

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"

Tuesday, November 18, 2003

San Antonio, Texas

**AZN-0278**

**TR 4**

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

[TRANSCRIPT PREPARED FROM A TAPE RECORDING.]

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

P R O C E E D I N G S

MS. : (in progress) for consumption, whether they eat it on site or whether they take it out. So it puts them into the realm of retail establishment.

MR. : As a follow-up question, there are a lot of companies, particularly here in Texas, that have their salsas, whatnot, private labeled, privately manufactured for them by a copacker.

Now if they take control of the product -- now keep in mind it has their name on the product, so-and-so XYZ Salsa Company. If they don't take control of the product, meaning it's warehoused at the copacker, shipped by the copacker, they're exempt; correct?

MS. : Right. You have to manufacture, prepare, pack, or hold, and it's facility related.

MR. : Right. Now if I have a warehouse, though, then that warehouse is going to have to register?

MS. : If you have a warehouse, if your facility has a warehouse, and you don't do anything else but you get your own -- you know, you have your food packed

someplace else, and you store it yourself, then, yes. And if you put it in a container and it comes to you in a container and you don't have a warehouse facility, but you keep that container in your parking lot, and you distribute out of that, that makes it kind of a warehouse.

MR. : Right.

MS. : So there's a term used in the rule of mobile facility. It was a surprise to me when I first saw it. When I thought of those, I thought of fish processing vessels. But this -- and then we heard the other day of something I never heard of before of -- a mobile facility was a mobile wine bottler, which apparently they have in Europe. I couldn't even conceive of it, but it was basically a truck that traveled to different wineries, you know, to their vats, and then bottled the wine in the truck, and that would have to register as a mobile facility.

MR. : Dual jurisdiction with FSIS. You've got a plant that makes FDA-regulated products and FSIS-regulated. Have to register?

MS. : Yes. It's only if they are under the exclusive jurisdiction, so that would be like a

meat packer that only does meats that are covered by the Meat Inspection Act. If they throw in some rabbits or ostrich, something that we regulate, then they would have to register.

MR. : Right. Last question. If I have a chain of retail stores, supermarkets, but I have a warehouse where I have products stored, has to register; correct?

MS. : Right. That facility has to register. The stores would not.

MR. : Okay. Thanks.

MS. : Now that Dan has asked all the questions you could ever possibly want to ask, does anyone else have questions? Just come up to the microphone.

MR. : If you have a product that's bottled at a foreign facility, is the glassmaker required to register?

MS. : No. No, the one exemption that we have is for that tasty food, the packaging and the food contact services. So the people that make the packaging don't have to; the people that put the water into the

bottle have to; the people that store the bottled water have to.

MR. : Okay. Is it also correct if the glass is imported empty into the U.S. and then bottled here?

MS. : If the glass is imported empty, it is not covered by registration and it won't be covered by prior notice. However, it is still a food under the Food, Drug and Cosmetic Act, so there would still be admissibility decisions. This is probably going to be harder on imports, I think, than in domestic. But even though a firm is not required to register, like a private residence, we still may do inspections of that firm. It just may not have to register.

So those bottles, when they come into the country, we still may -- we are still going to need information on them at entry and we still will make an admissibility decision. They just won't be covered by the prior notice.

MR. : Okay. Thank you.

MS. : Uh-huh.

MR. : Excuse me, I had a question.  
You said the transport vehicles are not required to register if they only transport food, only if they hold it. How long does it have to remain on there before it --

MS. : No, bless their hearts, they didn't put a timeframe in. They didn't put in a timeframe into the rule, and so now it's -- you know, you're not storing it if a truck is transporting it from point A to point B. But if a container -- you know, if it's a container on a truck, and that container is offloaded and then it's kept in a container yard, it's therefore storing the foods rather than transporting them, so they'd have to register it.

MR. : Okay.

MS. : I think that this is -- you know, this is my personal opinion, which is probably being recorded -- it is. Well, what the heck. It's my opinion that these are things that we need some experience with, and will make very interesting comments to the interim final rule. I think people are going to have to have a little experience and say, you know, my vehicle, you know, it got stuck and we had to keep it here, or they couldn't

take delivery, their warehouse was full, and so we had to hold it in the yard for a day, and then give us the opinion of whether those should have to be registered or not.

MR. : The second question had to do with the U.S. agents. What qualifies as a U.S. agent?

MS. : Okay. Thank you for asking that, because I didn't put it on the slide, but I figured it would come up. It's the most frequently asked question on any of this.

There is two criteria for the U.S. agent. The first one is that they have to reside in or maintain a place of business in the U.S.

The second is that they must be available for contact in case of an emergency or questions by the agency in the U.S.

So when we say reside or maintain a place of business in the U.S. we mean we really need to be able to contact somebody here in the U.S. That's it.

The purpose for having an agent was included in the statute, and it is included for the purpose of what I said, the emergency contact. So that's it. The -- you know, I think the other criteria is that the U.S. -- right,

each facility, each foreign facility must identify a U.S. agent, and to me one of the main criteria is that that facility know who their U.S. agent is. I mean they are the ones that have to tell us who the agent is.

Now as far as liability of the agent, that's basically their -- I'm sure there are liabilities, but not ones that involve FDA. They are ones that are primarily between the facility and the person that is their agent. And this is a little bit different than other FDA rules that you may be used to, like the medical device USA drug agent.

