

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

"WHAT YOU NEED TO KNOW TO ENSURE COMPLIANCE WITH
THE NEW FDA BIOTERRORISM ACT REGISTRATION AND PRIOR
NOTICE INTERIM FINAL RULES"

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P R O C E E D I N G S

(In progress, Tape 2, Side A)

MS. : And we deal literally with dozens of companies domestically and internationally in the food and beverage industry. And are we going to be held responsible for making sure that all of those firms are registered, and do we have to track their registrations?

MS. : Well, as far as registration goes, the owner, operator, agent in charge is responsible for registration of that facility. So as a third party, you would not be responsible.

When we talk about prior notice and what foods have to be covered by, you know, identifying the manufacturer and registration number of that manufacturer, then your responsibility would be if you import foods that that food be from a registered manufacturer, because if not, you won't get the food.

MS. : Thank you.

MS. : So there is a responsibility -- it's not a responsibility, it's more of a consequence.

MS. : Okay, thank you.

MS. : I'll make it quick. I have two questions. My name is Damarys. I'm with N&I Air Cargo. Two questions.

As a broker and a bonded warehouse, we import for customers many different products, food products. As a facility, what do I register, the current things that we have now, because we may have a customer that may start importing something that we have never done before.

MS. : Okay. The main thing to remember with registration is it's associated with a facility, so if you have a facility that stores food, then you register that facility, and when it comes to the food categories, we would expect you to use the option of most all, because that covers all the categories.

MS. : Okay.

MS. : So, yes, you have to register because you store foods. The optional information of most all makes the most sense for a warehouse.

MS. : Okay. And the second question, for my customer that imports let's say a certain product from different manufacturers, but it's basically the same product. He may make it in Scotland and England, et

cetera. Which do I tell him? Do I tell him to register each manufacturer, the same part, the same --

MS. : Right. The thing to remember about registration is that it's associated with a facility. That's a location. So it's different than a firm. You may have a firm that has 100 different facilities where they either manufacture, prepare, process, pack, hold foods. Each of those facilities must be registered.

MS. : So let's say this part is coming in from England. Let's say London. But it was produced in Scotland. The manufacturer that they will be entering will be the one in Scotland.

MS. : Right.

MS. : Even though the one who imports it will be from --

MS. : We'll probably discuss that a little bit more in prior notice as well, and we'll get into shippers and things for prior notice. But the thing to remember about registration, it's facility, and it's doing one of those four things: manufacturing, processing, packing, or holding food.

MS. : Thank you.

MS. : Okay.

MR. : Good morning.

MS. : Good morning.

MR. : Len Miyar, M&H Brokers. My

question is I'm getting a lot of questions from the truckers if they pick up, for instance, during the day they make a lot of pickups for the seafood industry for a particular customer, and then at night they load it all into a big trailer and transport it to them. Do they need to register as well, or are they still a transport vehicle?

MS. : Is it still moving? Do they store it overnight?

MR. : Well, they pick it up in the morning from an airline and it will go to their -- you know, to their -- the trucks will come into the warehouse and then they load them into a big trailer, a 40-footer, and it goes from there on to the --

MS. : Right. In the situation that you described, the warehouse would have to be registered, but the trucks are all doing their business as private transporting.

MR. : Well, they're all from the same
warehouse.

MS. : Right. But the warehouse has to
register.

MR. : They need to register.

MS. : When you get into a truck as a
facility, is if they had a yard, say, and they brought the
trucks in, plugged them in overnight, or let them sit for
two days plugged in, and then moved them. When they plug
it in and it sits there for a day or two, then you've got
what they consider a mobile storage facility. But what you
have described is really a warehouse where, you know,
everything comes in and goes out.

MR. : And they have a cooler, the fish
goes there, and they load it and it goes out.

MS. : Right. The warehouse has to
register.

MR. : Okay.

MS. : Trucks are okay.

MR. : Thank you.

MS. : Keep them moving.

MR. : All right.

[Laughter.]

MR. : Good morning. My name is Jeff Bailey from Del Monte Fresh Produce. I have a couple of questions. One specific, one general. I'll start with the general one.

It is my understanding that the registration number is not public information.

MS. : That's right.

MR. : Okay. We have had --

MS. : It's not -- it cannot be made public by FDA.

MR. : Okay. I guess that you might have answered my question.

MS. : Yeah.

MR. : We have had a series of customers who have required us to provide them with our registration number. Any comments on that?

MS. : You know, my comment on that is because of prior notice and because people want to make sure that the people that they are trading with are covered by registration, the only way to prove it is to say here's my registration number. The statute itself prohibited the

agency from disclosing registration numbers, required us to keep a list, and then it said we couldn't disclose that list.

So we can't. I know brokers have particularly asked, you know, how do I -- is there a drop-down list like where I can verify that this manufacturer is registered? Right now our answer is no, we can't do that, because we can't disclose it. But we are requiring it, so somebody has to disclose it. So I think that's basically the premise for that.

MR. : Okay, that's fine.

The next question is we import Clementines from Spain, and as you are aware, APHIS has very strict guidelines on importation of Clementines. One of the regulations requires on the reefer vessels that we use, that it goes into a sealed portion of the vessel, and it has USDA inspection on it.

Now the letters that we get from APHIS state that this is a cold treatment and it's to keep it in a cold chain. We've gotten a lot of questions from our Spanish operations as to whether or not that vessel will have to register because it uses the word treatment on there, if

that is just considered a reefer vessel or it's transaction and it's not.

MS. : It's a transport vessel.

MR. : It's a transport vessel, but because it's got -- it's the FDA's position that that's --

MS. : For our purposes, for registration, APHIS probably has a whole different concept of it because of the treatment.

MR. : Right.

MS. : But for us, that would still be a transport.

MR. : Excellent. Thank you very much.

MS. : Uh-huh.

MR. : Good morning. My name is Fernando, tilapia importer. I basically have two questions. First of all, our company itself never touches the product, we just market it and distribute it. Do we have to register?

MS. : No. Remember, facility. It's not a virtual facility, it's a real one.

MR. : Yeah, because we have --

MS. : Right. So you would not have a location, so it has -- no, if you don't touch the product, you don't.

MR. : Okay. And if the facilities that actually produce the tilapia, they are registering us as agents. Does that imply a liability on our part if anything happens?

MS. : The liability of a U.S. agent is between the agent and the company. It doesn't involve FDA.

MR. : Okay.

MS. : Okay? The FDA just wanted the agent, requires the agent for communication purposes. Now if an agent also is the registrant and they provide false information, then there is a liability. But it isn't a liability as an agent, it's a liability as the registrant. So, no.

MR. : All right, thank you.

MR. : Good morning. My name is Craig Pettit from Del Monte Fresh Produce. One question regarding the CBP has account managers for high-volume importers. Would the FDA be following along those lines to help the high-volume importers?

MS. : I think you need to refer that question back after the break for prior notice.

MR. : Okay.

MS. : Because volume and registration don't really go together.

MR. : Okay.

MS. : Okay. No problem. Hold on to those questions.

MS. : Hi, good morning. My name is Lorena Garcia. I'm from Service America. We're an import company. I had a question regarding the agents. We're going to be representing the manufacturer and the exporter in the foreign country. What information does the agent need to have if or when they do get a call in an emergency?

MS. : That's a really good question, and I think what the statute implies is that we would contact the agent, and the agent would then have the ability to pass that information to the appropriate people in the foreign facility.

MS. : Okay. Thank you.

MS. : Uh-huh.

MR. : Ward Chaplin, Southern Wine and Spirits. Are we going to talk about lot numbers in the next session?

MS. : Yes.

MR. : Okay. We have -- occasionally we will bring a trailer in on a Friday, but not unload it till a Monday. What -- is there a specific timeframe when the trailer becomes not transport but storage?

MS. : No. Not in the interim final rule. There is no timeframe, so when it stops and it becomes storage, you know, it's no longer part of the transport process, it's more a part of the storage.

MR. : I will register my yard, but we will deal with maybe a hundred different trucking companies. Do they have to register their trailers, or just register that it's in my hard?

MS. : That's my understanding.

MR. : That?

MS. : Because that trailer becomes the mobile transport facility.

MR. : So my yard is registered or the truck is registered?

MS. : Truck. Trailer, trailer.

MR. : That's real tough.

[Laughter.]

MS. : This is --

MR. : That's going to be very, very
challenging.

MS. : It is challenging, and just let
me interrupt because this is where I think the concept of
the interim final rule comes into play, that if you foresee
or you encounter difficulties with not having a timeframe
for something like that, these are the kinds of comments
that we would -- I would encourage you to send to the
docket.

MR. : During and after the 12th, this
is -- I'll probably have to hire two people just to keep
track of that. I know there's a window, but are there
implied penalties for like, you know, if you miss one?

[Laughter.]

MS. : For both registration and for
prior notice, we plan to issue enforcement discretion
guidance. You know, it's for us and for our field, but
it's also public information, and what that talks about,

what it's really focusing on is a period of time at the beginning to be used as an educational period, so that if we do encounter things where people just didn't know or they certainly found it complicated, that we would be -- we would have the discretion not to penalize, if you will.

MR. : Just two more questions. We have satellite, what we consider a sales office, but they do receive domestic samples from the primary warehouse. We should -- from what I'm -- you know, it's a sales office. We'll send them five cases because they have to go out for the salesmen all to show the customers. Should we register our sales offices then, because we're technically holding food for could be two, three weeks, you know, cases of samples? Do they all have to be registered?

MS. : I don't actually know the answer to that. I'm trying to think of those exceptions and figure out if it fits into one of them, but it doesn't seem to.

MR. : So better safe than sorry.

MS. : Right. It's also better safe than sorry. There's no penalty for registering when you don't have to.

MR. : I just had to register another
90 locations.

[Laughter.]

MS. : No, no.

MR. : Yes.

MS. : Well, we'll -- do you want to
wait on that until we get an answer? Because we could
certainly, if you leave your card, we can get you an answer
on that.

MR. : Oh, I'll definitely leave my
card.

MS. : Wouldn't that be better?

[Laughter.]

MR. : On CFR 21170.3, when it says
most or all, for example, we are mostly liquor, wine, and
beer, and water, but occasionally at Christmastime we will
get something that has chocolate in it, you know, once a
year. Do I check chocolate, or do I just say most liquor,
wine, and beer, and leave like chocolate off? As an
example question.

