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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
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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, March 16, 2004

Kansas City, Missouri

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P R O C E E D I N G S

MR. : Question on the slide that Ms. Scales covered. It said that pet shelters, kennels, veterinary facilities that provide food directly to animals--and the "directly to animals" was highlighted and emphasized.

If the shelter or veterinary hospital feeds an animal on site, I would call that "directly," but I'll give you a perfect example of this.

My pet food company provides food to shelters to send home with the cat or dog to be fed at home. So the shelter isn't providing it directly to the animal. They're giving it to a human who is taking it home. They're not selling it, so they're not a retail establishment.

So, where are we in the gray area here?

MS. SCALES: That would be take-out.

[Laughs.]

[Laughter.]

I mean, basically, a restaurant is still a restaurant if a human comes in and orders a pizza

and takes it home. So--we haven't gotten that question yet. I like it.

MR. : Well, there's a half a billion dogs and cats--

MS. SCALES: Right.

MR. : --that we know of in the U.S.

MS. SCALES: Right. So, if the shelter provides food to the owner to take home and feed to the animal, the shelter would still be a restaurant.

The pet food company that provides the feed to the shelter would not be exempt, because it's one step removed from providing it directly to the animal.

MR. : Okay. So we'd have to know we gave it to the shelter, but we wouldn't have to know which animal received it, or which human took it home.

MS. SCALES: right.

MR. : Great. That's the good answer. Thank you.

MS. : If a foreign facility is sending a sample into the U.S., but it's not for human consumption, it's just--it's food, and it's a sample, so they'd have to do a--I'm assuming--a prior import notice. But would they have to register? Or are they out of that?

MS. SCALES: If it's not for consumption, they would not need to register. So if it's just for research, if they're going to--I don't know--put it under a microscope, they won't have to register.

MS. : So they do the prior import notice, and just don't put a facility registration number, and that doesn't cause a problem?

MR. BAKER: We'll cover some of that in the next series this morning.

MS. SCALES: But we've gotten a lot of questions about "I'm just providing samples," or "I'm just doing research on a focus group of people." So they are consuming it. In that case, they would be--the facility would be required to

register.

MS. : Right. But if it's not being consumed, then no registration.

MS. SCALES: Exactly. Right.

[Pause.]

MR. : I've got a question. I one section you talk about live food animals--in the list to register. How's that different from a feed lot or a dairy farm? The farms are exempt.

MS. SCALES: Right, a feed lot or a farm that raises animals is exempt. This isn't my specialty, so I don't know. But if there is a facility that's kind of one step removed from the farm. They're not raising the animals. And, I mean, a feed lot is still considered raising the animals.

But if, after that, before the animal goes to the slaughterhouse, it's held for a short period of time, they'd need to register.

And, actually--I mean, that's a good point, because I don't know how often that happens. Usually, if the animal's alive, it's being fed. So

they'd still be exempt.

MR. : If I can go back to the sample thing for a minute--if it's declared a food ingredient, do I have to have that site registered? Because I'm going to do a prior notice of food ingredient, which requires a registration--right?

If I go overseas--

MS. SCALES: Right.

MR: : And I go to a grocery store and I buy something, and I send it over here. It maybe for research, but it's still a food ingredient. Do I have to register that site--grocery store or manufacturer--if I'm bringing the goods in as a food ingredient, as opposed to your other comment, it's coming for research.

MS. SCALES: Okay. Give me an example of--what would--so, you'd buy like a bag of flour at a foreign facility?

MR: : Right. Suppose I buy a bag of flour in Germany that I'm going to make bread out of over here.

MS. SCALES: Okay. And the bread will be consumed?

MR. : No. It could be for development of bread. It could be eaten. I guess you could say that--yes. It would not be sold. And the reason for doing it is to develop that flour into the bread, or whatever you're going to do it.

MS. SCALES: Okay. Umm--so you buy the flour in a grocery store in Germany. Then it's imported here. And the question is whether the grocery store and the facility here that makes the bread is required--

MR. : The one here is not a question. It's the question of the other side over there. Who has to register the other side if it could be--because of the prior notice coming in as a food ingredient, I have to declare it. I have to be registered by that rule.

MS. SCALES: Right.

MR. : And samples are a big question all the way across.

MS. SCALES: Right. Well, food ingredients are considered food. And, I mean, I guess it's kind of an interesting question, because if its bought at a grocery store, that grocery store would usually be considered retail. But if it's not--a consumer's not buying it, but if a consumer's not buying it, a company is buying it instead, and then they're bringing it in here to make bread out of it, then that store in Germany is no longer a retail facility--for your--well, actually let me think here.

It's--you know, I'm going to have to get back to you on that, because the grocery store probably wouldn't be aware that--

MR: : Right. That's the issue.

MS. SCALES: Yeah. Right.

MR. : The issue is the little guy on the other side that you're buying it from--whether it be a grocery store or a small manufacturer--may not be aware of the FDA requirement. That's the issue.

MS. SCALES: Well--

MR. HACKMAN: If it's a foreign facility that's manufacturing a food ingredient, they're required to register.

MR: : I understand that.

MR. HACKMAN: It's straightforward.

MR: : Yep.

MR. HACKMAN: Now, the twist that you're kind of giving to us is that you've stated that you're purchasing the flour from a grocery store, versus from that flour manufacturer.

MR: : Right.

MR. HACKMAN: So that's an interesting twist.

MS. SCALES: Mm-hmm.

MR. HACKMAN: Also, it depends on how much you're bringing back. If you're bringing it back in your personal luggage, versus if you're having the facility send it to you. If you have the facility send it to you, prior notice is going to kick in.

Now, we're getting ahead of the game.

MR: : Right.

