship.

SPEAKER: Well, what we do is, we get in product and then we would overwrap it according to orders and then ship it out.

MS. FRASER: You're a packer or a repacker, I think as the case may be.

SPEAKER: Okay. So then that would be non-transporter?

MS. FRASER: Right.

SPEAKER: Okay. And then if we distribute products say that sold over the internet, would we have to enter a contract with the immediate source

to keep the records of what we're shipping for them?

MS. FRASER: No, the contract is an option, and it's only if you don't want to keep records and you can find somebody who will volunteer or contract with you for a fee or whatever else to do it on your behalf. It is an option for transporters to comply only. Whether you enter into a contract for some other reason has nothing to do with FDA, but there is an option for transporters to fulfill their obligation of establishing and maintaining records by getting somebody else to do it for them.

SPEAKER: Okay, thank you.

MR. LaMOTTE: Dave LaMotte with Benny and Smith. The listed compliance dates that vary by business size are relevant to facilities that currently are responsible for distributing foods, selling, manufacturing, processing. In the future, if a company or a facility decides to start for the first time distributing foods and fall under this regulation, what then is the process and the timing

for notification, registration, record keeping, and so forth?

MS. FRASER: If a company starts up a business, just like any other thing, they would be complying with, you know, if you're building it from the ground up, you have to be in compliance with, you know, whatever you're -- building fees, construction fees, municipal fees, you're expected to be in compliance with all applicable laws the day you open business.

And so if you're starting up a business and it's in your large entity and it's next year, then the day you open business, you should be in compliance and be recording and maintaining records for all food you receive or release after that date.

For anything you -- there is no grace period, if that's what you're asking, do you have an additional year, no. It's like any other law. You know, when you get your driver's license, you're expected to be in compliance; or if you go to apply for a driver's license because you turned

16, as my son just did, he, you know, he needs to be in compliance.

So it's a law in effect that, you know, whether it applies. If you start up your business in September, this year, and you're a large business, December 9 is December 9, you need to have plans in place to be in compliance.

MR. LaMOTTE: This sort of is a follow-up to a previous question. I would assume that would mean two years from now, if we sell the first food product on such a day, we would have to anticipated and kept the records for the incoming ingredients ahead of time, it's not triggered by the first ship date of the final food, but anticipating the need for the records of the incoming ingredients before that time?

MS. FRASER: Well, that's a good question. I think that -- I think at the date the business is in effect. So let's say if you're -- I think from the perspective of if -- it depends on when you start your business. So if you start your business, and I don't know if you're thinking pre-

December or post-December, then if you're post-December and you're receiving food, then you're responsible -- you're subject to the rule for all ingredients you receive post-December.

And, yes, there is an obligation to be able to link those incoming ingredients with outgoing products, because that regulation has applied to you post-December. So it's only if you happen to be receiving ingredients pre-December and shipping later that you would have the holes that -- like Ms. Tuxbury talked about, that there's some gaps because you received product beforehand. But whatever you're doing, whatever activity you're doing, and it's manufacture, process, pack, transport, distribute, receive import, receive is its own separate trigger for being in compliance.

MR. LaMOTTE: Thank you.

SPEAKER: I represent an integrated poultry operation. At the same time that we registered all of our feedmills, we also registered all of our hatcheries. And my -- well, I have two questions, one relating to hatcheries. What are

the record keeping requirements for hatcheries as it relates to this particular act?

MS. FRASER: I thank you for registering. I don't think you had to register the hatcheries, because I think they're USDA, and things subject to just USDA were not subject to the registration rule. So you can actually go into the registration data base and cancel the registration for those -- USDA, you have no record keeping obligations under this rule. I don't know what you have for USDA, but none for here.

SPEAKER: All right. I've got my work cut out for me when I get back home.

MS. FRASER: Okay.

SPEAKER: The second question relates to the manufacturing processes themselves, and that is, for running a feedmill or any other operation, there are non-food items that are required for the maintenance and operations and what have you; are there any record keeping requirements as it relates to FDA and this act in regard to other than food items?