MS. : Most and all were really targeted for warehouses or for manufacturers that manufacture long, long lines.

MR. : I've got 28 warehouses.

MS. : If you know that you are occasionally going to have that, I would go ahead and just check the chocolate.

MR. : Thank you.

MS. : Good morning. My name is Tanya with (inaudible) Brokerage. I understand that restaurants doesn't have to be registered. However, if the restaurant is an importer, do they have to get registered?

MS. : If a -- oh, if a restaurant imports to sell food in the restaurant?

MS. : Yes.

MS. : No, then they wouldn't have to be registered.

MS. : They wouldn't have to register.

MS. : You'll notice an importer isn't one of the terms that's used. It's somebody who manufactures, process, packs, or holds.

MS. : Well, they hold food.

MS. : They hold food, but if they are selling that food to another restaurant or if they are selling it to a retail store, then they would be a warehouse. But if a restaurant imports food and they sell that food in the restaurant to consumers to eat only, then they wouldn't have to.

MS. : Because they wouldn't fit the four categories. They would fit the exception.

MS. : Okay. Thank you.

MR. : Bob Damon, Bacardi USA Importer. The emergency contact number, is that a 24/7/365 number you must have?

MS. : Pretty much.

MR. : Pretty much? And if we have an outside agency that handles our emergency calls, so obviously you would have to identify yourself so they could network down, that's satisfactory?

MS. : I think that fits into what they are asking for. I know for a U.S. agent, they want -- because the U.S. agent may be used as an emergency contact number, they say that they have to reside in and maintain a place of business in the U.S. and they must be present in

the U.S. Emergency contact number is somebody to contact in case of emergencies. That implies 24/7.

MR. : Twenty-four, seven.

MS. : Right. And that's why for a U.S. agent particularly that can be either an individual or a company.

MR. : Because sometimes it asks for a name, you know, a name, per se, but I'll put the company down.

MS. : Yeah, I think on the requirement for emergency contact for a domestic firm, we ask for the phone number. The optional information is to give us the contact name and e-mail.

MR. : But if you've got a domestic registration, you ask for a name. A foreign registration, you just ask for a number, but domestic registration, you ask for a name. Okay. So I put the company down.

Second, I guess I'm hung up, too, on the conveyance, because I attended a meeting in Washington, D.C. and we were told that if a trailer is en route and stops for -- I don't know, a certain amount of hours waiting for a delivery domestically, that facility where

that trailer resides has to register. And the same thing for port facilities, when it's offloading, it sits at the port waiting for it to be delivered inland, that terminal operator has to register that facility at the port.

MS. : Right. That's the conclusion that we have come to, especially it will come up on prior notice that bonded warehouses, port facilities -- Mike has a list of facilities associated with imports that we think will have to be registered.

MR. : Okay. Thank you.

MS. : And I'm sorry about the truck question. It was a surprise to me. So I know that the answer on, you know, the length of time the truck can sit was not handled by the registration itself, so these are good questions, and if we don't have answers for them, we will try to answer them, but if they are more of a comment to the docket on the interim rule, I would encourage you to send them in that way.

MS. : Ana Mole, Shaw, Ross International Importers, Division of Southern Wine & Spirits. We represent many foreign suppliers. Some of those foreign suppliers actually buy juice -- I mean by

juice in our industry, we mean wine. So we have some suppliers that use co-ops and some suppliers that they have their own vineyards and process and then ship to us. But a lot of times we have -- when we have the co-ops, for instance, we have a situation where we have a company in Germany that actually buys juice in France in tanks from many growers, and bring it into Germany to bottle. In that case, how many people have to register?

MS. : That bottler in Germany.

MS. : Just that? The grower is not involved?

MS. : No.

MS. : Thank you.

MS. : I wouldn't -- when you get into something like that where they have consolidated the raw material, you know, that -- if you remember the foreign facility that has to register, that bottling of the wine, especially since there's probably blending and all that, is not a de minimis activity. So that bottler in Germany would be the one that would have to register and the others wouldn't.

MS. : Thank you.

MS. : Now if it was bottled in France and sent to Germany and all they did was like put a label on it, then both of them would have to.

MS. : Thank you very much.

MS. : Marian Cochran, ADCO International. We're a consumer goods importer in Fort Lauderdale. We get samples of food products from all over the world, and our initial review of these samples is would it be palatable to a U.S. consumer in terms of smell, appearance, just the general type of product. Nobody would ever eat what we get the first time before we have done a vendor qualification. I'm concerned that all these samples are going to have to meet the same regulatory requirements as food that I am actually importing for human consumption, and I was wondering, can I label them sample, not for human consumption, and bypass the registration and prior notice requirements?

MS. : We need to address that on prior notice because there that's when we get into the registration of foods that are coming in for import, and your question is really more appropriate for prior notice. So don't forget it.

MS. : Okay.

MS. : Because I don't always remember to cover samples, because it's such a lovely category.

[Laughter.]

MR. : Hello. Thank you for your presentation. My name is Mike Sayres, LOC Brokers (phon.). We are Customs brokers. You mentioned about registration, who may register a facility, whether it be the owner or the operator. What happens in the event that nobody registers? Who do you hold responsible for that? The actual owner of the building, or the operator who is using the building for importing or holding food?

MS. : If you are talking about a domestic firm, that would be --

MR. : Well, foreign and domestic, actually.

MS. : Well, let's do domestic first. Okay. Domestic -- what the answer on that is is that when it comes to registration, either the owner or the operator or the agent in charge can register, but if the firm isn't registered, we could hold all three of those parties responsible for not registering.

When it comes to imported foods, because the owner, operator, or agent in charge would be in a foreign country, it is more than likely that the action that we would take is that the food wouldn't be allowed in the U.S. When it arrives in the U.S., it has to be held or at the port or in a secure facility until it's registered, and if nobody steps forward and registers it, Mike will take care of it, right? You're going to go over what those consequences are.

MR. : Yes.

MR. : Well, can you have a dual registration? In other words, the owner of the building would probably want to register in case the lessee leaves the building and a new lessee comes in, at least they have the facility registered.

MS. : That's a question that I'm hoping we see in our frequently asked questions, because when we talk about public storage facilities, my feeling -- you know, it would be my personal feeling -- is that if you have a warehouse that's traditionally used for warehousing foods, and you have people that store there in their account, but it's your warehouse, then you would register,

the owner, operator, agent in charge of that warehouse would register.

Then there's the other type of public storage facility where accounts lease a specific portion of that warehouse, and in that case the answer is the person who does the leasing registers. So it's possible that we'd have a variety of registrations at one location.

So I'm hoping that we will get into that in the frequently asked questions because I myself find that a little confusing.

MR. : Thank you. Could you tell when you talk about farms and facilities that are exempt overseas, when do they become nonexempt? What type of processing would they have to do to become nonexempt from the registration?

MS. : It's not just the processing, but what happens to that product. So if a farm manufactures or processes foods and those foods are consumed on that farm or on another farm that's under the same ownership, so you have two fields and you grow in this field and make juice, but your farmstand is in the other

field, those would both be exempt because the food is being consumed on the farm, essentially.

MR. : Well, you mentioned about a fileting vessel. Would a vessel be exempt just holding and cleaning, but then when they start to filet, that becomes nonexempt?

MS. : Fishing vessels, what we have said is that if it's incidental to harvest -- incidental to harvest for a fishing vessel is keeping that fish in a condition that maintains its quality while it's on the vessel. So that normal processing for that is heading, gutting, and either icing or perhaps freezing. But when you get into fileting, then you are changing the form of that fish and you are actually doing a processing. The fileting isn't for the purpose of maintaining the quality, it's actually the process. So a vessel that filets has to register.

MR. : So it could be possible on an aqua farm facility, for example, it may be exempt if it's just shipping the whole fish, but if it filets the fish, then it becomes nonexempt?

MS. : Right. Aquaculture facility, if they grow the fish, harvest the fish, ship the fish, usually live, if possible, then they are a farm. But if they do actual fileting and processing of the fish at that location, then that facility would have to register.

MR. : And gutting would be an example of processing?

MS. : You know, on a farm, I'm not sure. I would think not because again it is a process of getting that fish to the next step in maintaining the quality.

MR. : Could you explain the difference between sole USDA jurisdiction and dual jurisdiction between FDA and USDA? Is that the 2 percent rule?

MS. : USDA has the rule within -- the 2 percent rule -- sometimes it's 2, and sometimes it's 3. I think meat it might be 2 and poultry it might be 3. But sole jurisdiction means that the products manufactured, prepared, packed, or held in that facility are sole jurisdiction of USDA. So if it's a slaughtering facility and they only deal with the animals covered by the Meat

Products Inspection Act, then it would be sole jurisdiction of USDA.

But if at that slaughter facility they also slaughter deer -- I'm trying to think of -- I mean we basically are -- have jurisdiction of every other food animal that isn't included in the Meat Products Act.

MR. : Where you mention a product like pizza, when does -- how much meat does a pizza have to have before --

MS. : What we're talking about with pizza is that if a firm only manufactures pizza that's under the jurisdiction of USDA, and the sole jurisdiction of USDA, then that would be a facility that was under USDA's sole jurisdiction. But you will have some facilities where a portion of that facility is under constant USDA inspection but not the whole facility. That's a joint inspection. Pizza is an example that we used because most pizza places manufacturers will make some meat pizzas, but also some vegetable or some cheese pizzas. USDA does not have jurisdiction over the cheese pizzas or the vegetable pizzas. Therefore, it's joint jurisdiction.

So the ones that I think we will see that are under sole USDA jurisdiction are egg processing plants, poultry slaughterhouses, beef, lamb, sheep, hog. I'm trying to think of all the products that are covered under the Meat Inspection Act. I think the easiest way to determine the answer to that question is to go to USDA's Web site to food safety and inspection service and look at what they have under their sole jurisdiction.

MR. : And you are not referring to APHIS when you say USDA?

MS. : No, I'm not. I'm referring to the food safety inspection service, because it's those three specific acts that were excepted by the statute. So when the statute said under the sole jurisdiction of USDA, it explicitly targeted the meat products, poultry products, and egg products.