Other questions?

MR. : Just as a follow-up to the agent question. Is there any expectation as to what the agent knows about the foreign facility other than the telephone number and location?

MS. : No. There's no other expectations that are in the rule itself, or even in the preamble. Actually, there is a really good discussion of the U.S. agent and their responsibilities in the preamble to the rule. But, no, our expectations are the expectations that we felt Congress put in the statute, and

that's somebody to contact so in case of questions or emergencies -- not that they could necessarily answer them or take care of them, but they would be able to get that information back.

MR. : All right. Thank you.

MS. : Other questions?

MR. : On foreign facilities, how -- let's say in a Third World country or developing country, what is required to register? Is it address, the ownership?

MS. : The requirement for registration for a foreign facility is just the same as a domestic facility. So there's a list of required information that's covered in the slides. It's definitely covered in the rule. That's the same information. So it's things like the name, the address, the ownership, you know, and the same optional information would apply. Seasonality, those types of things. It's the same piece of information.

And for people who import, the best thing to do is to make sure that the foreign facilities that you import from are aware of the rule and are encouraged to register before December 12th, if the food is going to come in

before December 12th. And like I said, from what they have told us, actually more foreign firms have registered than domestic.

MR. : Another question, if you don't mind. Say there is an interim person between the actual making of the product and the packaging of the product and preparing it for shipment. Does that person have to also register?

MS. : Okay, I think the critical --

MR. : Or agent, if you will.

MS. : -- the critical answer here is persons don't register; the facility has to be registered. So like Dan had asked, you really have to have a facility that's associated with an activity of manufacturing, processing, packing, or holding.

So a lot of times, especially in imports, you might have a broker, a buyer, somebody who doesn't ever have the ownership or the custody, if you will, of the product. Then those people don't have to register. You have to have a facility, and the facility has to do one of those four things.

Again, on the imported product, if it's partially manufactured in one foreign facility and then it goes to another foreign facility, that finishes that processing, then that second one has to register. The first one doesn't. And if it goes then from that guy who finished processing it to somebody else who even labels it, that type of thing, then both of them have to register.

We'll go over it somewhat in prior notice, but if a shipper is also the warehouse, foreign warehouse, and they hold the product before it's shipped to the U.S., then they would have to be registered as well.

MR. : Thank you.

MS. : More?

MR. : I have a question going back to the U.S. agent. Is that a specific individual, or is it a firm, or an office?

MS. : I'm going to say it's a specific individual that we would call, but I think I would have to check, double-check that on the regulations. Do you know, Cindy?

MS. : [Inaudible; speaking off microphone.]

MS. : It's a legal definition of person, which includes a company. So it could be a variety of people in one company as long as they're identified as the U.S. agent, they know they are, and they are -- you know, we can contact them.

So my first answer was wrong. It's not just an individual; it's the legal definition of person.

Thank you, Cindy.

MR. : Thank you.

MS. : You're back?

MR. : Okay, let's say I am the agent here. I own the actual company, I distribute the product that is imported. Could I be the agent?

MS. : Of course. We are not really picky about who can be the agent, obviously. A person is -  
- [Laughter.]

MS. : -- a firm, and they have to reside in or maintain a place of business in the U.S. So it could be. You are a Customs broker. It could be you because you're the owner of a foreign company. It could be your cousin that lives in the U.S. that -- you know, it could really be anybody.

I think the main thing is that we can contact them. And the other thing that's important is really two things, is that the agent knows that they are the agent, because that apparently has happened already, where a foreign firm has registered and designated somebody as the agent, but they didn't know it. This is not good.

MR. : That's not good.

MS. : And also the other half of it is, you know, somebody who is saying I'm the agent and I'm going to register them, without the foreign firm knowing it. There has to be some sort of relationship at least so that they know it.

MR. : Thank you.

MS. : Okay.

MR. : Hi, Mary.

MS. : Hello.

MR. : I'm looking at some of the exemptions here listed. I think some of the language in here is potentially confusing to a segment of the industry. The animal feed manufacturing or distributing segment, and under the retail food establishment exemption, it mentions that they are exempt if they sell food directly to

consumers as a primary function, meaning that annual sales directly to consumers of a greater dollar value than annual sales to other buyers. What is other buyers?

MS. : Well, you know, what they were looking at for an example of that was a place like Costco that sells to consumers, but it also sells to businesses. And if the majority of their sales are to consumers, then they are considered retail establishment. If the majority of sales are to other businesses, that would make them a warehouse.

So for animal feed, I guess it would be the same thing. If -- on a farm, if you make animal feed and you sell it to someone else, then you are a manufacturer. If you store animal feed and it's all for yourself, then you are a farm. If you store it and you sell it to other people, then you'd be a manufacturer.

But if you are a retail establishment, let's think of what a retail establishment would be. Like a stockyard?

MR. : Well, let me back up one minute before I describe to you what a retail establishment would be. When you say if they are on a farm, for example, and

their own animals are consuming that feed, they would be exempt. But if they are selling to let's say another farm

--

MS. : Selling the feed.

MR. : would they be subject -- selling the feed.

MS. : Yeah.