MR. HACKMAN: If you brought that in and you were taking that flour to use in your home to bake bread and to consume in your home--

MR. : Right.

MR. HACKMAN: --it doesn't necessarily apply. But if you're bringing it in for research purposes in order to make a commercial product, then registration and prior notice kicks in.

MS. SCALES: but I'm wondering about--I mean, from the grocery store's perspective, you're still a consumer, because you haven't declared, "Okay, I'm buying this for XYZ company to make bread out of for research purposes." So I think we'll have to include that in our next set of guidances.

MR. : [Off mike.] The cat food industry has the same issue. Our scientists run into a grocery store--to GNC or wherever--and pick up ingredients, bring them back and make them into a new food.

MS. SCALES: Right.

MR. : [Off mike.] So we're

taking retail and bringing it back into the commercial chain again.

MS. SCALES: Right. Right.

Well, I guess in that instance--and actually, just thinking about it, the grocery store in Germany--I mean, if the grocery store knows that it's selling to wholesalers, then they have to start thinking about that 50 percent primary function issue. But I guess if the grocery store just once in a while is selling to a pet--well GNC is selling to a pet food manufacturer, or to a bread maker, I think they'd still be considered retail.

So I guess I've answered the question. I mean, it's just kind of incidental buying from a grocery store, that grocery store's not going to know that you're not a consumer. So, they're not going to--I mean, they're not even going to know about the primary function. So I'd say they don't have to register.

[Pause.]

MS. : Fumigating a container--is

that a manufacturing process?

MS. SCALES: It is. Yes.

MS. : And if it's done on a farm, do they have to register?

MS. SCALES: Yes.

MS. : Even the farmer is not exempt if it's done at the farm?

MS. SCALES: Right. Because that makes it a mixed-type facility. If something's being grown and then it's fumigated, that fumigation is considered manufacturing/processing. So that--because of that activity, the farm would need to register.

MS. : Okay.

Someone had a question about the U.S. agent and company name? Oh, that was you?

MS. : [Off mike.] Yes. I register about 55 companies, and I've always kind of how the form reads, it asks for an individual name. And I would prefer to list the corporation's name.

But I was just--I've just been putting

both, for now.

MS. SCALES: Right. This is the corporation the U.S. agent is involved with?

MS. : [Off mike.] Umm--yeah; registering a foreign facility, and I'm the U.S. agent.

MS. SCALES: Right.

MS. : [Off mike.] Do you have to put an individual's name, or can you put a corporation?

MS. SCALES: You can put the corporation.

MS. : [Off mike.] Okay.

MS. SCALES: And then you just leave "title" blank. I think it says "name" and then "title." Just put the name of the corporation and leave the title blank.

[Pause.]

MR. : I'm still not clear on the live animal situation. At what stage does a live animal--a handler of a live animal have to register?

I mean, for instance, in cattle, you have

the cow-calf producer, then it goes from there maybe to a backgrounder, then to a feed lot, and then finishing, and then to the slaughterhouse.

MS. SCALES: Right.

MR. : Which one of those handlers need to be registered?

MS. SCALES: Okay. So, first it's raised at a farm, and then what happens?

MR. : Well, it just goes through--I mean, it might go for--just to simplify it--the calf is produced on one farm. It might be fed at another location, and then to the processor for slaughtering.

MS. SCALES: Right. Okay.

MR. : Does the farmer--

MS. SCALES: The farmer--

MR. : --does the rancher who produces the calf have to register?

MS. SCALES: The farm is exempt.

MR. : The farm is exempt. The feed lot who feeds the calf out?

MS. SCALES: They're exempt, too.

MR: : Okay. So only the processing facility would need to--

MS. SCALES: Well, if we're talking about cattle, the slaughter facility's regulated by USDA.

MR: : Okay.

MS. SCALES: So then the slaughterhouse is exempt, as well.

MR: : So then which part--which handler of the live animal would have to be registered?

MS. SCALES: Well, it sounds like, in your situation, none of them would have to register.

MR: : Okay.

MS. SCALES: I guess the only situation that I can think of is--and I don't know if this ever happens, because this is cattle country, and Washington, D.C. [laughs]--I mean, the only situation I can think of is maybe if the animal's held for like 24 hours before going to the slaughter facility. If they're held and it's not being held for the purpose of fattening it up.

MR: : Okay.

MS. SCALES: Then they would have to register. Because they're not really raising the animals. We consider--feed lots aren't really raising animals either, but we kind of throw them into the farm exemption, too.

MR: : Well, I'm from Texas, and we're just going to have a lot of cattle industry people going to go, "Which ones of us have to register?"

MS. SCALES: Right.

MR: : And we're not sure what to tell them right yet.

MS. SCALES: Right. So, basically, any raising of animals is exempt as a farm.

MR. : Okay.

MS. SCALES: Any facility that raises animals is exempt.

MR. : Okay. And the slaughterhouse is exempt.

MS. SCALES: The slaughterhouse is exempt.

MR: : But if an animal is someplace where it's not being raised or

slaughtered, it has to be registered?

MS. SCALES: Well, that gets kind of tricky, and we're working with the USDA to kind of figure out exactly where our jurisdiction begins and ends versus theirs.

We're going to be publishing--we've got--there's probably like 20 questions in that guidance, and we're working on it now with USDA. So that should be coming out in the next month or so.

MR: : Okay.

MS. SCALES: That will help.

[Pause.]

MR: : What about U.S. ports where they're handling food waiting on a ship to arrive? Are they required to register? Or the fumigation of the commodity before it goes on the ship?

MS. SCALES: Yes, I guess a facility by a port that's holding food would be required to register. And fumigation is manufacturing/processing. So--yes, they would be required.

[Pause.]