MR. : Okay. Thank you.

When a person decides to become a U.S. agent and they are an agent and they decide they made a mistake and they don't want to be an agent anymore --

[Laughter.]

MR. : -- then is there a procedure for that, that a U.S. agent can discontinue their agency?

MS. : If a U.S. agent wants to discontinue the agency, they have to take it up with the firm that's registered, and then that firm would have to update their registration with a new agent because that's a required piece of information.

MR. : So the agent has no say, really, only the person who --

MS. : The agent doesn't have any say with us, anyway. It's the foreign facility that identifies the agent, not the agent that identifies themselves, but the foreign facility.

MR. : So theoretically once you become an agent, you could be an agent forever, unless that company --

MS. : That's up to you and the firm that you agree to be the agent with. Now there's three people behind you, and I want to handle their questions.

MR. : Oh, sure.

MS. : And then we'll take a break, okay?

MR. : Okay. Thank you.

MR. : Hi, my name is Ezilian Marr (phon.) I represent (inaudible) from Brazil and some exporters from Brazil, they are not fluent in English, so they ask us to put in the computer with the information they provide to us. You already talked about liability, but I want to try to clarify this. The information they give to us, we cannot verify if they are completely true or not. So what is our responsibility as agent to fit this into the computer? Because I read the form for registration, and we also signed as authorized agent, but we also have -- we have responsibility to inform the truth.

MS. : Right. You're exactly right. When you register for someone else, you not only have to say who authorized you, but you have to say that to the best of your ability, you verify that this information is accurate and true, and any liability would then be between you and the company, because you are registering for the company, so the company is the one that's liable because they -- we are assuming that you will have some sort of paper trail that this is what they provided you as information.

MR. : So it's a matter of contract?

MS. : Yeah.

MR. : Thank you.

MR. : Good morning. Christian Nadal, Mohawk Products (phon.), Miami. The restriction, we have more than the four DBAs, but the forms allows for four. Where do we file the others?

[Laughter.]

MS. : If the form only allows you four, you pick your favorite four.

[Laughter.]

MS. : That's all I can say. If there's no other ability -- I have never registered electronically, so I don't know if electronically -- are you talking about paper?

MR. : I was looking for an attachment or something like that, that we could --

MS. : I don't know. Can anybody answer if they have done this electronically and there's more than four? Because I have never done it. So I would say you may want to check the electronic and do it that way. Otherwise, I'd put the four that you pick and then

we'll put a comment in to our registration people and ask them, and we'll put it in the frequently asked questions.

MR. : We have a supplier problem. One of his customers registered him as an agent.

MS. : He registered the firm?

MR. : He decided to be the agent, and they registered him, and the supplier doesn't want it. Now the supplier has no access to the site to remove that because in order to get to the site, you have to give first your account number and your ID number, your password.

MS. : Right, your PIN number and password.

MR. : Which the supplier doesn't know. Then he has no way of getting in the system, and then he is stuck with this agent, even if he doesn't want it.

MS. : Well, he's not necessarily stuck with the agent. That's where I would bring into effect those phone numbers that I will try to get back up to and put on during the break. I would call them and explain to them what happened, and have the registration people themselves tell him what to do because he might be able to

-- because if he can verify he is the actual facility, he can probably have the other one voided.

MR. : Okay.

MS. : But I don't know the process for doing that, so I would send him to one of these numbers.

MR. : Yeah, because my understanding is when you have an agent, the agents are the one that are making that registration.

MS. : Yeah. The agent is -- the foreign facility registers and identifies the agent.

MR. : Practically, the agents are doing it.

MS. : Right.

MR. : For the supplier, that -- the agents, these agents are charging for their fees for that, and they do process.

MS. : Right. But one of the things, as we pointed out earlier, one of the things that you do when you register, if you are not the owner, owner, agent in charge -- and I mean agent in charge of the facility -- if you aren't one of those three, then you have to identify who authorized you to register. So I would assume, if that

person who didn't authorize you to register contacted us and told us what the situation was, that --

MR. : Okay, this is the question I already addressed, but all the foreign suppliers that are using agents instead of using their own importers or agents, but independent agents, these agents are creating accounts for the company, getting the ID number for the companies, and their PIN numbers, but they do not give to the suppliers their account number. Then everything is locked in. Now if there are disputes between the agents and the supplier, the supplier can do nothing at all. He cannot access the -- he has to write to FDA to --

MS. : So basically what you are saying is the agents are falsifying the registration --

MR. : No, I'm not saying that.

MS. : Well, that's -- if -- that's kind of what you're saying, because if an agent is registering a firm, and the owner, operator, or agent in charge of that firm did not authorize them to register, then they have falsified their registration.

MR. : Right; but --

MS. : If the owner, operator, agent in charge has authorized them to register for them, then we are kind of out of the picture when it comes to who gets what PIN number and what kind of communication there is. So it's one of the two.

MR. : The end result, when a supplier has appointed an agent and this agent has registered that company, the supplier cannot get out of it. He's stuck.

MS. : Well, if the agent was not authorized to register --

MR. : No, no, he has authorized him.

MS. : Okay, then, you're right.

MR. : He's stuck. He's stuck. He cannot change it.

MS. : It's between the --

MR. : He cannot change the agent, he cannot --

MS. : It's between the two of them.

MR. : Yeah, but there is no way to get out unless he writes to the FDA to explain the situation.

MS. : That would be the way to do it.

MR. : I think that's all I have.

MS. : I can't think of another way to do it.

MR. : Thank you very much.

MS. : Uh-huh.

MR. : Sorry, it's me again to bother you just real quickly. I know everybody wants a Coke, so. Jeff Damon from Del Monte again.

I was okay with the farm exception until you -- like three guys ahead of me, you started talking about some processing that took place on the farms. Let me give you an example.

We have farms in foreign countries where they harvest grapes or avocados, or whatever it may be. Those are then put into a -- there's a field packing house, and in that field packing house they put labels on, they put it into boxes, and they load it, they put it onto trucks and ship it to a cold storage facility.

As I understand it, if they are doing that packing in the field on a farm and they are not bringing in other farmers, then they would be exempt.

MS. : Right, if they are not bringing in products from other farms --

MR. : They still are exempt.

MS. : -- fine, then the cold storage facility they ship to --

MR. : Different story.

MS. : -- that's probably going to have to be registered.

MR. : But the packing house, if it's a field packing house on the farm or 100 yards away from the farm.

MS. : Yeah.

MR. : Perfect. Thank you.

MS. : And there's packing house and there's packing houses.

MR. : Excellent.

MS. : You know, they may process at a packing house and then --

MR. : Thank you very much.

MS. : Okay. Now why don't we take a break.

[Laughter.]

MS. : Come back in about -- I have 20 after. How about at 20 till?

[Recess.]

MS. : . . . (in progress) and I'm with Alboa International (phon.). We're custom brokers. And my question is with regard to the -- is there a two-hour window for air shipments for prior notice?

MS. : Four.

MR. : Four.

MS. : Four. Okay. Which means if something comes in at 12 o'clock at night, I need to have somebody there by 8 to transmit the information to you?

MS. : It needs to be confirmed by FDA for review, so by 8 o'clock you need to have transmitted it to us and have received back your prior notice confirmation number.

MS. : Okay. And then --

MS. : There is nothing in prior notice except the five-day -- no more than five days that prevents you from sending it to us as soon as you know.

MS. : But this is wheels up, air.

MS. : Yeah, I didn't say anything about wheels up for prior notice. It's four hours before arrival.

MS. : For air.

MS. : For air, so if you know five hours before arrival, there's nothing to prevent you -- is there, Mike?

MR. : Yes.

MS. : From transmitting it?

MS. : From transmitting it?

MR. : It depends on when it will be processed.

MS. : It won't be processed by you yet, but Customs -- from what I understand, Customs will -- you accept the information. You may not --

MR. : We hold it.

MS. : You don't process it.

MR. : Right.

MS. : But as far as internally between FDA and Customs, if you know about something early, you can transmit it. Customs will not process it until their timeframe so that they can tell you what their decision is.

MS. : Right.

MS. : And we'll process it as soon as we get it, so that we can do it within that two, four, or eight-hour period.

MS. : And then my other question is with regard to the truckers and their yards, which means that we would have to designate, if we need to have a merchandise stay at their yard overnight or over a weekend, and make sure this trucker has already been registered with -- correct?

MS. : Uh-huh.

MS. : And where would that information show on my prior notice?

MS. : You're talking about two different things.

MS. : Okay.

MS. : If you have given us prior notice --

MS. : Right.

MS. : -- and at least for a few months, if you try, we're going to count it, okay? That's what education means. You know, if you mess up -- if you try and you mess up, we'll work with you. So if you have

given us prior notice and it's adequate prior notice, which means you said it was carrots and it was carrots, it wasn't tuna fish, you know, that kind of stuff, then you don't need to deal with any of that.

MS. : Okay.

MS. : You aren't going to be holding something because you have given us adequate and timely prior notice. If you don't give us any prior notice, or if you give us inadequate prior notice and the food is refused, that's when you get into the whole situation of Customs saying you got to hold it at the port, or directing you to -- what's called it, constructive GO or a secure facility. And then that's what you're going to -- that's when you're going to get into it.

So right now focus on getting it right, and don't focus as much on the consequences, because that's pretty much what we are going to do for the first few months, right, Mike?

MR. : Yes.

MS. : We are really going to concentrate on getting it right, and not deal so much with the consequences. So the consequences are only going to be

needed for the people that don't get it or just won't get it. And we have always known they're out there, so --

MS. : Thank you very much.

MS. : We're counting on you.

MR. : Basically I just want to get it straight. Let's say, for example, on a weekend one of our employees comes in and finds a fax, say a registered fishery sent some fish over with no prior notification or anything. We can still issue the prior notification. We've got to wait to get a registration -- a confirmation number and then file our entry.

MS. : Uh-huh.

MR. : So the fish would just stay at the airline while we go --

MS. : Right.

MR. : That process is 24/7, like if that happened, we send the prior notification, even though it was late and we didn't make the -- will we get an answer that same day, like on a Sunday or on a Saturday or --

MS. : We're going to review prior notice 24/7. The system, of course, always reviews it 24/7.