MR. : Now but I look up into the farms exemption, and the last portion of that says that that farm can sell their food directly to a consumer and would be exempt from registration as a retail establishment. That seems like a similar case with their feed.

MS. : I think that's a good question that we'll have to put in there because what they were imagining as an example of something like that is if a farm sells cider and it's consumed like right on their property. I don't -- you know, with an animal, I think you might have to take the animal to the farm to eat it, which it doesn't make sense to me, but then neither did bottling wine in the back of a truck.

So there are situations out there that we didn't envision, and I think either through the questions to us,

through the e-mail, or even to comments to the docket about, you know, what do we do about these kinds of establishments would be very helpful.

MR. : All right. Now the retail establishments, the example there is just what's referred to as an animal feed dealer or distributor. They don't manufacture, package, label, they have someone else's product to warehouse, if you will, but they are selling that product to typically farmers and ranchers who have animals. They may be homeowners that have dogs, cats, companion animals, a horse or two. Those feed dealers, do they -- are they considered under this retail food establishment exemption?

MS. : I would put them in retail food. A feed dealer in the way you described it, they are not warehousing for sale to somebody else to sell it at a feed dealership primarily. They may have a silo of feed, but they are dispensing it basically retail, just like a bulk food establishment would. You know, you go in, you scoop out a couple pounds of something and take it.

I would put them in the retail category. But then again, I would ask that question, too. So maybe we'll

just make a record of it and see what -- if we get a different answer, but I don't think we will.

MR. : Who will provide those answers?

MS. : Lawyers.

MR. : The lawyers?

[Laughter.]

MR. : Okay.

MS. : And those of us who work with them and help them. So, you know, you have to imagine, we tried really hard to envision things and I thought they did good to come up with the kennel, you know, as a retail establishment. So I think it's fair to ask them about feedlots and feedstores that store stuff in bulk. But I think they're retail.

Is yours going to be easier than that?

MR. : No, it probably will be simpler. U.S. importer who drop-ships and ships direct to their customer. They never take possession, they don't have a warehouse, no distribution. Are they required to register?

MS. : No. Registration, the key -- there's --

MR. : You have to have control?

MS. : You have to have a facility that

--

MR. : Well, they have a facility.

MS. : No, that does one of those four things.

MR. : Four functions.

MS. : Manufactures --

MR. : Okay.

MS. : -- prepares, packs, or holds.

So if you don't do one of those four things in your facility, then you don't have to register.

MR. : Okay.

MS. : Okay.

MR. : I've heard some farming operations categorized as businesses, and so that comes back to the farm retail farm store, where they are selling their primary customer base, and the majority of it is directly to large farming operations, and now they're selling directly to the people that are going to consume it, but we need some clarification on whether that is a wholesale or whether that falls in that retail exemption.

MS. : To me, it falls in that retail. I mean it makes sense to me that a farm store would fall right into the same retail category as a grocery store, or a Costco or a Sam's Club or something like that.

MR. : I would agree, but the confusion came up. I saw some comments where large farming operations were purchasing wholesale and the question that came up is are you selling to a business or are you selling to a consumer.

MS. : Right.

MR. : And where does the retail wholesale, as you said.

The second question that I've got is regarding feedlots. Some feedlots make their own feed, and I'm assuming that they must register?

MS. : Well, if they make their own feed and they feed it to the animals in the feedlot, then that would be exempt. They would be a restaurant.

MR. : Yeah, if they don't own those animals --

[Laughter.]

MS. : I'm trying here. That would be a restaurant, yes. If they make feed and sell it to other feedlots, then they are a manufacturer.

MR. : So the integrated operations would be considered manufacturers if they --

MS. : If they own the other feedlot, then they wouldn't. Because with farms, it's if they are under the same ownership and they go from farm to farm, but if those two farms are under the same ownership, then that's not considered to be -- that would be exempt.

MR. : There are convolutions there, contract farmers --

MS. : Sounds that way.

MR. : -- where they may or may not own the animals. It depends on their contracts.

The other question I had was finally you were talking about the animals having to go someplace to eat again. They do that.

MS. : Oh, thank you..

MR. : Some places don't manufacture the feed.

MS. : That's true. That's true.

MR. : And they bring them in, particularly smaller preconditioning lots, but they are selling the feed. They don't own the animals, in some cases; some cases they do. And then those animals are being transported for further processing.

MS. : Well, I would think in that interim one where you bring the animals there to feed, that would still to me be like a restaurant.

MR. : Okay.

MS. : But we do actually have one of our lawyers that deals with veterinary stuff, and we'll try to get hold of him if we can before the end of this. Otherwise, we'll record these and just make them part of our frequently asked questions.

MS. : I had a question about holding food. I work for a freight forwarder, Logistics Provider, several hundred locations around the world, and we handle everything. So some facilities may purposely store food for a particular customer, and others may only see some food of some kind go across their dock and may get held for a day or two days or a week or whatever. We have no idea of what it might be. Maybe some of our facilities have

freezers and so they might hold it for a month on a short-term arrangement.

Is it better to register everybody for contingency's sake?

MS. : I think so. Because they are warehouses. There's -- because of the nature of your business, it's likely that they could store food, whether it's once a year or one week a month, something like that.

There's really no penalty for registering if you are exempt, or if you don't have to.

MS. : You're not doing anything.