MR. : What if you're in a facility that does both USDA processing and FDA? You make a product that's a non-meat product--it's a cereal product--in the same plant you do a USDA. Do you have to register that particular end of your production?

MS. SCALES: Can you repeat the first part?

MR. YOUNG: I'll answer that.

MS. SCALES: Okay.

MR. YOUNG: The answer is yes, because that's a mixed facility that's not under exclusive jurisdiction of USDA.

MR: : Okay.

[Pause.]

MR. YOUNG: Any other questions? Okay good.

MS. : I'm still a little confused on the samples.

If, for instance, we have a facility in South America that has some orange juice that they

want to sell us--or send to us to sample.

When you answered her question, you said if it's for test purposes only, they don't have to register. But yet, on the other hand we're hearing: "No, they have to register. It doesn't matter if it's consumed or not."

Now, we're not talking prior notice here. We know about prior notice.

But as far as registering goes, can that little orange juice maker over there send it to me without being a registered facility?

MS. SCALES: Okay.

MS. : Just for testing.

MS. SCALES: I'm sorry if I contradicted myself. I didn't mean to do that.

Okay. Samples that are sent into the U.S., either for research purposes or just for kind of like a test market--

MS. : Right.

MS. SCALES: --if they're consumed, then that foreign facility is required to register. If they're not consumed--if they're just analyzed,

then the facility--because the food is not being consumed--that's the key--the food is not being consumed in the U.S., then the facility that sends the food in is not required to register.

MS. : Okay. So, for instance, if a taste-test is done, that's considered consumed.

MS. SCALES: Yes.

MS. : But if it's not, then it's not.

MS. SCALES: Exactly.

MS. : Okay.

MS. SCALES: Yep.

[Pause.]

MR. HACKMAN: Good questions. Any others?

MS. : What if a salesman travels from the U.S. with samples; goes overseas and then comes back bringing the sample back in? Any problem?

MR. HACKMAN: The intent, though, is commercial. It's not for personal consumption--correct?

MS. : It could be ultimately consumed?

MR. HACKMAN: Then registration would kick in and prior notice would kick in.

MS. : When he comes back?

MR. HACKMAN: Unless it's for personal consumption.

Now, you're saying he's taking a sample from the U.S. overseas and bringing it back? What is it going overseas for?

MS. : [Laughs.] They're going to analyze it over there, and then he's going to bring it back, and maybe it's going to be consumed, eventually.

MR. HACKMAN: I would say that the better part of valor would be to register.

[Laughter.]

Because when it comes back in--and even if it's in luggage, and it's considered for commercial use, then it's no longer going to fall under an exemption for non-commercial, non-business use.

MS. : So the U.S. company's

doing the prior notice of the sample coming back in--right?

MR. HACKMAN: Yeah. Right.

MR. : This may get a little bit to the prior notice, but on the registration, what's the timeframe? We've gone through, since December 12th, when theoretically everybody should have been registered--we've gone through a period of the last three months which, from our perspective, there's been no input violations, notice, anything like that.

Before we get lulled into some kind of security, what's the time frame for the emphasis on regulation?

MS. SCALES: We published a compliance policy guide in December that basically explains our enforcement policy for both registration and prior notice. And, let's see--which one is it?

MR. HACKMAN: There's going to be an eight-month phase-in for regulatory--okay?

MR. : Starting--

MS. SCALES: For prior notice.

MR. HACKMAN: That's for prior notice. For registration, though, I believe if a product is coming into the United States from an unregistered firm, we're still in an education/communication mode until May 12th.

After May 12th--May 12th is the beginning of when Customs can issue civil money penalties for failure to have registration. Full enforcement begins August 12, 2004.

[Pause.]

MS. : On a foreign registration--I made one--he actually used me as the U.S. agent, but I never got the confirmation e-mail, which I think I should have got, even though he did it himself.

He's got a number, but I never confirmed the registration as the U.S. agent. Is that going to eventually expire, or is there some way--you know, is there going to be a list that says, "This number is no longer valid?" Or, you know--is there any way we can check to make sure, if someone gives you a registration number, that it is a valid

registration number?

MS. SCALES: If you call the Help Desk--it's--

MS. : Yeah, I called the Help Desk, and he just said have the Indian shipper re-register. But I haven't mailed the--had him do that yet.

MS. SCALES: So he registered.

MS. : As a foreign facility, using me as the U.S. agent.

MS. SCALES: Okay. And did he get the confirmation?

MS. : Uh-uh.

MS. SCALES: Okay.

MS. : Yeah--he--I imagine he probably got the confirmation and sent it back in. But, typically, it goes to the U.S. agent to confirm.

MS. SCALES: Well, actually--basically, the confirmation goes back to whoever registers. There's a separate confirmation--there's so many confirmations--[laughs]--but there's a separate

confirmation that should go to the U.S. agent saying "This facility designated you as its U.S. agent."

MS. : Yeah. I never got that.

MS. SCALES: Okay.

MS. : So I was just wondering, since I never answered that step, is that eventually going to expire?

MS. SCALES: It shouldn't. I don't know why you haven't gotten it. When did he register?

MS. : Probably eight weeks ago.

MS. SCALES: Okay. It might still be coming.

VOICE: [Off mike.] Another possibility is that he entered your e-mail address.

MS. : Yeah.

VOICE: [Off mike.] Now, if he gives you the registration and the PIN number, you can use that to get access to that registration and check it yourself, and [inaudible]. But you couldn't directly e-mail [inaudible].

MS. : Okay. And what if you're

not a U.S. agent, and someone just gives you a registration number? Are you just--is there going to be like a list or a--something that throws it out and says, "This is not a good registration," when you're doing a prior notice, or--you know, we're kind of taking everyone's word that this is the registration number.

MS. SCALES: Right.