MR. : So it will take maybe a couple
of hours or --

MS. : Yeah. We hope not to take
longer than you did.

MR. : Okay.

[Laughter.]

MR. : But once we do get it, we file
our entry?

MS. : That two -- that four hours that
we're talking about for planes is for us to be able to
review it.

MR. : Right, right, right. Okay, I
just wanted to make sure. Thank you.

MR. : Bob Damon from Bacardi in Miami.
I have four questions, maybe three questions. First is a
lot of confusion in the industry I think for the start
date. In a seminar I attended in Washington, D.C., it was
bill of lading date, not arrival date in the U.S. Because
our understanding is that the prior notice requirements
start at 12:01 on December 12th, so how can your prior
notice for arrival on December 12th, unless you guys are
considering it's going to be eight hours after the start of

the business day on the 12th? So we need some, you know, clarification on that because the FDA office in Washington is saying bill of lading date. That's number one. I don't know if you have any answer or not.

MS. : We have an answer, don't we, Mike? What I have been told is 12:01 on 12-12, which means that enforcement discretion starts then.

MR. : So you have arrival date. So when the brokers come -- but the system will not be up until they come to work that morning.

MS. : That's right.

MR. : Is that right? So the --

MS. : So you get a buy.

MR. : Yeah.

MS. : You get a buy.

MR. : You get a buy.

MS. : Yep.

MR. : So anything is going to ride, let's say, from 4 o'clock or 6 o'clock that day, prior notice should be in the system?

MS. : Yes.

MR. : On the ocean?

MS. : Right.

MR. : Or anything else?

MS. : Yes.

MR. : Or air would be four hours.

Okay.

MS. : I mean it's just the way it worked out. I mean I just found out about it a couple of days ago, when we said 12 o'clock, so my interpretation of that is you get a buy.

MR. : Second, foreign to foreign. You mentioned if it resides in the same port, there's no prior notice. However, we have a -- one of our entities in the Bacardi globalization ships from Nassau to Spain and it goes from Jacksonville, and then Jacksonville it goes to Charleston, and Charleston, it's exported out. There's no middleman per se because we are not in charge of the shipment. So who is required to do prior notice? The ocean carrier?

MS. : That's why with prior notice, whoever has the information is required to submit it. It could be them in the foreign country; it could be a carrier; it could be anyone who has that information.

MR. : But there's no definition as far
as who does it?

MS. : No definition of who.

MR. : On foreign to foreign, so we
need that.

MS. : Uh-huh.

MR. : Okay? Thank you.

And then on the prior notice, I heard that the
entry number is going to be the controlling number. So, in
order words, you go into the system, you do the entry, but
you don't submit the entry. You get the entry number, and
then based upon the entry number, then you go into the
prior notice system and do your prior notice. Is that
correct?

MR. : Well, that's the preferred
method if there's an entry involved. If not, then it would
be a bill of lading number or an in-bond number. But there
has to be some way of -- some mutually understandable
control number that we can marry the information up with.

MR. : So it can any of the three,
entry number, bill of lading number?

MR. : Yeah. If there's an entry, we prefer the entry number because that's a real clean, easy - - you know, because when we start getting the bill numbers, then you get into how people format them and then we have matches and mismatches, and it gets harder to match a bill number.

MR. : Okay.

MS. : If it's a regular ABI entry, the entry number is what we use, right. And it only gets into that question if it's in the -- what did you call, the WB?

MR. : Or WP.

MS. : WP. Where it's --

MR. : Where it's not tied to an entry, per se.

MR. : Okay. My last question is on ITs. Many of our shipments come from foreign sources, and their IT -- say they entered the port in Norfolk and they're IT to Chicago, and is the -- I think under what the -- the prior notice requires and also you, FDA, requires is that that container cannot move forward until it clears FDA. Then it can move forward. Is that correct?

MS. : Basically, yes, that's what in the statute. What we are dealing with, with enforcement discretion and just the operational part of it, is you need to give us prior notice before the container gets to the U.S. That would be Norfolk.

MR. : That would be the port of Norfolk, okay.

MS. : Right.

MR. : Right.

MS. : If you don't quite get it right, you know, if you are refused or, you know, the information isn't -- it's not an adequate prior notice, like there's something missing in it, then you will be allowed to move to Chicago, and then finish it up. But we need to have something --

MR. : Before it moves.

MS. : -- before it arrives.

MR. : Okay, so the --

MS. : And for the most part, I think you're going to get it right because it's primarily the information you give us now eventually.

MR. : But the broker in Chicago is the one that does the entry into the system. So I understand this FDA system that's been developed, which the software is still under review, is going to be -- entry is in Chicago, so the FDA in Norfolk will see it. My concern is that no, he won't see it.

MS. : No.

MR. : So who's going to give the clearance in Chicago?

MS. : These guys in the central location are the ones that are going to review the prior notice. Okay.

MR. : Okay.

MS. : So before it gets to Norfolk, we should get the prior notice information. At that point we'll make a decision on whether we need to look at it in Norfolk.

MR. : And who is going to tell the ocean carrier that it's a go or no-go, because they are usually the ones that cut ITs.

MS. : Customs. We are going to make our decision communicated to Customs. Customs then, based on that decision, lets the container move or not move.

MR. : So Customs in Chicago will notify Customs in Norfolk?

MS. : No.

MR. : No, Customs in Norfolk would know.

MS. : It's going to be a systematic thing, an electronic thing.

MR. : Visibility to all?

MS. : Right.

MR. : Uh-huh.

MS. : To -- well, us.

MR. : Okay. Thank you.

MR. : Hi. Good afternoon now, I guess. My name is Ralph from Imperial Freight, and I thank you for the trade outreach. I have a couple of questions.

One thing, you said that if one of the results of prior notice is that merchandise comes in and there's no prior notice, then it has to be exported, provided it doesn't leave the entry port. We have a container load at

the port of Miami that leaves, no problem. What happens in the case of consolidated merchandise that comes in, it's moved on a 6043 to a CFS, and then is going to be exported right away, it's never entering the commerce. Is prior notice required in that instance?

MR. : No, because as long as the CFS is within the port limits and is being immediately exported, no, prior notice would not be required.

MR. : Okay.

MS. : If it moves from port to port, then it really falls within the TNEs.

MR. : Which would be an error, a 5206 or 5201, now that that's considered a TNE?

MR. : Uh-huh.

MR. : Okay. Number two, if there is going to be an entry filed, obviously by a broker, via ABI, will that still permit, let's say, a shipper to file prior notice on their system or on the FDA system? For example, I'm the broker here. I'm going to clear a food substance, and my shipper says, oh, by the way, don't do prior notice because I took care of that on the FDA system. Is that going to be permitted, that they themselves --

MS. : It's permitted. It's really not preferred because the primary reason we got so many comments about the way to give us prior notice is people said they didn't want to duplicate their effort. They didn't want to have to give us prior notice through a prior notice system and then give entry to Customs and FDA.

MR. : Okay, great.

MS. : Through another system. So what I would recommend in that case is to get the word out to your shippers, your exporters, whatever, is if it can be handled through ABI, it makes more sense because you only have to do it once. Even with the new transaction, it's -- you don't really have to repeat stuff that you have already put in.

MR. : Now in the event -- because there are some shippers that are going to want to have control over that process. In the event -- and even though it's not the preference and we're going to dictate it to them, in the event, you know, they don't know FDA codes and they don't know -- you know, their tariff schedule is always wrong. We have brokers deal with that every day.

MS. : Which means they aren't going to want control for long.

MR. : Exactly. But if their information is incorrect and they submitted their prior notice, how are we on our end going to have that -- are going to have capability to fix their wrong prior notice? Do we have to shoot it back to them, fix your mistake before I can do my entry, or are we going to have a mechanism to deal with this?

MS. : Well, what's going to happen is you're going to have to cancel it and resubmit it. So at that time you may convince them that you'd do a better job resubmitting it.

[Laughter.]

MS. : And then they wouldn't do it again. Because you're exactly right, that the brokers have been trained in, are familiar with the codes. I can't imagine, other than like you said, somebody wants control over it, but they don't have control over -- I'm sorry, they don't have control over the entry. Why would they want control over that? So --

MR. : Right.

MS. : -- that's kind of multiplier effect you can take as a trainer.

MR. : Okay. My final point, being that I do deal quite a bit with perishable cargo, I'm sure every broker here can talk about their frustrations with the SET team examinations, where Customs has embarked on this wonderful product to protect our borders, but it's resulting in infinite amount of storage and headaches and problems for the importing community.

One of the results of the admissibility could be that FDA decides they're going to inspect the cargo. Are they going to -- upon its arrival. Is there going to be any sort of time mechanism or can my \$500,000 container full of lobster tails sit because FDA hasn't had a chance to go out and inspect it?

MS. : This isn't like admissibility decisions where we tell you FDA wants to inspect and you call and tell us the location. This is inspection at the border, and it will be done by either FDA or by Customs.

MR. : Right.

MS. : That's why it's extremely important, even though the statute said you have to give us

anticipated port of arrival, that's why it's really important that you tell us to the best of your ability where it's coming in, and when it's coming in, because what we want to do is to inspect it before anyone else gets control of it, but we don't want to hold it up.

MR. : Correct.

MS. : So these review guys that are centrally located and will be the most hated people in the FDA field -- not by you guys, but by the FDA field, because if there's something that needs -- you know, you say it's coming in at 2 a.m. on a flight, they're going to call somebody and say you need to meet that flight at 2 a.m. and this is what you need to look at. And that's going to be the same thing with our communication with Customs.

So as far as timeframes, our intention is to look at it when it gets here, which is why it's really nice if we know when it's going to get here, and that there aren't many changes, although we had to put that into the rule because that's the way the act says, we can't limit where something comes in.

MR. : I agree on the intention. You know, and I'm sure it wasn't the intention of Customs to

have the SET team be so -- my concern to that intention is if FDA -- you know, you only have so many inspectors, and the central field office says, hey, you got to inspect all this cargo and it's only five of us doing inspections.

What -- I mean what mechanism is there --

MS. : That isn't the way it's going to be done.

MR. : Okay.

MS. : This is really a case-by-case thing.

MR. : Okay.