MS. : Yeah. It's -- in a situation like you have described, it's just much easier to do the registration.

MS. : Okay.

MR. : Kind of a follow-up to a couple of the questions that have come up. Drop-ship locations, Frito-Lay, Mrs. Baird's Bread, whatever it might be. If they have got warehouses all over the state where they drop-ship overnight, warehouse it overnight, register?

MS. : Yes.

MR. : Okay.

MS. : Each facility.

MR. : All right. Public food storage warehouses. Do the individual companies who store product in those warehouses register or are they operator of the warehouse?

MS. : There are -- I have heard two different answers for that, and I think it depends on the way it's asked, and it also depends on the nature of the relationship with the public storage warehouse. A public storage warehouse that puts itself forward as storing food, which many of them just routinely do, that facility should be registered.

Somebody who rents a specific location in that public storage warehouse specifically for storing food should register.

So I think that's another one that we have to get some clarification on because you don't necessarily want two registrations at one location, but the way I had heard it described is if you own -- you know, if you rent space for storage, then you should register. But then I can envision like 50 different registrations for the same address.

So on that one I think we need to get some clarification. I would think the easiest thing to do is for the public storage warehouse to register.

MR. : We're dealing with that with our own registration requirements here in Texas, and so we --

MS. : And so what are yours?

MR. : -- we have had 100 people register at the same warehouse, and we are having to backtrack now, and we are going to register -- we are going to license the warehouse operator and register the individuals, which is no fee for registration, but it's a license for the warehouse.

MS. : Okay. And ours is different because it's just the one registration. So we'll try to get clarification on that.

MR. : Good morning. If a foreign facility manufactures a variety of different products and have different routes into the U.S., are they going to be allowed to have different agents register for that -- for the variety, or is it going to be just one?

MS. : No, just one U.S. agent per facility. Because the agent for the purpose of food

facility registration is just for contact purposes for FDA. A foreign firm may have all sorts of different agents, you know, regional sales agents, that kind of stuff. That is beyond and different from food facility registration U.S. agent. So it's just one agent per facility.

MR. : Okay. Because what I was envisioning was that the foreign facility could use a custom broker in one port for their product, another custom broker for their canned products, et cetera, et cetera, so -- but there will be one person.

MS. : Right. You could use a Customs broker in one port, and a different broker in another port, and your mother-in-law could be your U.S. agent, is the way to look at it.

MR. : Okay. Thank you.

MS. : It's totally different.

Any more questions? Is this a good time for a break? Oh, you can come on.

MR. : I have one quick question. And it's probably a very stupid one, but I wonder if anyone else has had a problem with what is de minimis activity?

MS. : De minimis -- it must be some Latin term that means itty-bitty.

MR. : Oh, itty-bitty?

MS. : Yeah.

[Laughter.]

MR. : Thank you.

MS. : It means -- I think it means small or it means it doesn't have a great deal of impact on the end product. So that's what it means, is my interpretation.

Okay, if we don't have any other questions, then we will take a break until about 20 after.

[Recess.]

MR. : After we receive the confirmation number that our prior notice was successfully transmitted, how long does it take to get the response back that you have a release status or everything is okay?

MR. : The timeframes will depend upon the mode of transportation. If the timeframes run and we do not have a response back from FDA, you will be in at default to release.

MR. : Okay.

MS. : But other than that, like I said before, we don't plan to communicate our decision on the prior notice information to anyone but Customs. So if you get a prior notice confirmation number, that means that we have received it. We may decide to take a look at it when it crosses the border, and you won't be notified of that.

Then based on that, we may release it, we may defer it for admissibility decisions to the district, and then it's back in the normal timeframe.

MR. : As this new system gets into place and up and running, what kind of delays are we expecting to occur at ports of arrival and movement of shipments? I mean how soon will --

MR. : The law takes effect on December 12th. There will -- unless there is an actual threat that we have identified, are not going to stop shipments for paperwork errors.

MR. : Hello. Here I am again with those questions. What's GO?

MR. : GO is a general order warehouse.

MR. : Thank you. And what's BRAS?

MR. : BRAS is cargo --

MS. : Border release and something.

MR. : Border release automated system.

It's an acronym.

MS. : Customs acronym.

MR. : For stuff we use on the northern and southern border. And it's only on the northern and southern border.

MR. : Only on the northern and southern border?

MR. : Right. It was for an expedited release.

MR. : What's T&E?

MR. : T&E is transportation and export.

MR. : What's FTZ?

MR. : Foreign trade zone.

MR. : 321?

MR. : That's a section of the law that allows release of goods under a manifest without filing of an entry.

MR. : And what's carnet?

MR. : Carnet is a document used basically on the trade for bringing in samples, where they don't have to meet normal requirements, like salesmen samples coming in. But under the Bioterrorism Act, it's subject to the prior notice requirements.

MS. : Is it like temporary importation?

MR. : It's along those lines, but you don't even have to file that kind of an entry. There's no bond behind it.

MR. : Thank you.

MS. : That's a very good list, and I think Howie did a marvelous job of defining them.

MS. : On warehouses having to be registered and requiring a prior notice, so basically we have a product that is needing to stop at several warehouses. Would each warehouse, besides being registered, need to post a prior notice?

MS. : No. Prior notice is associated only with an article of food.

MS. : Okay.