MR. BRUSH: Apparently the way the system is set up, we certainly don't want to discourage people from entering prior notice. This is an education phase. So right now, we are not flat-out rejecting registration numbers if they're improperly entered.

MS. : Okay. But eventually it will click it out and say "Something's wrong?"

MR. BRUSH: After May the 12th.

MS. : Okay.

MS. SCALES: Basically--I mean, if--just a little follow-up on that--if you get a registration number from, say, an upstream foreign manufacturer, and you need that to submit the prior notice, it's

kind of--I mean, I guess it's like anything else, it's kind of a contractual agreement that they're providing you the right number. If they don't provide you the right number, it's kind of to their detriment, because if they don't give you the right number, the prior notice won't be correct.

So--and I don't know why they wouldn't give you the right number.

[Pause.]

MR. HACKMAN: Yes?

MR. : Okay, a farm that stores grain before shipping on to a processor--he may fumigate that grain. He is required to register--do I understand that correctly?

MS. SCALES: If a farmer grows the grain and holds it in a silo, he's exempt. But fumigation kind of kicks it into that other category of manufacturing and processing it. So, unless he's using it on his farm, he is required to register.

MR. : Okay. Now we have over--probably around 7,000 growers out there that

would supply our facilities. What's my obligation for knowing who has to register and who does not? I mean, we'd have a mixed bag. Some people would be fumigating grain on the farm in their storage, and other people will not. And I won't necessarily know.

MS. SCALES: Right. If your facility is required to register, that's your responsibility is registering your own facility.

With facilities you deal with, it would be good to let them know that they have an obligation to register, but it's--there's--it's not a prohibited act or anything to get a product from an unregistered facility.

MR. : Okay. Thank you.

[Pause.]

MR. : Type A medicated articles that come from Canada or Mexico, are those required--those facilities required to register?

MS. SCALES: What's a "type A?"

MR. : It's a drug.

MS. SCALES: Oh. Okay.

MR. : An animal drug.

MS. SCALES: Oh, okay. Okay.

MR. HACKMAN: Is it straight type A?

There's no other--it's just the straight drug?

MR. : Type A--

MR. HACKMAN: Type A's are typically high concentration drugs.

MR. : --[inaudible] drug.

MR. HACKMAN: So, if it's purely a drug, then it doesn't fall under registration, because it's not a food. It's considered a drug.

MR. : Okay.

MR. HACKMAN: Okay? But if, in fact, they're doing mixed operation, where they're doing Type A and Type B, then the facility should register.

MR. : Okay. Type A is exempt, but not Type B, you're saying.

MR. HACKMAN: Type B is typically not, because they're diluted and they're added with other grains and silage or whatever other materials, you know--carriers--for the Type A

medicated feed, which is then going to become food for animals. So, therefore, I would say that the Type B or Type C--Type C being the complete feed, definitely is considered food, and which would be required.

So if you have a facility that's exclusively manufacturing Type A, they'd be exempt, since it's pure drug. But if they do Type A, B, or C--you know, on top of the Type A, then I would suggest that they register.

MR. : Okay. Thank you.

[Pause.]

MR. : I'm still a little confused on this registration. Let's say you have a plant to manufacturer something, and they're bringing in, let's say, a component of your product form, let's say, England. And then components of other products are compounded with chemicals that could come from foreign countries.

Is it my duty to ask these companies to find out if they're registered? Or where--if we would have an inspection or something, is that

question going to be asked? Is everything that you use registered?

MS. SCALES: Well, it's by facility, so each facility is required to register independently. I guess the only thing I can think of is--and you might want to kick in with this--just, if you're trying to get an ingredient from another country, and they're required to register but they're not registered, and they're required to submit a prior notice but it doesn't have that registration number--

MR. HACKMAN: It'll be refused.

MS. SCALES: Right.

MR. : I mean, if they're in England, who tells them they're going to register. I mean is this worldwide, or--is this--I mean, is this something I should ask: "Are you registered?" Yes?

MR. HACKMAN: Yeah, you should ask that if you want to get the product in the country.

MR. : Okay. If it's not registered. It's food ingredient--

MR. BRUSH: If it's a food ingredient, you need to ask the question. But you mentioned a mixed bag of things, of food ingredients, or "chemicals." Depending on what the chemical is--

MR. : Well, that--see, that I don't know. I don't know--I've never seen a declaration of some components of, you know--have several different ingredients, and where they come from, I don't know.

Like, kind of the, the ingredients of the ingredients type thing.

MR. BRUSH: Ingredients of ingredients for food are still considered food, unless it's a contact surface or a pesticide.

MR. : Okay. And then it would be recommended that we get a letter from these companies that they are registered?

MR. BRUSH: I mean, it's fair game for you to ask that question. If you're doing business with a foreign facility that's manufacturing an ingredient for food, that facility should be registered.

MR. : And if they would refuse,  
then--

MR. HACKMAN: Then you won't get the  
ingredient.

MR. : --we're kind of in a gray  
area?

MR. BRUSH: If it turns out that it is a  
food ingredient and it's from a foreign facility,  
and we don't have that information upon the entry  
of the product into the United States, it will  
ultimately be refused entry into the United States.

MR. : Okay. Thank you.

[Pause.]

MR. BAKER: Other questions?

[No response.]

MR. BAKER: Okay. Let's take a very short  
15-minute break. If you'd be back here about 20  
minutes 'til, we'll start the second session.

[Taping stopped; taping resumed.]

MS. : [Off mike.] --page 22, you  
said the revised information is actual  
manufacturer--registration number for manufacturer

and shipper. But then when you go into the prior notice, what's required, you never say where you have to list manufacturer and the registration number. It's only "shipper" and "registration number."

So are you saying we do not need, on prior notice to have a manufacturer and registration number?