MS. FRASER: Not other than food items, but recognize that we do count as food items things that you don't eat. So the packaging and food contact substance, but technically, as you've asked it, if it's not defined as FDA food, then there is no obligation under this regulation for anything else that's not an FDA food.

SPEAKER: Thank you.

MS. ECHOLS: My name is Marsha Echols, I'm representing the National Association for the Specialty Food Trade. With regard to the ingredients and giving you information about the ingredients in a product, for what now would be listed under flavorings or spices, how much detail do you want in the information and records that you would have access to?

MS. FRASER: I think it's the, you know, it's the list of ingredients you would be -- and the way we specify the regulation is, for each food that you receive, in the form that you receive it, you need to keep a record. For each food that you release, in the form that you release it, you need

to keep a record. So the answer is really back to you in terms of however you receive those flavorings or spices, that is a food product, that is the specificity at which the records must be kept, and then linking the incoming ingredients, which are how you received it, with the outgoing product, however you released it, is what's required.

MS. ECHOLS: So giving you the name of the ingredient without a brand, for example, without a manufacturer's name, but just that product?

MS. FRASER: Well, look in the regulation because it's pretty specific what we mean by type of food, and it does, you know, it does say, you know, not just brand, but type. But it's pretty specific in terms of identifying it beyond vanilla, you know, it's asking for -- and again, if you think of the picture, this is so that we can do a trace back investigation, and in a public health emergency, focus our attention on whatever might be the suspect product, and conversely not implicate and have economic implications and market

implications for anything else unnecessarily.

So the more specificity there is, it both helps us achieve the public health mission, which is our primary objection I think on your perspective; it also helps limit how much you have to make available, it helps limit potential market impact, it helps limit our communication of what might be a concern, so it's -- it is pretty specific what we ask for.

MS. ECHOLS: And under this regulation, are you going to request access only if the public health emergency seems linked to bioterrorism?

MS. FRASER: No, you know, the bioterrorism rules I think in some ways become a misnomer for that reason. People think of this as only related to terrorist activity or bioterrorism events. But if you actually open up the act, it's to assist with the prevention of bioterrorism and other public health emergencies.

So we got the authority because of 911, and we got the authority because of the concern with bioterrorism, but it is applicable whether

it's an intentional contamination from terrorists, whether it's an intentional contamination from a disgruntled employee, whether it's an accidental contamination, whether it's a naturally occurring toxin that just kind of went rampant, it's -- if it causes a public health emergency, then administrative tension can kick in, our access to records could kick in, we just have to have met the standard of serious adverse health consequences or death to humans or animals, and that's the trigger, it's not the cause.

And half the time, or most of the time you're not going to know whether it's intention or not until months later after you finish the investigation and found out, yeah, it was, you know, it was Joe Blow that got fired three months ago, or no, it was a terrorist activity, or no, it was the manufacturing line, nobody knew there was a leak in the line, I mean you find that out in the investigation long after the public health emergency, you've seen the effects of that.

MR. HACKMAN: You could have a sick

employee one day, you know, and they're not having malicious intent, but it's still causing illness. So when you look at the full title, I mean we shortened it, I will say we truncate the actual letter of the law to say the bioterrorism act, but the true title is the public health security and bioterrorism preparedness and response act, so it's the first portion of the part of the way that it's written, the public health security, that's the aspect that we're looking at. And any type of illness, regardless of what the cause is, we need to look into because we're in the business of protecting public health.

MS. FRASER: Lorrin, let me go through these and let me get through the first ones before I take second round questions, if you'd be so kind. We have Bob Budoff with Discus. A food producer receives shipments of bottles on an ongoing basis for use as food contact containers. Bottles are shipped in a number of lots and are removed from storage in a single hopper on an as needed basis. The food producer does not and cannot reasonable

track the lot of the specific bottle used for a specific unit of bottled product. Is the producer required to maintain one up, one down records which show the lot of the -- of each specific bottle received, each specific bottle product it is used on, and each specific shipped out as yes.