MS. : And registration is associated with a facility that manufactures, processes, packs, or holds. So an imported article of food requires a prior notice be submitted to FDA two, four, or eight hours prior to arrival, depending on the mode of transportation.

MS. : But once it's arrived, that prior registration does not apply to all the movement of that product within the country?

MS. : Not prior registration. Prior notice is just associated with the article of food that's imported. So it has to be before importation. If it's going to be then stored in like three different warehouses, the warehouses all have to be registered as a food facility.

MS. : Okay. And then I just need a little clarity on prior notice on shipment or mailing of product. If samples are being sent for product -- it sounds like pretty much anything that is mailed needs a prior notice.

MS. : Any article of food unless it's covered -- unless it's not within the scope, and not within the scope is the Aunt Tillie's fruitcake, you know, made by

one person, sold to another, something that is accompanying or if it's imported for export. So you're right, almost anything coming through the mail, unless it's that person to person, is going to require prior notice.

MS. : I had never heard of carnet before this, I don't think.

MS. : So if something is being, let's say, overnighted from Mexico, their prior notice requirements and ours is going to be -- I think it's the four hour?

MR. : No. If it's sent by mail, prior notice is required at the time of the mailing.

MS. : That's it?

MS. : Right.

MR. : You have to have all your information done before you mail the package.

MS. : Right.

MR. : Just like you would -- okay.

MS. : Right. If it's being overnighted by the mail, that takes effect. If it's being overnighted by an express courier, that depends on the mode of transportation. If they're flying it in, it's going to

be, what, four hours. If they're trucking it in, it will be two hours. So you don't want to confuse overnight mail with overnight courier.

MR. : A question in regards to those that are on the border. For example, the ones that go to Nuevo Laredo to shop, what is the prior notice timeframe? I mean they bring back cheese, bread.

MR. : If they are bringing it back for personal use, it's not subject to prior notice. If they're bringing it back to go into a small shop to sell, it's subject to prior notice. And if it's coming back by truck, it's two hours.

MR. : Okay.

MR. : Mary, you gave an example earlier about corn husks that were being brought in for I think you said between -- somewhere between packaging and dinnerware would require prior notice -- would not require prior notice?

MS. : Right. Very good.

MR. : But if it was brought in as an animal feed?

MS. : Even for animal, then it's an animal food.

MR. : Okay. Good.

MS. : And I'm hoping that is our only example of a combination food product that's either a package or a food.

MR. : I'm sure it won't be.

MS. : But I'm sure it won't be, either. The challenge is to come up with them.

MR. : To someone within SWID (phon.) or Customs, if you have -- is there a mechanism -- what is the mechanism in place to prevent someone from moving in an article such as animal protein byproducts or mineral products that are not considered food or feed? They're brought in as fertilizers or even grains are brought in as seed, planting seed? But upon arrival, it gets diverted to a different consignee and goes into a food.

MR. : Our system is based on the tariff number, and the codes within the system are based on harmonized tariff numbers. So if it is a certain product item, it will hit under a FDA 4, which is mandatory, subject to bioterrorism, subject to the prior notice. It

could be an FD 3, which may or may not be, in which case you'd have to declare what you're bringing in as to whether or not it's subject to it or not. And if you make a false statement to us, then you're subject to all the penalties that come with Customs when you lie to us.

MS. : Also FDA, you know, will have the firms registered that manufacture foods or store foods, human or animal. So I mean we'll have our ways of finding that out. We start out by flagging the tariff codes that require or may require prior notice. So there are different product codes in most -- or tariff codes in most instances, whether something is identified as a food or not food.

What we did with a lot of the seeds is that we flagged them as that they may require prior notice just like they do now. A lot of seeds don't have special codes, whether they're going to be sprouted for human food or whether they're going to be planted. So we do our best on that of just indicating that it should be, and then we'll have other ways of following that up.

MR. : Are there follow-up inspections performed at the designated consignee?

MS. : Well, one thing that we do, both Customs and FDA do evaluations of Customs house brokers, so we look at their paperwork that is the backup paperwork for electronic submission.

We also do routine inspections. We collect samples of importers at which time we may notice that things are different, and we do inspections at processors.

MR. : Thank you.

MR. : Hello. This question is regarding the registration of the facilities. I'm sorry, I know we are past that subject.

MS. : That's okay.

MR. : But it's rather simple. Well, you mentioned that registration -- a registered facility needs to have a representative in the U.S., right, and that could be anyone, basically? What kind of responsibilities does this representative incur?

MS. : The responsibilities for FDA purposes for a food facility registration is that they answer the phone.

MR. : Okay, but --

MS. : That's basically it. It's for communication purposes.

MR. : Okay.

MS. : They have to reside or maintain a place of business here. We have to be able to contact them here in case of questions or emergencies, threats.

MR. : So if something should happen or whatever, they are -- they are responsible to the manufacturer or whatever happens?

MS. : That's right. That's right.

MR. : Okay. Thank you.

MS. : The only time I could think of where the agent could be held responsible for something, if the agent is also the registrant.

MR. : Okay. Thank you.

MR. : Are food products that are being sent in as gifts, say commercially produced outside the United States that are being sent in as gifts to say multiple individuals, are they subject to prior notification?