MR. HACKMAN: No, you have to. You need it.

MS. : So, is that in addition to the shipper and registration number?

MR. HACKMAN: Yes.

MS. : So--there's--okay.

MR. HACKMAN: Remember, we need the actual manufacturer there.

[Pause.]

MR. : We operate some egg and poultry plants in Europe. If we're sending quality-control samples to the United States, and we have an FSIS permit allowing those samples to come in, do we need prior notice on that?

MR. HACKMAN: No--that's--again, if it's exclusively under the jurisdiction of the USDA--no.

MR. : Our laboratory facility is not USDA inspected. We have the permit, but we're not inspected.

MR. HACKMAN: What--you're just doing analytical work on this? Is that what you're telling us?

MR. : We may make angelfood cakes and eat 'em for lunch.

[Laughter.]

So it could be consumed.

MR. HACKMAN: At the point it hits here, if it's exclusively, F100, USDA jurisdiction, then you wouldn't have to file a prior notice with us.

MR. : Okay.

MR. HACKMAN: If you make that product overseas and you use those components in making an angelfood cake, then we're going to have to have prior notice.

MR. : Okay.

And then I had another question. We make

some meat products under USDA inspection, and some meat flavors that are not USDA inspected. We might use MSG in both ingredients.

How do you know, at the port, whether the MSG we're bringing in is going into the inspected or the non-inspected product?

MR. HACKMAN: Well, the MSG would be a food in and of itself on entry. So you would be declaring that.

MR: : Right. But if it's going into the USDA-inspected product, it's exempt from these regulations. No?

MR. BRUSH: No. It's the commodity--if it's a commodity that's under the exclusive jurisdiction of the United States Department of Agriculture, it's exempt. Monosodium glutamate, I don't believe, is derived strictly from animal sources that would be under exclusive jurisdiction of USDA. Therefore, the monosodium glutamate is considered an ingredient of food, on which prior notice would be required--regardless of what its intended use at the end would be. It's the

ingredient itself that's coming across the border that requires prior notice.

MR. : Hi. I'm Jeremy [inaudible] with [inaudible], and we're involved in the transportation and the brokerage end of it. You put a big emphasis on registrations. I just want to kind of make sure we cover our bases.

Will our facilities overseas that hold product for the export clearance, and for consolidation be required to register--one.

MS. SCALES: Yes.

MR. : Okay. All those facilities all over the world--okay.

And then, coming into the United States, will our facilities along the coast and whatnot have to register, whether they're bonded or not?

MS. SCALES: If--they're holding food?

MR. : Yes.

MS. SCALES: Yes, then they are required to register.

MR. : Okay. And it is still if it's over 24 hours, right?

MS. SCALES: Well, we don't have a timeline.

MR. : Okay.

MS. SCALES: If it's--basically, the distinction is, if it comes to a stop for purposes of storage, then it requires registration. If it's kind of moving along like a post office, and the intent is not to have it come to a complete stop for any period of time, registration is not required.

MR. : Okay. Well, we would never intend for it to actually stop, but if it does need to be held for Customs clearance, or FDA and things like that--and it's just stored there for those purposes--bonded--in that case I would have to be registered.

MR. HACKMAN: You're safer if you go ahead and register, since it's free to begin with.

MR. : Yeah.

MR. HACKMAN: You know, that's the easiest--I think the easiest way for everyone.

If you, for example, were coming into a

facility and you were off-loading on one truck and loading onto another truck and moving out, you wouldn't necessarily have to register that facility. But if you set that food aside and stored it there, and waiting for another truck to come in, then you would have to register.

MR. : Okay. Thank you.

[Pause.]

MR. : I have a handful of questions. The first one, I'll give you scenario.

The product is produced overseas. The manufacturer sells it to a broker. The broker then exports it to the United States. When it arrives in the United States it goes to an inland warehouse, but the inland warehouse is not the ultimate consignee, it belongs to another company.

Does the manufacturer have to register?  
Or the shipper?

MR. HACKMAN: Both--isn't it?

MS. SCALES: Right.

MR. : You can't transmit both, I don't think.

I mean, they can be registered, but is it just on paper? When we transferred--when we've sent a prior notice, do we send the manufacturer and the shipper's ID?

MS. SCALES: Yes.

MR. HACKMAN: Yes.

MR. : And then, the ultimate consignee? It's not the warehouse, it's someone here in Kansas City that doesn't own a warehouse. Who would be the ultimate consignee? They're just holding it for sale.

MR. HACKMAN: Now, are you telling me that the warehouse is holding it for sale?

MR. : Yeah, it's holding it for sale.

MR. HACKMAN: But they don't own the product?

MR. : They don't own the product.

MR. HACKMAN: In essence--you're talking like a terminal warehouse?

MR. : Mmm--sort of.

[Laughter.]

The warehouse holds the product until it's sold to the ultimate company. But the ultimate consignee, or owner, is not the warehouse. All they're doing is holding the product.

MR. HACKMAN: Yeah, we're interested in the ultimate consignee, for the purposes of prior notice.

MR. : So the ultimate consignee, even though they don't hold, manufacturer, ship, would have to have a number, and that's the number that you'd want transmitted to Customs?

MR. HACKMAN: Well, they're going to have to at least be identified.

MR. : Well, in this case, the importer--the submitter--ultimately the consignee are all the same people. The warehouse is the outside product.

MR. HACKMAN: Well, the warehouse will have to be registered.

MS. SCALES: Mm-hmm.

MR. HACKMAN: Because they're holding

food. And insofar as how you would identify that chain of events in prior notice, I'm having difficulty understanding exactly what you're doing with the product. But, you know, as we mentioned in here, we need to know the manufacturer, the shipper. Obviously we ultimately have to know the importer. We have to know the ultimate consignee.