MS. : So if those guys that are centrally located all of a sudden call Miami and say you have to look at everything that comes in, that isn't going to happen. It's a case by case. They're going to call Miami field office and say you have to meet Continental Airlines flight such-and-such at this time, and look for this product which is covered by airway bill. It's very, very specific.

MR. : Okay. Thank you.

MS. : And I'm assuming Customs will handle it the same way, right, Mike?

MR. : Yes.

MS. : And that's why they're the most hated people in FDA.

[Laughter.]

MR. : Thank you.

MS. : My question is, prior notice supposed to be given four hours before the flight arrive; is that correct?

MS. : For air and --

MS. : Yes, for air.

MS. : -- rail, it's four hours, yeah.

MS. : Okay. Most of the time when you call to an airline, they don't even know what is coming on the airplanes. I mean you call an hour before the plane arrives and they tell you that airway bill has no record. On top is the broker's responsibility to give prior notice. I don't know. I mean how are we going to handle this?

MS. : Well, it's not necessarily the broker's responsibility to give prior notice. It's the person who has the required information. So if somebody asks you to give prior notice and they can't give you the required information, then we do have a problem.

MS. : It basically has to be given by the broker since the broker is the one who knows the FDA codes. No shipper, no importer, nobody else knows the FDA codes except the broker.

MS. : Well, the brokers use a product code build routine, unless you have memorized certain codes.

MS. : Yeah.

MS. : Well, that routine is going to be available -- it is available now to anybody that wants it.

MS. : No, but that's not the issue. The issue is --

MS. : No, you're just -- for practicality purposes, yes. So for practicality purposes we need to work with people who are shipping by air and tell them there's a four-hour prior notice period, so you need to get us that information.

MS. : Well, are you going to enforce that to the airlines for them to give the correct information? Because usually there's no information at the airlines when you call. I mean they don't even know when

the flight is arriving, they don't know what is coming on the flight.

MS. : I think they're going to want to know that for Customs' proposed advance manifest.

MR. : Right. Under the Trade Act, eventually they are going to have to -- they are going to have to do an advanced electronic filing with Customs, and that's going to be wheels up, or four hours prior to arriving with their manifest data.

But on the practical side, you know, I understand your point, because if you call the airline, the airline says, well, we don't know what's on the flight until the flight shows up, the practical operational side of that is the second you know it's here and you've got to file your prior notice, that stuff is going to sit in their warehouse for a minimum of four hours.

[Simultaneous discussion.]

MR. : Eventually they are going to --

MS. : Excuse me, how about in a two-hour flight?

MR. : -- if it backs up enough, they are going to run out of space.

MS. : How about in a two-hours flight?
How about in a two-hours flight that, you know, we don't
even have four hours to give advice of what is coming? I
mean it's very difficult.

MS. : Right. My prediction, having
looked at the proposed rule on advance manifests, is it's
going to work out because the consequences on advance
manifests are much more severe than they are for prior
notice. Is that not right?

MR. : That's true.

MS. : Right now they're --

MS. : But the proposed consequences is
that they can't land.

MS. : Right now they are --

MS. : No, they're not in effect and
prior notice isn't in effect either.

MR. : Right.

MS. : So we have this period of time
and we have been meeting with them.

MR. : Right. Now, remember, earlier
in Mary's presentation, in March of 2004, both agencies are
to present a plan on how we're going to integrate these

processes, and that's one of the things we're going to be working on.

MS. : Okay. So --

MS. : But it will make a difference if people try, and I'm talking about the airlines, and we have worked with the airlines.

MS. : There's no other choice. I mean we have to try.

MS. : Yeah.

MS. : There is no other choice.

MS. : I just think with both of these rules coming in fairly close proximity that the information that you get on air shipments is going to be much more exact and timely. Do you think?

MR. : Uh-huh. Yeah.

MS. : Okay. And another thing is if I have to IT merchandise from Port Everglades to Port of Miami because of problems, that has to be cleared in Miami. Do I have to give prior notice for that IT, I mean before the ship arrive, and then give prior notice before I do the entry? I don't understand.

MS. : Prior notice before the food arrives in the United States. So if it's going to arrive in Port Everglades, it's prior notice before it arrives in Port Everglades. So once you have done prior notice before the food arrives in the U.S., you are done with prior notice, as long as it was accurate.

MS. : Okay, so that prior notice before the food arrive to get the IT cut or to have the IT, to have the merchandised IT'd to Miami, is the same number that I'm going to be used to do my entry later on?

MS. : You mean the prior notice confirmation number?

MS. : Yes.

MS. : Yeah. Uh-huh.

MR. : Uh-huh. Yeah, you only have to do it once.

MS. : And another thing, once the merchandise arrive here, we didn't know anything about it, then the merchandise is going to stay at the airport until we do prior notice and you have four hours to review that prior notice and give an answer back?

MS. : Right.

MR. : Uh-huh.

MS. : So that means that the merchandise might be at the airport for five hours, six hours, sitting there until we get a prior notice number?

MS. : Right. I do believe the congressional intent behind the Bioterrorism Act and prior notice and also behind the Trade Act is that we don't get surprise shipments into the U.S. That people know something is coming, they know what it is, they know who made it. That's very obvious from the prior notice provisions in the Bioterrorism Act, is that you know what it is, you know who made it, and you know about it before it came.

MS. : So basically the prior notice is before the entry is done, not before the merchandise arrive.

MS. : Right.

MR. : Right.

MS. : No, it's before the merchandise arrives.

MS. : But the merchandise already arrive.

MS. : Well, then you have failed prior notice, so you aren't giving us prior notice, it's not going to move until you have fulfilled those requirements.

MS. : Okay. So my option is once the merchandise arrive and I fail to give prior notice for whatever reason, my option is then to give prior notice, wait, and then get the entry release?

MR. : Uh-huh.

MS. : Yeah. Next.

MR. : Thank you.

MS. : Well, it's prior notice, it's an odd terminology, but what you have done is you failed prior notice, so you are overcoming that refusal by satisfying the requirements.

MS. : I just have a very simple question. When is Customs going to give the exact specs to be able to do the software for the prior notice, so that the great IT department that we have gets their act together and does it for the system for the ABI? When is that going to be finally -- we only have like three weeks.

MR. : Yeah. I can't give you a definite date.

MS. : You gave us a date. Why can't we give you a date?

[Laughter.]

MS. : It's a simple question.

MR. : I know. It's a work in progress.

MS. : I mean for us, we have to know what we're going to do.

MR. : Right.

MS. : By the time the software company gets back to us, we're going to be the prior notice on the Web site, and it may take about another week or two before we get the software.

MR. : We're aware of it.

MS. : There's probably another option is that we would give us prior notice that wasn't quite complete through ABI.

MR. : If they can.

MS. : If they can. But -- yeah, that's true, depending on the timeframe.

MS. : But if you have no date --

MS. : But if it's something that's coming by ship, so that you have a longer timeframe, you could probably give us everything that you could through ABI now if the software isn't done, and it would be giving us prior notice, but it may not be quite accurate. But even now, you can give us -- you know, you can give us a manufacturer, you can give us a country of origin. You give us quantity, you give us the product code. There's not much in there that you don't give us now except for perhaps the manufacturer's registration number, and you might even be able to figure out how to get that.

MS. : No ballpark figure?

MR. : No. Every time I ask our IT people, they just tell me soon.

MS. : That's what my IT people tell me, too.

MR. : Hi, my name is Luis Teijeiro with Webb Foods (phon.). I'm off the hook because I'm not a broker, but I do have the same concerns, because at the end of the day I can't bring product in. And one of the things at least I understand now that if for prior notice -- see, because I'm right with them. I head our IT

department, so I can tell you right now it's going to be, with all due respect, it's going to be nasty, because in three weeks to deal with lines of code and tens of thousands, to add another transaction, which means there will be no or very little beta testing, and you're basically going to go online and pray that the fuses don't burn out. Okay?

So my only question, and I think you've answered some, but I still have a few more is, so obviously in the case of where the ABI -- not because you're not functioning, but because the software on the broker's side isn't working, they can then go ahead and use your Web site and then manually, I guess, enter the -- either do an entry -- I guess my question is can they do an entry prior to a prior notice, so only they can reference the order entry -- I mean the entry number into the prior notice?

MR. : Or use the bill.

MR. : Well, right, that would be my second one, but obviously I think the order entry makes more sense or will be a better process for you.

MS. : If there's something coming by ship, my preference would be you just do the entry and

we'll consider that as prior notice if the software isn't complete.

MR. : Well, but it's not. See, that's my --

MR. : It gets into our enforcement discretion policy.

MR. : You have to have the prior notice done.

MR. : Right.

MR. : I'm just saying, if you understand where I'm coming from, let's just say the software side on the ABI isn't working, because the reality is I don't think there's going to be many people out there, and you may have some good companies out doing it in two weeks, and some of these brokers happen to pick the right company, and there may be other brokers picked another company and it may take them five months. So I'm just saying at some point there's got to be the ability of doing that. I'm asking the question, because I'm sure brokers are going to want the same answer is, okay, my software ain't communicating through ABI and prior notice, what do I do? Do I send the order? Do I do an ABI order entry and

then do a prior notice once I know what my entry number is?
Is that what would be the process then? Could you do that?

MR. : Yeah.

MR. : Okay. So number two, now I'm going to ask as an importer, now I have an issue. I understand that because the law says that you can't give information out, somebody can send me a registration number. I'm clueless whether it's right, wrong, or indifferent, okay? Yet I'm responsible and I am going to be, I guess, financially burdened to some extent, depending on how it goes. So I'm asking -- and it's really more of a comment -- is it possible to give a simple information that somebody could go onto a Web site, put a registration number now, and just say registered, yes or no? Nothing else, I don't want to know who that person is --

MS. : We have been asked that, and we -- I have said it to the registration people, lawyers, to take into consideration based on the prohibition in the statute that we disclose, you know, is there something people can do. Our validation, our initial validation, when you give us a name of a firm and a registration number, is the initial validation that we do may be able to

tell us that that firm does not have that registration number, at which point we would either reject it or, in the educational period, we would tell you uh-uh, this number does not go with this firm.

So there will be some educational point. I think it's a great idea to have some sort of interactive validation that you could do yourselves, but like I said, we've more or less turned that over to lawyers to see if they can squeak that around the statutory limitations.