MS. : Yeah, they are. The only difference that we put on those is if you -- say you are

traveling and you buy something and you are going to ship it to somebody as a gift, you may not be able to find out who the manufacturer is, and certainly might not be able to know their registration number. So in that instance we say if you are unable to do that and it is an individual to an individual of a processed product, then you can provide the name and address of the firm that's listed on the label, because for most retail size packages you have to -- they have to be labeled properly for FDA regulations, anyway, and that would be the name and address of the manufacturer, packer, or distributor.

If it's a company that's sending gifts to a whole variety of -- you know, same gift to a whole variety of individuals, then we'd expect you to be able to have the manufacturer's name and the registration number.

MR. : All right. Thank you.

MS. : Any other questions? Oh, come on. There you go.

MR. : A follow-up to the agent question. Can you be an agent for five different companies?

MS. : Yep. If you want

to be. That would be a busy phone number at times, but that would be it. Yeah.

MS. : Regarding registering a facility, you said that farms were exempt, in particular aqua culture farms, but they still have to be processed? Would then the processing facility, if it's still owned by the farmer --

MS. : That's right.

MR. : -- would the facility have to be registered?

MS. : Right. The facility that manufactures, processes, packs, or holds the food has to be registered. So if you have an aqua culture farm, that on that farm has a facility that heads and guts or fillets the fish, and then sends them to a retail store, to a warehouse, that facility would have to be registered.

If you have an aqua culture farm like they have up in the Pacific Northwest, which is just a big net in the middle of Puget Sound and they, you know, vacuum the fish out of the net and then transport them to a facility where they are killed and headed and gutted and all that stuff,

that facility has to register, but that net in the middle of the sound doesn't, because they are the farm.

MS. : Okay.

MS. : I'm hoping that's what they were envisioning. It's the only one I've ever seen. But, yeah, if there is any processing that takes place, unless that fish is also going to be consumed there, then if they have a facility that actually processes, then they would.

MS. : Okay. And then also the holder or storage facility has to be registered also?

MS. : Yeah.

MS. : Okay. Regarding a foreign farm, aqua culture farm, the facility that those are processed in has to be registered with an agent in the United States?

MS. : Right.

MS. : Whether or not whoever owns that facility.

MS. : Right.

MS. : But the farm does not have to be registered?

MS. : That's correct.

MS. : Okay. Thank you.

MS. : Thank you. She got it. I like that.

[Laughter.]

MS. : You get points for that.

MS. : In regard to the U.S. agent that needs to be listed for emergency contact purposes, does that emergency contact have to be on a 24-hour basis?

MS. : Yeah, and that's the same for a domestic facility, too. It has to be any time type of contact.

MS. : So the U.S. agent would have to register a cell number and all that kind of -- just so that they would be a 24-hour contact?

MS. : For the emergency contact, we ask for name, address, phone, fax, e-mail, I think. So that's why the question about whether the emergency contact could be an individual or more than an individual, you know, like a whole firm, made sense, because otherwise it's 24/7.

Also for foreign facilities, they have to give us the identity of their U.S. agent, but if they want to, they

can give us a different name as the emergency contact. So it could be two.

Other questions?

MR. : One more clarification on aqua culture. What about a farm that normally trades in live product, a product that is normally traded directly to the consumer as live? Crayfish. Sometimes they are processed by boiling, but there are a lot of farming operations that deal directly to the public, consuming public as live product. Lobsters also.

MS. : I don't know. I think I would like to reserve that one for getting an answer back to you, just because the product, you know, the definition of food includes live animals, so it's not a question of whether they are food or not. But on something like that, if they are dealt directly to the consumer as live, then --

MR. : It's one I hadn't thought of before, either.

MS. : Thank you so much for bringing it up. But that's fair because there is trade in live like that.

MR. : It's very restricted to the industry.

MS. : Yeah.

MR. : Related to that, though, if it's caught on a U.S. flag vessel, then it's not subject to prior notice. Anything caught on a U.S. flag vessel, you're not going to make an entry because you're not making an importation. So nothing caught on U.S. vessels are subject to prior notice.

MS. : So for prior notice it wouldn't, but registration, you're talking about an aqua culture here. And maybe the answer is going to depend on who it goes to from the farm.

MR. : My question is regarding registration. What are the consequences for a company, let's say Kraft, who manufactures mac and cheese, if they do not register that facility?

MS. : The consequences for failing to register are civil or criminal action. It's a prohibited act. This is kind of unusual for FDA for this law. The statute included specific prohibited acts, because our prohibited acts are based on adulteration or misbranding,

and this act for both prior notice and registration gave specific prohibited acts.

So it's a prohibited act to fail to register. Therefore, we could take criminal or civil action, so that's injunction, prosecution, and if it's an imported product, then also debarment.

MR. : Okay. And as a follow-up, let's say Kraft is the example and did not register by that December 12th. If they register on the 13th or 14th, any consequences from that?

MS. : We are also planning to come up with -- I think with enforcement guidance, like we have talked about for prior notice, we'll be coming up with the same type of thing for registration. So I think for both, for registration, as well, we will be doing educational outreach.

MR. : Very good. Thanks.

MR. : One thing I wanted to add is on prior notice, normally you are going to have five days prior to file your information. That will not be available on December 12th. Prior notice applications will not be accepted by FDA until December 12th. So anything coming in

within that five-day scope, you're not going to be able to file earlier than the 12th.