This is a food -- this is basically -- think of it as a food ingredient. It's a food contact substance, it is coming in with a lot number. This is an entity that is -- this is the one place where the requirement says if you are -- have a -- if you are the person putting the food in contact with the finished container, then the requirements on establishment or maintenance apply to that product, same as it would apply to canned string beans being received or an ingredient being received.

There is a duty to record and link incoming ingredient, incoming finished food product container without going product, and that is an obligation. To the extent the information is reasonably available, the information is reasonably

available, it's coming in with a lot number, and so that is part of the requirement, that is one of the -- one of the reasons for giving up to a year for large entities and up to two years for small entities to come into compliance, was for companies to be able to make adjustments to record the information mandated by the rule. Lee Sanders, American Bankers Association; when bakeries send a variety of product -- something, a product to an animal food plant, it would be most logical to assign a lot code to the vehicle rather than to have to keep track of the variety of products on the truck. Can FDA consider this allowance for record keeping purposes; at this stage, no.

The rule does have requirements in it to require an alternative such as this as a change, an amendment to the rule, which would have to go through notice and comment rule making. And as a practical matter, FDA, you know, we have completed this rule making. I don't recall that this was a comment made during the comment period, and FDA, at this point, given the other public health issues we

have on our plate, is -- this is very low on the -- I don't see us reopening this rule any time in the near future, barring some public -- significant public health reason or change in statutory authority to do that. The rule does require the lot number linked to the product and the food, not to the vehicle itself.

Another question, how will you, the same person, how will you handle record keeping for small suppliers to large companies, difference in record compliance dates? This is not really -- the record keeping -- this really gets to can we do an effective trace back when there are different compliance periods as opposed to records from small to large. There is no obligation for the records you are subject to keeping to move with the food. Your records are your records, you keep them until we demand access under authority. The small entities have no obligation to send records to you, and they don't have any obligation prior to their compliance dates to keep records for you to send to you, or to keep records ahead of time.

The compliance dates are based on the size of the business. If we are in a trace back, and it's between the one and two year mark, or if it's even now, we're limited to records we can access under the law, and the records we can access are either those you keep as a matter of business practice, small or large, or it's those you are required to keep under our rule, which is only as of the date of your compliance date. So, you know, the trace back will be as effective as it can be based on whatever records we can access at the time that we're doing the access request.

Bob Hahn, Olson, Frank, and Weita, if a processor receives grain from over 1,000 farms, must it keep records for all farms? Yes, you have to keep records of incoming ingredients, date received, for all food received, and the source of that is required. Is a transfer from parent company to the subsidiary an intra-company transfer? That would depend on ownership. My guess is it is not an intra-company transfer because they are, and, you know, this will be fact

specific, but the fact that you called it a subsidiary leads me to believe it is incorporated as a separate entity, it is, therefore, a separate person under the statute, because it is not the same association, corporation, or I forget what the other one was, partnership.

And so we look at personhoods, and if you have established different subsidiaries under different -- they're different persons for purposes of law, then they are not intra-company transfers, they are transfers from one person to another person.

Matt Frederking, Southern States Cooperative, is the expiration date considered other identifier? Example, a bag of trace mineral has an expiration date on it, but no other lot number of code. We don't really think of the expiration as a lot identifier. The lot identifier usually is, you know, the lot number, sometimes the manufacturer puts on its own code, and they can translate that code or decode it within the facility, you can use the manufacturer's

identifier, but the expiration date we generally do not consider the unique identifier.

Do retail facilities have to comply with the immediate subsequent recipient requirements if the customer is not a business? No, retail facilities, nor anyone else, if you're distributing to consumers, even if you are a manufacturer distributing directly to consumers, there is no requirement to record records of those transactions. Example, do they have to track the lot code but not the name, or do they not have to track any of it other than the immediate previous source? They don't have to track any of it other than the immediate previous source.