MR. : Thank you very much.

MS. : Uh-huh.

MR. : I don't have any question. I just want to bring you this. This is what has been sent out in France to all suppliers.

MS. : Yes. This is -- what he is showing us I think the worst thing I've ever done. I'm -- what we did is in the proposed rule, we decided that people would like to visually see, to see, to visualize what information is required in prior notice. And because, even though it's electronic information, we are still required by the Office of Management and Budget to go through the Paperwork Reduction Act hoops and give it a number.

So in the proposed rule we had a proposed form. We don't have a form for prior notice. You will never see a form for prior notice. It is an electronic either through ABI data elements or interactive, yes, believe me.

MR. : What about when the systems do down?

MS. : When the systems go down, we are going to -- we are posting a list of the information required, and that's why I keep referring you back to the table 1-A. That's a list of the information required. By golly, you send that to us any way you want, because the systems are never going down.

[Laughter.]

MS. : They may never be coming up, but by god, they're never going down.

[Laughter.]

MR. : Once they're up, they're up.

MS. : We are really pretty much focused on, you know, if the systems are down, it will be for a short period of time and we will just ignore that time period.

But if we do have to go to paper, I didn't want to be so restrictive that it would be a form, so if you want to take that information in table 1-A and come up with your own format. But this form was only in the proposed rule. It's not in the final rule. It's not a form, and I wish we had never done it. But we had to.

MR. : [Inaudible, off microphone.]

MS. : Well, I guess so. Well, they should panic, because it's not even the right information. Because it was the proposed rule, we have changed the information considerably, so you know, it's not that bad. It's too inclusive. If they get all this information, they're going to be fine. Send them -- what I would recommend is instead of asking your suppliers to read 500 pages or something like that, take that table 1-A, and I'll see about when I get back, see if we can segregate it out of the rule and just post it individually on the Web site so you could pull it down real easily.

MR. : [Off microphone.]

MS. : I know, I know, I know. But when you are dealing with your suppliers and if you want them to give you the information that you need to submit a

prior notice, I'd do it with table 1-A, because that summarizes everything. I would tell them to destroy that, yes. That would be my preference.

MR. : It does have an endorsement on that form.

MS. : Well, it was on the proposed rule. It's legal for the proposed rule, but it's not in effect.

MR. : Hello, my name is Luis with Absolute Freight. My question to you is, is the system going to be set up so that you can go from prior notification straight to an entry, Customs entry?

MR. : Which system?

MR. : The prior notice and notification, the prior notification.

MR. : On the FDA Web site?

MR. : If you do a prior notification, will you be able to do an ABI entry at the same time?

MR. : No.

MS. : Well, if you're doing it in the FDA Web site, no.

MR. : Okay.

MS. : That's why we joined together with Customs, to make it so that you can give us prior notice, your ABI, so that you don't have to submit twice.

MR. : Okay.

MS. : And so that, if possible, that information fulfills the entry process.

MR. : So our software company vendors should be able to set it up so that you can go ahead from PN to the ABI entry?

MR. : Right, the same way you do your 701 data right now.

MS. : It should be pretty much invisible, shouldn't it? It will be sort of one and the same.

MR. : Okay. What happens like an ocean shipment, sometimes we get an arrival notice from the steamship lines, and the shipment is going to arrive on a certain date, but sometimes they get delayed, sometimes two, three days, even weeks, or they change vessel and they don't arrive for another week or two.

MS. : Changing vessel is a problem. Changing vessels means that you've changed a carrier, you

would have to cancel the prior notice and resubmit with the appropriate information because it's a different carrier.

MR. : But the carrier will be the same, it's just a vessel name.

MS. : Well, it's going to be a different carrier just because of -- if it's the exact same carrier --

MR. : It's going to be the same.

[Simultaneous discussion, off microphone.]

MS. : It could be. It could be.

MR. : Yeah, we have like Mediterranean shipping --

MS. : Well, any time you don't have to cancel and resubmit, I think that's a good thing. But if it's a water -- you know, water vessel and it's going to be late, we have that limitation of the five days. What does Customs do now on something like that, if you -- if they plan -- if the expected arrival date is March 10th, and they have submitted on March 5th -- you have probably already processed it.

MR. : Uh-huh.

MS. : So, you know, what can I say.
Don't worry.

MR. : Don't worry, you guys will
accept. Okay.

MS. : Yeah. The only times that we
are going to really look at that, where it's going to like
a ring a, you know, a buzzer is if somebody says that they
are bringing it in on a carrier through Mexico and it
arrives from Canada, we're going to go what happened here?
Or if you say it's going to come in on a ship that usually
comes from the Mediterranean and it comes in through the,
you know, shipped from Mexico, then we're going to --
that's going to be ringing bells.

But I think for the actual satisfaction of prior
notice, you just do what -- you do your best.

MR. : You always referred to the prior
notice notification number, and that tells you the
information that you need. It doesn't matter if it was
delayed or not; right? Is that correct?

MS. : Yeah. When we're talking about
ships, you know, you're not just waiting for the ship for

that one thing on prior notice. Everybody is probably looking for the ship, right?

MR. : Right.

MS. : Because there's other merchandise on it and there's other reasons that it's supposed to dock, so I think that that's just something we've always dealt with. Right.

MR. : Also the transshipping, I'm still confused because on the transshipments, the steamship line normally issues the IT inbound from the port, the first port of arrival, and then they move it to the final destination. It's their responsibility based on the bill of lading, because the bill of lading says final destination Miami. So the broker is not involved at all in coding an inbound.

So if we do a prior notification for it to arrive in Savannah, for example, I mean we have to do it, we have to know exactly when it's going to be arriving, and do it, and then supply the notification number to the steamship line so they can do their inbound? How are they going to be able to code their inbound if I do the prior notification as a broker?

MS. : Especially if you do it as an
ABI entry.

MR. : Right. And if I already submit
an ABI entry.

MS. : Mike, haven't you worked --
isn't there something in the advance manifest about
different parties supplying different information?

MR. : Yeah, because I couldn't do an
entry at the same time because I still don't have an
inbound number from the steamship line. So I would have to
do the prior notification, and then how is the steamship
line going to --

MR. : That's part of the dilemma of
inbound movements, is the information for prior notice
doesn't necessarily have to be supplied by the broker. It
can be supplied by a party that has enough knowledge to
fulfill the requirement.

Now this is going to be a change in practice for
carriers because they are going to have to be looking for
that prior notification number from someone before they can
move it inbound.

MR. : Okay. Well, they are not going to be able to do the prior notification. They are not going to have the information the broker will, so I guess the broker will have to submit the prior notification and supply that information to the steamship line, the number.

MR. : At least give the prior notification number to the --

MR. : So that they can proceed with the in-bonds.

MR. : Right. Coordination.

MS. : And then cancel the prior notification and include the IT number with our entry?

MR. : No. No, because you are going to be able to use the same prior notification number on your entry.

MR. : Right. We just can't do the entry at the same time.

MS. : So what are you going to do, by the entry number?

MR. : Uh-huh.

MR. : Yeah, you won't be able to do the entry at the same time, I guess. You have to wait until the inbound is issued.

My other question is there is some instances when importers bring products, food products like candy, cereals, that are manufactured in the United States, but you know, they were a few months or maybe a year ago were shipped to another country. That particular distributor sold it to another distributor in the United States, so they are bringing that product back into the United States. Who is responsible? What registration do I need?

MS. : You need the registration of the manufacturer.

MR. : I would need the registration of the manufacturer?

MS. : Manufactured in the U.S. and went traipsing around the world, and it's coming back into the U.S. When you file prior -- your prior -- submit your prior notice and file entry, if you do have to file entry, then you have to -- it's American goods returned, it's covered by prior notice, you have to give us the

manufacturer's name, city, country, and registration number.

MR. : Well, you know, normally those transactions have no link with the U.S.A. manufacturer.

MS. : They do now.

MR. : No, I'm saying --

MS. : I mean they do now. The statute requires the manufacturer --

MR. : I'm talking about there is no business relation between the importer and the manufacturer and the distributor overseas, so how are we going to get this information if it is not posted in the Web site for the FDA?

MS. : You'll have to call the manufacturer and ask them their registration number because --

MR. : They will never agree to that.

MR. : Well, what happens is the merchandise is going to sit.

MS. : Or the distributor may have it, the foreign distributor may have it, but the way the

statute was written is to include -- that's why I said it's a challenge.

MR. : You have to coordinate.

MS. : Because the manufacturer will -- you know, it's no longer the invoicing party or whatever, it's the actual manufacturer. The congressional intent to me was very clear, that it expected some form of relationship between a manufacturer and an importer.

MR. : Right, but --

MS. : Even if that manufacturer is here in the U.S.

MR. : In these cases, in these cases -

MS. : Well, there's -- well, you didn't even get in line and you asked that question.

[Laughter.]

MS. : An out-of-business manufacturer, right. We are trying to -- I think by December 12th, we won't have come up with an easy way on that because if you do bring something in and the manufacturer is out of business, you won't be able to give us a registration number. So what's going to happen is you would fail prior

notice because it would be inadequate, and then in the review process, you would have to give us some form, whatever you can come up, of documentation that the firm is no longer in business.

So we hope that in the next iteration of this process, we will be able to come up with a little bit more affirmative way of saying right at the outset, this is old product, the firm is no -- you know, the manufacturer is no longer in business.

MR. : The way the system is going to be set up with the FDA system, how many registration numbers is the system going to allow to enter? In other words --

MS. : Per prior notice, which is per article of food, there would be two.

MR. : Okay.

MS. : The manufacturer --

MR. : And the distributor.

MS. : That means the facility that manufactured that food.

MR. : Right.

MS. : So if there are four facilities, you've got four articles of food and four prior notices. And the shipper, if the shipper is required to be registered.

So it's those two per article of food. Now you may find that what used to be an article of food is now more than one article of food because there are different facilities that produced it.

MR. : So what happens to all of these U.S. goods that are going to come in and the manufacturer is not going to be willing to provide you with the information, their registration number?

MS. : Well, Mike pointed out that it will be held at the port --

MR. : There's going to be a lot of people in the trading business that are going to go out of business.