MS. : That's built-in enforcement discretion, based on the systems.

MR. : Correct.

MR. : Let's say you're importing food product from one manufacturer, and there is another manufacturer -- this manufacturer you have been importing food product from, and it's registered and compliant and all, and then all of a sudden you need to switch manufacturers in midstream and get a different manufacturer in the same country, possibly related to the previous manufacturer, to supply you with goods. I guess the question is how would the registration affect the company importing goods?

MS. : Well, the company importing the goods needs to be able to -- or whoever. Remember, whoever has the required information needs to submit prior notice. So if you change -- even if you have the same manufacturer, if that manufacturer has five different locations, you are going to know which is which. So because facility registration is specific to location, so you need to know

which plant manufactured the product and what their registration number is. If you change suppliers and go to a different manufacturer, it's in your best interest before the product arrives to be able to find out, to make sure that they are registered and that you have their registration numbers so that you can provide that in prior notice two, four, or eight hours before the product arrives.

MR. : What if they are not registered?

MS. : Then you won't get their food.

MR. : And -- okay. Well, what if they are not registered, could I register them?

MS. : That would be up to them and you.

MR. : I see. But what I'm saying is I guess --

MS. : What we are saying is that you need to form a relationship of some sort. If they are not registered and they say I don't want to be registered, then it's probably not a real good idea for you to register them or to import their food.

MR. : Gotcha.

MS. : If you have a relationship with them and they say, okay, fine, you do it, I guess that would count for authorizing you to register. But, remember, in the registration you not only have to say who you are, but if you are not the owner, operator, or agent in charge of that location, then you have to give the name and address or whatever, the information, the identity of who authorized you to do it.

So if they haven't authorized you to register for them, then you would be missing that piece of information.

MR. : Of course.

MS. : So there's three options: You either don't; they register; or they authorize you to register for them.

MR. : Even after the 12th, December the 12th?

MS. : Oh, sure. If the food doesn't arrive into the U.S. until after the 12th, then it doesn't have to be registered until two, four, or eight hours before it arrives, we need -- that's a piece of information that's required in prior notice. So, therefore, they have to be registered before you give us prior notice, or else

the consequences kick in, and with food from an unregistered manufacturer, it's a double whammy consequence. It can be refused because it failed to provide the adequate identity of the manufacturing facility, and it would also be held for basically the same reason until it's registered.

So you're looking at all the stuff that Howard talked about with the general order -- all the initials that he told you about, well, they all kick in. How's that?

MR. : Thank you.

MS. : Okay.

MR. : Getting back to examinations, given the current climate where Customs is doing many more examinations, various types, and there's been delays being experienced with those examinations, how timely are these FDA examinations actually going to be carried out?

MS. : Well, FDA exams are going to be carried out by either Customs or FDA when the product arrives. And that's the only problem that we've had kind of internally with the statutes that anticipated port of arrival. That means if you tell us it's coming into -- and

I'm going to give you just a crazy example -- but if you tell us it's coming into Laredo and you bring it into El Paso instead, that means FDA really wasn't able to get prepared to examine it, we'll make sure that Customs does. But that might cause a delay. It might be -- you know, those types of things might cause a delay. Otherwise, I don't expect a huge -- anything more than this.

MR. : Let's be more direct, then. I tell you the shipment is coming into the port of Baltimore on December 12th. The shipment arrives on December 12th in the port of Baltimore, and it is available say at 7 a.m. I could expect, if it was flagged for examination --

MS. : Right.

MR. : -- I could expect the examination to be concluded that day?

MS. : Depends on what --

MR. : We would process it the way we would normally process anything else. It depends on why it was flagged, what the examination purpose is for.

If we believe it's an actual threat, it's going to be stopped right then and there, it's going to be isolated, it's going to be secured, we're going to pull in

HazMat. If it's just a regular thing to verify prior notice, it's going to be examined in due process without any additional delays that normally would occur when we target something for examination.

But if you're asking for a guarantee that you're going to get it in and out the same day, no, we're not going to guarantee you that. We're going to try.

MR. : No, I --

MR. : It depends on why it's being stopped for sampling.

MR. : Okay.

MR. : And if it's sampled and there's a reason to hold it -- I mean we may do the sampling that day and still hold the shipment.

MR. : Okay.

MR. : Yeah, I just wanted to add a comment to that question, too. I think also you need to understand, too, when they are talking about examination, they are talking about prior notice examination, too, but you would still be subject to the regular FDA admissibility process. So your product may come in December 12th, may receive, you know, not a prior notice examination, or we

decide to examine or do not decide to examine, but that does not mean that you would then be free to distribute the product at that point. You would still have to wait for an actual admissibility decision from the local district or FDA folks whether or not they want to collect the sample to check it for regular adulteration or misbranding under section 801 of the FD&C Act.

So you still go through the regular admissibility process in addition to a prior notice process.

MR. : The military procures small quantities of different products from overseas and then we have them shipped back to a lab in the States. These are tiny quantities, let's say bottled water or sandwiches for analysis. I assume that's going to be prior notice?

MR. : Yep.

MR. : And then as far as the registration process, it's in the hands of the government.

MS. : The registration process is different for that. What we described for samples relates to prior notice. But those foods are not intended for -- you are talking about lab samples.