MR. : Okay.

MR. HACKMAN: That's the basics of the information we have to have.

MR. : Okay.

Coming in from Canada, going into an inland port, you file your entry, along with your prior notice, on an IT. Everything's been sent to Customs before the four hours, but the product comes on through the border into the final destination--say, Chicago. You don't get anything back from Customs or FDA until the product arrives in Chicago.

How are we going to know if prior notice is correct?

MR. HACKMAN: Well, first of all, you're

not going to get it to Chicago if you don't have prior notice; you know, you don't have the confirmation number.

You should get your confirmation number saying, "Okay, we've got your prior notice notification."

MR. : It hasn't been happening.

MR. HACKMAN: Okay. That should be happening.

MR. : It comes along with--when it clears in Chicago, the prior notice comes with it.

MR. CRAIG: Right. That's part of the evolution of the systems. That will change on March 12th. Because what will happen is, when your cargo first arrives at the U.S.-Canadian border, if it's an in-bond, and it's merchandise that's subject to the Bioterrorism Act--if it's food, or feed, or any of the components thereof--you're going to need to show that you filed prior notice before the CBP officers will allow it to leave the port of arrival.

Now, if there's something that is--during--how this rolls out is, you're going to need to have that prior notice when then in-bond documents are executed, because the inspectors are going to have to check that; they're going to have to check the prior notice database to see what the FDA wants us to do with that merchandise. Because if it's a threat we have to hold it at the port of arrival. We don't want that stuff transiting.

There are--there's certain leeway with correcting--or, not "correcting", but perfecting the prior notice along the way, before you get to the port of destination, or where the entry is going to be made, which is particular to just in-bond itself. But you've definitely got to have that prior notice number before that shipment hits the border, or it will have to--it just sits there. It won't be allowed to proceed to any other port.

MR. HACKMAN: I believe that's--and I think Melissa appropriately pointed out--I think that's May 12th, and not March 12th.

MR. CRAIG: Yeah--May 12th.

MR. : What happens if you have to cancel a customs entry that has the prior notice along with it, because they delivered to the wrong port? And you have to file your entry two or three days later, after it actually arrived--not knowing that it arrived--you're thinking it's coming to the right port, and it's been delivered to the wrong port? You cancel the complete entry and refile--

MR. CRAIG: That's what you did?

MR. : Yes. When you cancel the entry, does that also cancel the prior notice?

MR. CRAIG: It would depend on the mechanism; how prior notice was created. If it came through ACS/ABI, there's a transaction for canceling prior notice.

MR. HACKMAN: File a new prior notice, and the clock starts all over.

[Pause.]

MS. : I have a problem in Brazil. The farmers of coffee are uniting and taking the farmer exempt with the FDA--that their farmers are manufacturing it, but they're

processing it, but they are farms.

So how--will my prior notice--you know, if I had to put manufacturer and registration number, I'm not going to have that, because they're doing farm-exempt. It's coming directly from the farms to the United States. And it might go to a holding facility, but it's not a manufacturer.

So how are we going to treat that with prior notice, if I do not have a manufacturer registration number, because it's a farm.

MR. HACKMAN: They can't be exempt if they're processing it.

MR. CRAIG: What processing are they doing?

MS. : They're farms. They're drying, milling, bagging--

MR. HACKMAN: If they're milling, then they're now into manufacturing. The drying aspect of it, it would still be exempt, under the farm exemption.

MS. : So, if they're sorting, even, they're processing; they're manufacturing.

MR. HACKMAN: Sorting may not--

MS. SCALES: Sorting is not--

MR. HACKMAN: --is not considered manufacturing. But if they're milling, that now becomes a manufacturing step.

MS. : Okay.

MR. HACKMAN: And, in essence, if--

MS. : And even if it's on the farm, they have to register then.

MR. HACKMAN: Mm-hmm. If they're milling, they're no longer under the farm exemption.

MS. : Okay.

And milling would be--

MR. HACKMAN: Grinding--whatever.

MS. : Drawing?

MR. HACKMAN: Grinding.

MS. : Grinding--okay. It's not milling, then. We call it "dry mill." It takes a coffee bean, it's drying it out, taking the husk off, putting it in a burlap bag; possibly sorting it to bean size.

They're [inaudible] by Brazil as they are

farms.

MS. SCALES: If they're drying it naturally; if they're putting it like a warehouse or something and drying it--

MS. : Uh-uh--drying it naturally in the sun.

MS. SCALES: Okay. Then that's still exempt.

MS. : Okay. So how do I make my pre note, when I don't have a manufacturer registration number.

MR. HACKMAN: You've got a grower, though.

MS. : But they're exempt.

MR. HACKMAN: I know, but you can give us the grower.

MS. : So you would list it as a grower, not a manufacturer then?

MR. HACKMAN: Mm-hmm.

MS. : And then you wouldn't have to have it?

MS. SCALES: [inaudible] there's a distinction between manufacturer of commodities and

raw agricultural commodities. So, you'll be asked for the manufacturer if it's not--I guess if you don't provide the grower, you'll be prompted for the manufacturer.

MR. HACKMAN: And also it ties back into your commodity codes, too.

MR. BRUSH: Yes, it's the FDA product code that you provide, actually drives the requirement. So, if, based upon the product code that you've provided, if it makes the determination that the product has been altered from its original state, then it's going to be looking for a registration number.

MS. : Okay.

[Pause.]

MR. : If I have goods brought in that are classified for prior notice as food ingredients, accompanied in the same shipment with non-food ingredients, do they all get held, or are they isolated? The better way is not to do it together, I understand that part. But if they ship it together, and it doesn't pass prior notice on

the food side, do the non-food items get held also?