MR. : You'll put a lot of people out of business.

MS. : No, let me go back to the congressional intent.

MR. : I'm sure this is not the intent of the FDA.

MS. : The congressional intent was clear, that they asked for the actual manufacturer, the identity of the manufacturer.

MR. : Right.

MS. : Of an article of food that's imported or offered for import into the U.S. It didn't say a foreign food, it say an article of food.

MR. : Yeah, because -- I think it's because the idea is that when you are importing, you are importing a foreign good, you are not importing a U.S. good.

MS. : Well, to be fair, this is the same people in Congress that passed the pharmaceutical -- what is it, prescription drug marketing act, who are well aware of U.S. goods returned.

MR. : Right. But that's for medical supplies, that's not for food.

MR. : Part of the problem is it's the limitation of the law, so in order to rectify that would require a change to law, and it's beyond our scope.

MR. : The law required the manufacturer be identified. You're requiring a specific number be on there to do that. A lot of these guys can identify the manufacturer or the facility. What they can't give you is a number that you have that you won't give us -

MR. : Won't give us because you won't publish it.

MR. : You have the information, you have the name of the facility, you have the manufacturer --

MS. : If the firm is required to be registered. Just because a firm is in the U.S. doesn't mean it's required to be registered.

MR. : If it's producing, it's required.

MS. : If it's producing product only for export, no, it isn't, because the food isn't for consumption in the U.S. So if you have a firm -- and it's not necessarily that there are lots of these, but if you have a firm, a facility, and the only purpose of that facility is to manufacture foods for export, they do not have to have a registration number.

MR. : Yeah, but that's not the case most of the time. These are companies that are selling their goods, you know, in the stores in the USA, and that same product they sell it to other countries, and then it's just traded in --

MS. : Right. It's not that I don't understand this, and it's not that Congress didn't understand it. However, what we are taking back for comment is what's the ability to confirm -- you know, confirm a registration number or just give us the address and not the registration number, and let us look it up itself. And that was in the comments.

MR. : What everyone is concerned about is if we are bringing something in, it's made for Hershey Foods in Hershey, Pennsylvania, and we put Hershey Food down, but they won't give us the number, will you accept that and say okay, Hershey Foods in Hershey, Pennsylvania is No. 12345? I can't tell you, but we'll put it down.

MR. : Would you be able to identify them by their name?

MS. : Just a second, just a second.

MR. : I'm sorry.

MS. : I don't want you to get confused with firm and facility.

MR. : Facility. We're talking facility of Hershey, Pennsylvania.

MS. : They may have 17 facilities in Hershey, Pennsylvania, at different locations. Those would all have different manufacturing registration number. Therefore, you have not identified the actual manufacturer.

MR. : What if we give you the address?

MS. : I know -- we understand what the frustration is. This came to us in comments. We addressed it in the preamble. I think it's a fair thing to put in for comments to the interim final rule, with a full explanation of what the concern is.

You know who the manufacturer is by what it says on the label.

MR. : We can give you an address, too, because when we put in the manufacturer's ID code, that code tells you where the manufacturer is located, you know.

MS. : You mean the MID that you give to Customs?

MR. : The MID, right.

MS. : It might.

MR. : It might, if the shipper --

MS. : But then again, it might not.

MR. : Well, normally --

MS. : You could have a company with 17
different MIDs and all be at the same location.

MR. : But there might be one company
with one location and we don't have the option here --

MS. : There might be, right.

MR. : See, we're basically taking
these rules and saying okay, there might be 17, so even
though there's only one, we're not going to allow it. So
you're taking the position that even though the information
is adequate and complies with the statute, the regulations
as you are enacting them are not going to allow these
people to --

MR. : It's not illegal to import U.S.
goods back into the country.

MS. : Uh-uh.

MR. : So why -- but these rules is
going to put a hold on these tradings.

MS. : Let me just go through this again. I understand the question, I know what our lawyers have told us in the past on the congressional intent and how we responded. It's not like we didn't get the comment the first time around. But I still think it's fair to say okay, now that you have got your final rule, by the way this final rule is written, this is what it disallows, and this is how we think that can be overcome.

I mean a comment doesn't help us if it just says this is no fair. Because, you know, we heard that. What you need to do is say this is what you could do to overcome this so it would work, and it still has to work within the confines of the statute. And you may have lawyers that interpret the statute differently than we did. That's fine. That's what they should do. And tell us that. But you have to keep those things in mind.

MR. : How do you suggest that we do that? Go to the Web site?

MS. : No. I suggest you do it through e.comments. You need to comment to the docket.

MR. : Dockets management.

MS. : Because this isn't a question about -- this is a comment of a change that you want, right?

MR. : I don't have a problem with everything you said, and you're trying to live up to the statute the way you interpret it. The only question is for everybody, we can put the comments in now, but this is going to be enacted in three weeks. We're not going to get much change in three weeks from these comments.

MR. : That's right.

MR. : What happens in three weeks when we don't have that answer back and we're faced with the reality of not being able to put the manufacturer's code in?

MR. : What can the FDA do?

MS. : The answer back has to be in rewriting the rule or confirming that the rule is the way we want it now.

[Simultaneous discussion off microphone.]

MS. : Right. So we've told you what happens in three weeks. But we have also told you that there is enforcement discretion for a period of time, right, and that does -- one thing that enforcement

discretion period gives you is also a way of proposing in comments an actual change that's workable within the auspices now of not just one rule, but both rules.

MR. : But you're going to reject it if it doesn't have the code in it.

MS. : Right.

MR. : We're never going to get the entry through if you don't have the 11-digit code, and if it's not in there because you don't have it, then we can't even file a prior notice properly. So you're not even going to respond to it.

MR. : And I'm sure there's lots of cargo under those conditions coming in right now on the way into the United States. So that's going to create chaos. Even if you put the supplier's facility registration -- let's say it's coming from Panama, for example, if you register their facility, if you use their registration, you still couldn't get it through without the manufacturer's identification, registration number?

MS. : They haven't manufactured the product, have they?

MR. : No.

MS. : No, so the one thing we do want to make clear is that we don't want you to give us somebody as a manufacturer who isn't the manufacturer.

MR. : No, no, that's not what I'm suggesting. I'm suggesting -- you're saying that we need to declare the registration of the manufacturer, and the facility that's shipping it, because they're holding those goods over there. They've probably held them for months. Now they shipping it, so don't they have to be registered, too?

MS. : The shipper, yes.

MR. : Yes. So even if we use their registration, which we will know, we can get it through without a manufacturer's registration; is that what you're saying?

MS. : No. You have to give us both the manufacturer and the shipper. The actual manufacturer and the registration number, the actual shipper and their registration number if they have held the food.

What we have tried to explain through the process of enforcement discretion is that there will be a period of time where we may not refuse because of that. Okay? And

that is also going to coincide with the time you get to make comments.

I'm just -- we can't comment on comments, for one thing. You know, you give us your comments and we deal with them. But you should go back and not only look at the preamble to the proposed rule, but also look at the comments that came in on the proposed rule, and see how we dealt with those comments about disclosure of the registration number. Okay?

MR. : Okay. My last question is that is there any training being offered by the FDA right now and how do we access to that?

MS. : Training?

MR. : Training about these new regulations.

MS. : This would be at -- you're at it.

MR. : This would be it?

[Laughter.]

MS. : Yes.

MR. : You're certified.

[Laughter.]

MS. : I don't know if there will be additional -- I mean we're doing a series and we're finished tomorrow with a series of regional outreach about prior notice and registration. I don't know about Customs and FDA about some of the operational issues or the system issues.

MR. : There will be help desks.

MS. : And then we'll -- there will be help desks. I think we are doing like some trade associations, and we plan -- you know, part of the educational period that we're doing in that four months is we plan additional outreach. I just don't know if it will be a series of meetings like that, or the district personnel will take over and do it. If they come to these, they won't, right? You're going to say no, I'm not doing this.

MR. : Even through the Internet, sending e-mails about questions?

MS. : Right. That last e-mail address that I put up, that's where you can send questions, not comments about the rule, but questions for clarification. And that's going to be up for quite a while.

And now the guy behind you is going to knock you over. Well, no, he isn't.

MR. : Hi. My name is Ray and I work for a software provider, Editrade (phon.). I got just two pretty simple quick questions.

First one might be directed maybe better to an ABI rep. Just let me know. The case that they have mentioned a lot here is if it comes in to say Miami and gets in-bonded to Atlanta, Chicago, whatever, in Miami when you submit the prior notice, you would submit all the FDA information, the FDA product codes, et cetera. Will it be possible through ABI for say the broker in Atlanta to not have to do the FDA product codes, just merely put in the FDA confirmation number and that's it? Because FDA wouldn't really care anymore once it's cleared in Miami, right?

MS. : You're talking about after we've received prior notice?

MR. : Yeah, because part of the prior notice would be the normal stuff that you'd get, anyway. So basically through ABI the person in Atlanta just would

put in the confirmation number and that's it, wouldn't have to put in their product codes and --

MR. : Right. That way the system knows that it isn't looking for another prior notice.

MR. : Okay. Okay. Good.

And then one last question. Are there any exceptions to things that are required by FDA that you wouldn't need prior notice, you might need to submit to FDA, but you wouldn't need prior notice, or is everything that requires FDA --

MS. : Food, foods for humans and other animals, except for dinner -- you know, food contact substances like packaging and dinnerware and pesticides.

MR. : Oh, those would be the ones that --

MS. : Those are the exceptions to foods for humans or other animals, and then just things that are included in the -- that are excluded because they don't fall within the scope of prior notice, or the fruit, you know, Antilles fruitcake, if you carry something on. But there are many, many things that are covered by prior notice that you may not traditionally think of.

MR. : Okay. But something like silverware, you would still need to submit FDA information?

MS. : Very good, yes.

MR. : But not prior notice?

MS. : It's still a food under the Food, Drug & Cosmetic Act, it's still subject to admissibility decisions. But you don't have to tell us about it ahead of time.

MR. : Okay. Okay.

MR. : You don't have to register; correct?

MS. : Right. You don't have to -- if you are --

MR. : If you stored silverware, you would not have to register?

MS. : No.

MR. : Because it doesn't come under the act?

MS. : Right.