MR. : Right. Right.

MS. : They are not intended for consumption in the U.S., so you are not going to have to.

MR. : Okay.

MS. : There's one thing that I failed to mention. In the proposed or in the interim final rule, somewhere in the first like 50 pages, there is a table 1(a) and that lists all the information that is required, and then it lists different circumstances when it is and when it isn't. And one of the primary things that you brought up is food that's not for consumption here. Still requires prior notice, but there's specific information that isn't required. The most specific is no registration number. So you might have to tell us who the manufacturer is, but you don't have to go all that stuff with registration.

MR. : Okay.

MS. : We all know that there are quite a few changes being implemented at the border due to homeland security and preventing terrorists from entering our borders, but is the FDA looking at anything for maybe a specialized treatment, implementing a specialized treatment program, something like CT PAT (phon.) for importers, for foreign importers or even domestic?

MS. : I think right now for the prior notice process, we want to let it go for a while before we decide. We have talked with Customs about CT PAT, and other programs, but I think for the outset we probably won't. CT PAT right now has not been associated with the manufacturing of foods. It's more dealing with transportation issues, and that's only one part of food security.

MS. : Okay.

MR. : But if I could add onto that, the Mexican government is extremely concerned about shipments being refused, especially the mom-and-pop shipments coming in. We have been working with the Mexican government. In fact, a week ago Friday there was a meeting in McAllen with Mexican Customs and U.S. Customs officials that work the border along the region, all the way from San Diego all the way across, and basically they were talking about what to do with these shipments and how to process them, and come to terms with being able to deal with a lot of these shipments that we think are just going to end up abandoned. Because in Mexico, for those who aren't familiar, in order to export out of Mexico, you have to

file an export with the government, no matter how small the shipment is. Even the mom-and-pop has to use a broker in Mexico to bring the goods across.

If the goods are refused because of prior notice, an entry would have to be made going back into Mexico under I think it's a K-1, if I'm not mistaken. And those issues have been raised, they have been raised by the embassy, they have been raised by your Customs folks, and we are very well aware of it. We are terribly of a border disaster, and we have been working closely with the Mexicans to try to avoid something like that.

MS. : So there is some cooperation going between our neighboring countries?

MR. : We are trying to work together. Hopefully the Mexicans won't allow a shipment to cross the border unless they verify on their side that prior notice is met so we don't have to turn the goods back.

MS. : For those foreign companies, are there in documents in --

MR. : I'm sorry?

MS. : For the foreign companies, are there any documents -- say, for example, in Mexico, are

there any documents on the Web site in Spanish to help them expedite?

MR. : My understanding, unless it's changed, is that the --

MS. : Yes, there are. The rule hasn't been translated.

MR. : Right.

MS. : But the presentation slides have been translated. I think we are probably -- the fact sheets have all been translated. We are working on -- we have Spanish and French. I think we are working on a variety of different languages. As each fact sheet, frequently asked questions, as all of that gets initiated, we are having them translated.

We are also planning, I think we are still planning a border flier to go to the truckers, as they come across the border. And so those we are doing in English and Spanish.

So before I left town, I think we had already -- we had sent them for translation. They are just one page, and it's to alert especially truckers that starting with December 12th, they have to have this information.

So there should be at least that background type of information should all be translated.

MR. : We have also met and FDA has met with the Mexican brokers in Mexico City on at least two occasions that I'm aware of.

MS. : Okay.

MR. : So they're aware.

MS. : Thank you.

MS. : The downlink that I talked about, the satellite downlink for the 28th, that's also in Spanish.

MR. : Does USDA factor into any of what we are discussing today?

MS. : No, the Bioterrorism Act, this part of it, was focused only on FDA, and that's why Congress put in the exemptions of the products or the firms that were under the exclusive jurisdiction of USDA.

MR. : However, APHIS, which was a part of USDA, came in under Customs under the Border Protection, and people from APHIS have been to our training internally.

MR. : That's wonderful because I mean there are products that do get held even after FDA and U.S.

Customs do the releases, they still do get held by USDA, and I see that things are being streamlined here between Customs and FDA, but I guess USDA does not factor into this at all.

MR. : Well, as I said, APHIS, which was under FDA and has come under Customs and Border Protection, has been involved in the internal training and they are aware.

MR. : Forgive me, what's APHIS? Is it an Army-Air Force exchange?

MS. : It's animal and plant health inspection service, and it's their plant protection quarantine. That whole group is no longer streamlined, they are --

MR. : They're under Customs and Border Protection.

MR. : Thank you.

MS. : Okay, since you're up.

MS. : Regarding registering retail establishment, like you say, a grocery store, what about a street vendor that sells fresh product on the street? Would they have to register?

MS. : No, they're the retail restaurant. They're the exception. I think they're excepted under the restaurant provision.

MS. : Okay.

MS. : Just like fast food. A retailer, a restaurant can be -- you know, you don't have to stay there to eat your food. So that street vendor would fit in there.

MS. : Okay. Thank you.

MS. : Uh-huh.

Well, thank you all for your attention, and we'll hope to -- Cindy said that she took your card, those of you who asked these questions that we can't answer, and we'll try to get back to you or make them part of our -- so thank you for that.

[Whereupon, the conference was concluded.]

- - -