MR. CRAIG: When you have what they called "comingled shipments," if--it will be allowed for you to separate out the stuff--the merchandise that isn't covered by the act.

But, it will generally need to be done under the rules for how we would do that in a non-BTA situation. Probably you'd have to be under Customs' supervision, in a warehouse facility. It may require a manipulation order in order to do that.

So, again--additional costs. And, you're right, it's better to keep the stuff segregated before it gets here. I know sometimes that can't be helped.

MR. HACKMAN: And you could kick in--depending on what the other articles were, it could kick in some 801(a) concerns for us; what you comingled in that shipment with the food articles.

So, that's another reason why it's best to keep them separate.

[Pause.]

MR. : I'd like to follow up on his question.

If you cancel your entry and you have to re-transmit your prior notice, and you're saying your clock starts over, but according to his scenario the food's already at the other port. Are you automatically in violation, and thus risking having your food held?

MR. CRAIG: Well, what will happen is once you cancel and then resubmit--

MR. : Mm-hmm.

MR. CRAIG: --the systems are going to enforce the time limit. So, you know, if it's a four-hour window, you just won't be able to pick up your merchandise for the four hours, or until FDA completes their processing. Because our officers will be precluded from releasing the merchandise. Our systems won't allow them to release the merchandise until the FDA has a chance to do their risk assessment.

MR. : So it will be treated differently than if the food just arrives, and no

prior notice was ever submitted.

MR. CRAIG: Well, their food's not going anywhere either.

MR. : Right.

MR. CRAIG: Right.

MR. : Okay.

Next one is if you're FD-4 code, but it's a sample--and you already said earlier, samples don't have to--as long as it won't be consumed, it doesn't have to be registered.

So you're an FD-4 code. you have to submit prior notice on an FD-4, but it's not food.

MR. CRAIG: Okay. Are you--what he's referring to, in our automated system, along with--in the harmonized tariff schedule, there are other government agency flags that are in there. And FDA is one of those flags. And there's, I think, five or six different value settings for those flags. And each one of those numbers determines what level of FDA information needs to be filed.

An FD-4 applies to the Bioterrorism Act,

and it says that for that particular HTS number or commodity, prior notice is required. It would be something that is not--it's something that clearly identifiable, from a system perspective, that our system would be looking for prior notice.

In this situation, where you have a sample, what the system--how you--the work-around for that, because although the system says, "Yes, this commodity requires prior notice," its end-use, because it's not for consumption, would theoretically exempt it. And you'd use an affirmation of compliance--

[End tape side A]

[Taping interrupted.]

MR. CRAIG: Yes, the broker's software should have that ability to provide the disclaimer for that particular thing.

MS. : [Off mike.] [inaudible]  
Can you come out with it. Sorry.

MR. HACKMAN: I do need to let you know that Melissa has to catch a flight, very shortly, I think. She's got a one o'clock flight. And if

you've got registration--any further registration questions, you might want to get them forward here so that she can make her flight. I would hate to be the one responsible for having her miss the flight and not get back to Rockville.

MR. : I have two questions, and I'm following up on Mike's question.

The first one would be: you said use an affirmation of compliance. Is that in the OASIS module, or is that in the prior notice, that there's an affirmation.

MR. CRAIG: There are affirmations of compliance codes that were added on--added on to the prior notice--that were added on to cover the prior notice scenarios. So, you know, they're compatible with OASIS. When we move the data back and forth between CBP and FDA, the systems know what's happening.

so it was augmented onto the standard FDA 701--or the 801(a) type codes that were used.

They're still, because it's FD-4, going to have to submit something. But then at the time

that they're actually filing through the OASIS link to receive the "may proceed"--you'll be able to disclaim for BTA purposes, but you may still have admissibility issues under 801(a) that you may still--you know, have that type of data in there.

MR. : Okay. And it's at that point where you put in the disclaimer.

MR. CRAIG: Right.

MR. : Okay.

Another question also about the FD-4 flags--sorry about this--

MR. CRAIG: No problem.

MR. : Issues come up with several of our clients in the pharmaceutical area, where they're being kind of sucked into prior notice on things that are, to them, clearly pharmaceuticals and not food. One of them may be--just for an example--somebody bringing in a Type A medical drug; as we talked about before, no need to register. however, when you bring it in, there's a Customs' ruling, putting it in the provision--the food provision. They're stuck both

ways--okay? Because of the ruling, which puts them in a particular classification, they're subject to FD-4, and they're saying "which way do we go?" Which agency do we even start fighting?

I guess my question for you guys: is there a way to go back and say, "FDA, will you reconsider the FD-3 versus FD-4 flags on some of the products that are out there?" There's general people to contact with questions and comments, but is there a way to just go about doing this?

MR. CRAIG: The Type A article, though, is not going to be used by itself. It must be added to other ingredients before it can be fed. So I think that's the--and I don't want to use the word "trap," but that's kind of where it's falling into under the FD-4 code, because we know that Type A medicated article cannot be fed directly to an animal. It has to be added to other ingredients. those other ingredients are considered food components, or food ingredients, therefore--that's why it's falling under FD-4.

But if you want, I mean you could send--

MR. : So you're saying--

MR. HACKMAN: There are a lot of different places with regard to the flags. We have a Division of Import Operations that deals with flags, and they have a Customs liaison officer who can deal with those questions. But also at the Center for Veterinary Medicine we have what's called the Division of Animal Feeds, which we could give input onto that question.

But, in general, because it's a type A--like I said in the beginning--and I hate to be repetitive--Type A medicated articles cannot be used straight by themselves. They must be added to other ingredients before they're fed to an animal. So that's why I think it came up as an FD-4 flag--even though it's a drug substance.

MR. : Okay. You say you don't need to register, but you do need to provide prior notice. So effectively, then you need to register.

[Pause.]