MR. : That was it. Thanks.

MR. : It's me again.

MS. : Oh, you.

[Laughter.]

MR. : One, I think you guys are doing a great job. And I want to say thank you.

Two, is it possible to get a copy of your executive summary, because it would make my job --

MS. : Slides?

MR. : Yes, slides. Showing it to my boss, it would save me having to rewrite all this, and I could just use my notes.

MS. : Oh, no, you don't want to do that. Go into the Web site, cfsan.fda.gov.

MR. : Okay.

MS. : Go into Bioterrorism Act. Go look at the October 28th satellite downlink and it has two subsections. One is registration --

MR. : I went to that and I have that.

MS. : Then do you have the slides?

MR. : I have the slides because I went to the --

MS. : Right. Those are the only slides that we can hand out.

MR. : Okay.

MS. : Lawyers like their own slides.

MR. : I understand.

You were going to talk about samples. Is there anything special on samples?

MS. : I was hoping no one would ask after we went the U.S. goods returned.

MR. : No. Well, I just want to ask about samples.

MS. : Yeah, they're covered.

MR. : They're covered?

MS. : Yeah. Samples -- there are samples that are covered, are covered by prior notice. Samples of foods for humans or other animals. But the preamble discusses that there are samples and there are samples. So if it's a sample that is meant for analytical testing and in its form it could not be eaten, then, you know, it would be like a sliver of celery or something that was coming in for a pesticide analysis, things like that, then, no, it's outside of the scope. But -- because it's not a food.

But if it's a sample like sales samples or any of that kind of stuff, it is covered by prior notice.

MR. : Now could you just give that Web site again?

MS. : Yeah, it's cfsan -- that's Center for Food Safety and Applied Nutrition, .fda.gov.

MR. : And then where do you go from there?

MS. : You look for Bioterrorism Act. It should be like in the center column. And then when you are in Bioterrorism Act, it's pretty self-explanatory. You look for the satellite downlink of October 28th, and they'll have the slides and I don't know if it's up yet, but we also plan to have a video stream. So if you miss the downlink, you can see it in the privacy of your own room. Why you would want to do it, I don't know, but --

[Laughter.]

MS. : But it's there, and then the fact sheets are there, and then these brochures that should be coming out are all there. And I think those have been translated into Spanish.

MR. : Good afternoon.

MS. : Hello.

MR. : My name is Larry Reid. I'm from
Howard Reader.

MS. : And you're still here.

MR. : And I'm a custom broker.

MS. : I know.

MR. : I thought I was the guy you were
looking for, the last one in line, but I see somebody else.

MS. : No, somebody came behind you.

MR. : It's nice to have you back here,
Mary.

MS. : Thank you.

MR. : You add a lot of sparkle to a
kind of a controversial subject.

MS. : Yeah, it's not dull, is it?

MR. : No.

MS. : No, not anymore.

MR. : Three simple questions. The
first one is when the Food & Drug designates a shipment for
inspection because of the Bioterrorism Act, is that also
going to be coordinated with Customs' homeland security
effort, or are we -- is it possible that we're going to end
up with an FDA inspection for bioterrorism, an x-ray

inspection for that inspection, and then we have -- for homeland security, and then we have the SET team, drug enforcement team wanting to take a look at a shipment?

MR. : Part of our -- the FDA targeting is going to be in conjunction with our national targeting center, so if there's something that -- they're going to coordinate these things. So that if it's a hit for bioterrorism, it would be a hit for our security purposes as well. So that the targeting centers would coordinate the activity to make sure we're not duplicating effort.

MR. : So then we should have one inspection for all three?

MR. : Yeah.

MR. : Okay. That doesn't happen now. We can end up with a --

MR. : That's part of our more closer working relationship that we're building right now towards.

MS. : You still may have a separate exam for admissibility determinations if it then hits --

MR. : Well, I understand that sampling and that sort of thing after the fact could be, but I'm just talking about the freight sitting at the dock and you

don't have any idea what's going on, because basically we are in the dark when those processes are happening.

MS. : Right.

MR. : We just have to wait and see.

MS. : And you'll stay there.

MR. : So the answer really is, is that the likelihood is it probably could happen, because we have x-ray and drug enforcement inspections separate from each other now.

MS. : Right. Provided they are all coming out in the national targeting center, that's where we plan to be.

MR. : We can hope for one joint --

MS. : Right.

MR. : Okay.

MR. : That's the intention.

MR. : I think this question may have been answered, but I would just like to clarify it. There are many possible registration facilities, or there are many facilities that need to be registered in a particular shipment, but they don't necessarily all have to be listed in the prior notice; is that right?

MS. : That's right, just the manufacturer and the shipper, if the shipper has a facility and if the food is destined for consumption here.

MR. : Okay. So we are talking two --

MS. : Two different things, right.

MR. : Okay. If we -- the last question. If we have an air shipment, for example, that we know about two days ahead of time that's coming in from Europe, and it's -- and we transmit it to Customs, will we receive back a prior notice number, prior to response from Customs? We know that Customs will not respond to us on the -- until the day of arrival or when wheels are up.

MR. : Right.

MR. : Are we going to be able to transmit prior to the arrival of this prior notice in the ABI system?

MR. : No, we're going to hold it until the appropriate window opens up, and then we will -- I think the idea then is to send the information to FDA. So we're going to store it.

MR. : So actually we're not, on an air shipment, getting five prior days to send the information other than having it in the system?

MR. : No.

MS. : You can transmit it --

MR. : You can transmit it, but we won't act on it until that -- until the appropriate four-hour window opens up, or the wheels-up message.

MR. : So all our responses are going - - so we would get a response back for prior notice and for entry?

MR. : Right.

MR. : Two?

MR. : Uh-huh.

MR. : At the same time. Okay. Thank you.

MR. : Uh-huh.

MS. : Okay, we've got about, I think, five minutes before -- Max has already missed his plane. So before we have to get finished up. So --

MR. : Mike Sayres, LOC Brokers (phon.). We had been told that the submitter is liable to

FDA for the accuracy of the information on the prior notice, but not the transmitter; is that correct?

MS. : Uh-huh.

MR. : And what is the violation if the information is not found to be correct, what is the course of the violation and the submitter?

MS. : Now we're looking at two different things. If the information is not correct, then the food is not covered by an adequate prior notice. Therefore, the food will be held or sent to secured storage until that is taken care of. Okay, so that's the consequences for the food.

Consequences for failure to provide adequate prior notice or failure to provide prior notice are prohibited acts covered by the statute, and that is a variety of civil or criminal actions by the agency. That would be injunction, prosecution, primarily; or a new prohibited -- a new sanction, I guess, provided by the Bioterrorism Act, which is debarment.

MR. : Is that against the submitter?

MS. : Against the person who was responsible for submitting the information. So according

to the registration, the submitter is any person who has the information. The transmitter is only the person who transmits that information on their behalf. And that -- if it's a broker, that gets back into Customs broker registrations and enforcement.

MR. : Okay. There was a few times you talked about the importer, owner, and ultimate consignee, as if they were one person. But how do you define, for example, the ultimate consignee?

MS. : I don't necessarily think they are one person. In the preamble to the statute, when we discuss importer, we refer to Customs definition of importer of record. When we talk about ultimate consignee, that's ultimate consignee in the U.S., and again we refer to Customs -- if it's not a registration, it's a description of what the ultimate consignee is.

And the owner was provided to us by Congress in the statute. It's also in the Food, Drug & Cosmetic Act 801(a) section, and it always refers to owner, and no one has ever defined owner, so we decided not to, either.

So the owner could be the importer, they could be the consignee. If not, then you're supposed to tell us who

the owner is. And by owner, we describe it in the preamble as a person who owns the product at the time you give us the prior notice.

MR. : So you don't need to know who the importer is selling to?

MS. : We need to know the importer, the owner, or the ultimate consignee. So if there are third -- you know, if there are fourth, fifth and sixth parties in there, for the purpose of prior notice, no. I don't know about for the purpose for Customs. But Customs usually asks for the ultimate consignee as well.

MR. : Yes.

MS. : I don't know how many more firms there are, but there is a lot of them.

MR. : So if the importer resells it to five different people, you don't need to know who those five firms are?

MR. : Not once it clears after prior notice.

MS. : Yeah, not if that's -- that happens after prior notice.

MR. : Oh, okay. Good.

MR. : 801(a), cargo admissibility,
it's the importer of record. Two different things.

MS. : Yes. And the ultimate
consignee.

MR. : [Inaudible, speaking off
microphone.]

MR. : Yes, it is.

MR. : Okay. So like in our industry,
for our importers, because the order has to come through
us?

MR. : Right.

MR. : [Speaking off microphone.]

MS. : It is in the preamble.

MS. : [Speaking off microphone.] The
importer of record has nothing to do with that transaction
except they have sold their license. They don't own it,
they don't touch it.

MS. : They don't have the bond that
covers the duty?

MS. : Yes, they do.

MS. : Well, that would be the
definition of importer of record that Customs has, pretty
much.

MS. : The owner is actually ABC Company, and they are the ones that are responsible for the integrity of the shipment and the FDA registrations. So --

MS. : No, the importer of record is pretty much the Customs description, that bond holder.

MS. : [Speaking off microphone.]

MS. : All three. The importer, the owner, and the ultimate consignee are all -- could all be the same firm, but if they are different firms, it's not either/or, it's and.

Are you still standing there?

MR. : Yeah, I sure am.

MS. : Okay. One more. Oh, you have one, too? Well, boot him.

MS. : Does the entry need to be in the Customs computer to be valid? Does it need to be transmitted to be used in the prior notice?

MR. : If it originates through our system, then it would come in with the entry transaction, then we would create the entry. But if you are using it through the prior notice system, through the FDA Web site, it doesn't have to be in our system yet.

MS. : So you want them to be the same.

MR. : Just about the electronic filing, will we be able to electronically file a prior notice and then later electronically file a Customs entry?

MR. : I would think so. It would depend on the software system.

MR. : I mean in the ABI system.

MR. : It depends on how your software is set up. Everybody's software is set up differently.

MR. : But you don't need a Customs entry in order to accept the prior notice?

MR. : No.

MR. : Okay. All right. Thank you.

[Whereupon, the conference was concluded.]

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