Marsha Echols representing the National Association for Specialty Food Trade, the access to information -- you state that intra-company transfers are not covered under record keeping, this is no name on this one, in a situation where the intra-company transfer from a common storage site is transferred to another common storage site for manufacturing, is the potential immediate

previous source the sum of both common storage sites?

The immediate previous source is somebody outside your person, so someone outside your company, so whatever, you know, if you're transferring it from one storage site inside your corporation to another storage site inside your corporation, that's not a transfer we look for. We're looking for where did you get the product from outside of you, who sent you the ingredient or the product in the first place. When you're linking and when you release it, assuming it's not to a consumer, and you need to link incoming ingredients to outgoing product, that's your obligation to keep track of the transfer from one storage site to another, that's not something we need to see in the access to records. We're just looking at outside as somebody described it outside your bubble.

George Pisula at the Gallagher Dairy Company, is a dairy still required by regulation to receive lot codes for items delivered to retail

outlets? I don't know. That's outside the scope of this rule, which is my area of expertise. This one, we can, whoever George is, if you see me afterwards, we can get you in contact with the folks in the center who are responsible for dairies to answer this. But in terms of -- so to answer the are you required by regulation to receive lot codes for items, I just don't -- I don't know the answer to that.

Jeff Barach, Food Products Association, for a large company with more than 500 FTE, if they are not in compliance after December 9, what may they expect; would there be any warning to comply say within the first year? Will FDA validate compliance by a company without going through an actual SAHCODHA threat? If you're not in compliance by December 9, you're not in compliance. I hope we don't have a public health emergency for the public health's benefit that effects your entity, because then we have a hole in the trace back chain, and I think that is the most significant concern of not being able to move as

effectively as possible. From a public relations standpoint, I don't think you would want to be the company that has that on top of you as part of the problem in the trace back.

You know, whether we have an emergency, whether we find out whether everybody is in compliance or not is exactly what we're exploring under the second part -- validate compliance. We are exploring with our General Counsel's office, can we validate compliance, can we do spot checks, pick a random product and ask you to show us the records.

If we determine we can do that, we will issue a draft guidance document notifying you to that effect and what our process for doing that ahead of time. But I do think, or some other notification, but I do think from our perspective, from the public health perspective, it is critical that we figure out how we can make sure people are able to comply before we find out we're in the middle of a public health emergency and have a problem.

Shirley Walker with the Pennsylvania Liquor Control Board, for direct import, is the immediate non-transporter the person noted as the shipper on the prior notice submission? It probably depends. I think sometimes the shipper is the manufacturer, sometimes the shipper is a warehouse. You know, really what we're looking for is, you know, it is the person who has custody and control of you, and you know, the non-transporter that had custody and control of the product before you. And if you look at the definition of a non-transporter immediate previous source, it is the entity that owns or has possession, custody, or control of the product.

So it very well could be the shipper, it also may be, you know, some other entity, you know, I just don't know, it depends on what you're looking at as the records for that transaction. It's going to be case specific, but look to the definition of non-transporter immediate previous source and then figure out which in your supply -- who in your supply chain can fit that, and it may

be more than one entity. To the extent you know the direct, you know, it's, you know, you may find people that fit on the -- side or the possession, custody, and control side.

Rebecca Piston, HP Hood, if a firm is subject to a class one recall, does this regulation also apply? It could; I mean this regulation applies if you fit into -- and I'm taking it does the regulation apply, I'm guessing the question had to do with records access. The regulation applies if you meet one of the criteria for being subject to the regulation. If you manufacture, process, pack, hold, transport, distribute, receive, or import food in the United States and aren't subject to an exclusion or an exemption, then you're subject to the establishment and maintenance provisions. You're also, even if you are subject, you're likely, other than farms, restaurants, you may be subject to the records access provisions.

The standard for class one recall is pretty similar to the standard for accessing records. You know, they're both serious adverse