MR. HACKMAN: Umm--I would say, again, the better part of valor is to register.

MR. : But it's a drug substance, so it's going to be kind of confusing to the manufacturer why they have to register.

MR. HACKMAN: But if you put it in the way that I just articulated it, that you cannot the Type A medicated feed by itself--it has to be added to other ingredients--therefore it's becoming a component of food--even though it is a drug.

MR. : Okay.

MR. CRAIG: The issue is that the HTS code is improperly flagging it as an FD-4? Is that what we're looking at?

MR. : Well, that's what we would argue, I guess--on behalf of the client. The client has a Customs' ruling mandating their use of a particular HTS code.

MR. CRAIG: Mm-hmm.

MR. : That code is flagged as an FD-4.

MR. CRAIG: Okay. If that's your argument, you can see me when we get done, and I'll take that up with our Division of Import Operations.

MR. : Okay.

MR. CRAIG: We get a number of those that we've evaluated.

MR. : Okay.

Another example may be--I think it's Heading 3001: Pharmaceutical Products; it's glands, organs--okay? Those are all marked FD-4. But they're for therapeutic or prophylactic use--by name in the heading. Okay. So it couldn't be there for food, but it is marked FD-4.

And those are the kinds of issues we're finding, and they're saying "What are we doing? Why do we have to provide prior notice on this?"

MR. HACKMAN: We'll reevaluate those.

MR. : Thanks.

MR. HACKMAN: Sure.

[Pause.]

MS. : I have a question on port of arrival.

MR. CRAIG: Okay.

MS. : I've had some debate on this, and some tell me that it is first port of

call, and others are telling me it's the port the container's taken off on. Can you verify?

Port of arrival? Is it where--the first port of call, or where the container is actually unloaded from the vessel?

MR. CRAIG: It is where the article is brought into the Customs territory of the United States; where--you mean, if it's like a coastwise movement; it's moving down--

MS. : It's on a vessel--

MR. CRAIG: It's on a vessel--

MS. : It's going through various ports--

MR. CRAIG: --goes to Seattle first, and--

MS. : --and mine's not getting off--

MR. CRAIG: --but that it's going to be discharged in Los Angeles. Prior notice would be filed before arrival in Los Angeles.

MS. : Even though it stopped at Seattle first.

MR. CRAIG: Right.

MS. : So it would be L.A.

MR. CRAIG: Right.

MS. : Okay.

Umm--a question that's come up--and this maybe is out of your realm, or it's just a fluke: my office in Argentina wanted to send a product to my office in Denmark; had a U.S. courier, that's international, go in, pick it up. Instead of having a direct flight, they fly via Miami to Denmark.

They wouldn't pick it up because they were not registered, but they didn't have to be, because they weren't sending it to the U.S. But the courier said, "Because we're landing in the U.S., you have to be registered." And, to me, that would have fallen--it wasn't trans-shipped, it should have been in and out at the same port.

Now, am I correct in assuming that the courier was just totally off base here and didn't know what they were talking about? Is there any reason--

MR. HACKMAN: In this case, it should have

been--the scenario is similar to others that were given where a product may come into the port, but it's not off-loaded and nothing's done with it, and it goes immediately out of the port, then that would get you out from underneath it. So I think they probably just made a mistake on that one.

MS. : Okay.

And then my last one is: I have been receiving notices of non-conformance from the FDA. And this is something that I'm just starting to receive. I've never received these before. But, according to--in here it says that used to be the old way of doing it, not the new way of doing it. And it just gives me an entry number. It sends it to me, either as the importer or the consignee--either one--but it doesn't tell me why, what, anything. When you call the phone numbers, they do not call you back. Some of the brokers have yet to find out why it's on hold.

Do you know what's generating these notices, and what's going on with these?

MR. HACKMAN: That's the first I've heard

of it.

MR. CRAIG: Yeah. It's not related to the Bioterrorism Act.

MR. HACKMAN: What's the title on the notice?

MS. : "Notice of Non-Conformance/FDA." I've never received them before. I've gotten two in the last month.

MR. CRAIG: You may be getting a notice as a result of non-compliance with 801(m), which is the registration/prior notice side of things, and not necessarily 801(a). Because if you're getting a notice under 801(a) that your product, for some reason, doesn't meet the requirements to enter the United States, it states on there the reason why it's being detained.

MS. : "Inadequate or improper information," is what--

MR. HACKMAN: That sounds like it's an 801(m) issue. So that's one of the new notices that are coming out.

MS. : Now, is that to do with

FDA clearance, or FDA prior notice?

MR. BRUSH: I think it's actually 801(a). If I can see you when we're all done and you can give me those entry numbers, I'll get back to you on those.

MS. : Okay.

MR. HACKMAN: Any other questions?

MR. : Yes, I guess I've got to ask a stupid question. What's the difference between 801(m) and 801(a) to the rest of us?

MR. HACKMAN: Sorry. 801(a) has been the import procedures that have been in effect for a long time. The new regulations for registration and prior notice fall under 801(m), which are still--that's part of the interim final rule. That's where we're getting the authority to do what we're doing under the Bioterrorism Act.

801(a) basically is stating that the product that you're offering for import meets all the requirements of the United States; and also that the product meets the requirements of the country which is exporting it from. So if it's a

product that's a prohibited product from a country that it's being exported from, it won't be allowed into the United States, because it's a prohibited product. But 801(a) is how we've done business for years and years and years, up until the Bioterrorism Act regulations came into effect.

[Pause.]

MR. BAKER: Any others?

[No response.]

Well, with that, I'll thank everyone here for your attendance. Thank the panel for doing a great job. And if you have any questions--again, you've seen, you've got copies of the slides. By all means, you know, get on the web, get on the phone.

[Session concluded.]

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