

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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

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

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P R O C E E D I N G S

MR. : Good morning, and thanks for doing this for us.

In terms of registering, U.S. agents representing foreign facilities, I've had a lot of trouble trying to make people understand in different countries what is the legal ramification of the U.S. agent, and they have trouble understanding what kind of contractual agreement they need to have with a U.S. agent, and I can tell you as of this morning in Europe they were still unclear about the legal ramification of U.S. agency.

MS. : In terms of the -- it usually comes up as a question of what's the liability of the U.S. agent. There is a whole body of case law or legal law governing agency -- agents in this country. So basically under that, agents have a duty of care, but we don't specify the liability in our rule because there is a whole set of laws that governs agency relationships and people serving as agents are under those obligations now.

In terms of registration, what we say is that really we view the U.S. agent as a communications link.

They are responsible for their actions, so if they knowingly submit a false statement to us, they are liable for that. If the -- because they are certifying that the information they are submitting is true and accurate.

For example, if they tell us they are authorized to register the facility and they are not, that's a false statement on their part.

If the facility gives them false information and they have no way of knowing that and they submit it to us as part of just sending forward what the facility has sent, we will not hold them liable for that, we will hold the facility accountable for that. So it really is a matter of the legal liability from our perspective really is just going to what they know on their own, and then other than that, the relationship between them and the facility that they are contracting with is governed by any other agency law in your country, or agency law here.

MR. : Okay. Now in terms of the foreign registration for a facility, you have a case where you have a bottling truck going to a facility who is producing wine in this case. Who needs to register? The actual producer who has the liquid in his vats, or the

trucking with his bottling plant within the truck, who is bottling the liquid? One of the problems that we have is that we have the growers, we have the people that are bottling the product. Sometimes the product is bottled within a facility which is very easy to understand who needs to register, but who has the responsibility to register when the product is being bottled within a facility that has bottling facilities?

MS. : In that case, that is an excellent example of a facility that's a mobile facility that is manufacturing and processing, and so that is where the bottling facility must register. That is not a usual course of business as a carrier. That is a manufacturing and processing facility that is moving from site to site.

Another example could be a feed mill that moves from site to site and grinds up the grain. Those would have to register. They would be the second foreign facility that's manufacturing and processing that would exempt that first facility that actually has the wine in its vats.

MR. : Okay. So that would be the mobile facility.

MS. : That would be the mobile facility would have to register.

MR. : All right.

MS. : And I'm going to ask you to let me take the next one. And if everyone could hold it to one question, and then try again, because that's probably the fairer thing to answer other questions.

MR. : That's fine. And I hope you get a vacation after all this.

MS. : Me, too.

MR. : When it comes to something like a doctor's office or a vet's office where you are giving out food samples, but they are not necessarily a retail business, would a doctor's office -- say dietary supplements they give to patients, would they have to register? The same with the vets?

MS. : They fall, if you look in the rule, the preamble to the rule, they fall under the restaurant example because their consumers happen to be animals, so they would fall -- they are preparing or serving food directly to consumers for immediate

consumption. In those cases the consumers are the animals.
So, no.

MR. : So that holds true for doctors' offices, too, where they give dietary supplements?

MS. : A doctor who is giving -- a doctor as in a vet --

MR. : Well, a regular doctor for humans.

MS. : Oh, yes. Same. You know, the restaurant exemption is -- it's really broad. It's not what you think of typically as only, you know, the restaurants you and I go to, but it's any facility that prepares or serves food directly to consumers for consumption is exempt. And so it could be a doctor's office, it could be a vet's office.

MR. : Okay.

MS. : It could be an animal shelter.

MR. : And that's true even if they take it home and eat it at home, then, as opposed --

MS. : Yes. When we say immediate consumption, we recognize takeout also.

[Laughter.]

MR. : In a business environment, there are many facilities overseas that manufacture food but don't export. Given that your deadline is December 12th, how do you intend to handle new registrations for a facility that came onboard with an intent to export after December 12th?

MS. : The requirement to register by the 12th is for facilities that are doing business now. So if you are doing business now, you have to be registered by the 12th. If you start doing business after the 12th, whether it's January or two years from now, then the obligation is that you must be registered before you begin to export food to the United States. So if they come online in six months or change that facility that is only doing domestic abroad and now decides to do business with the United States, they would just have to register before they started doing business in the United States.

The registration system will be available now and forever.

MR. : Thank you.

MR. : Actually you just answered one of the questions I had, which was the ongoing process. So

the deadline is not necessarily December 12th. Next year they can register, the year after that they can register.

MS. : The deadline is December 12th if you are doing business now.

MR. : But if you are not?

MS. : If you are not doing business now, then the deadline is before you start doing business in the United States. That is your deadline.

MR. : Well, basically the December 12th deadline is when the goods arrive into the United States or when they get shipped out of the facility?

MS. : In terms of registration, the duty to register is if you are manufacturing, processing, packing, or holding food, and that food is for consumption in the United States, you need to be registered by December 12th. For prior notice, you are not going to be able to file the prior notice until December 12th, so shipments that start before then we'll worry about in terms of enforcement discretion. I don't think that is really going to be an issue.

MR. : So the December 12th deadline is for the prior notice, really?

MS. : It's for both. It's for both.
If your facility is doing business with the United States
now, you need to be registered by December 12th.

MR. : Okay. Thank you.

MS. : Just a point of clarification.
So if your manufacturing plants are USDA-inspected plant,
whether you are processing chicken, meat, cooked sauces,
you are not -- you don't have to register?

MS. : It depends on whether your
facility is exclusively a USDA facility. For example, if
you are making pepperoni pizza, that is a USDA process, but
if your facility also makes cheese pizza and there's no
meat on it, that's not a -- that is in FDA's jurisdiction,
so your facility is not solely regulated by USDA, it is
coregulated by USDA and FDA. So you are correct with
respect to if your facility is solely under USDA's
exclusive jurisdiction, then you do not have to register
with us.

MS. : So many of these plants do have
a USDA officer in plant or visits and does the inspections,
so I mean a lot of plants will make, you know, cheesecake

and they also do products that have meat in them. So they have a person who comes around. Are they to register?

MS. : If they're making cheesecake and have -- the fact that you have a USDA inspector in the plant means that you have USDA-regulated products. That does not speak to whether you don't have any FDA-regulated products. So your facility needs to look and see whether they have FDA-regulated products.

In the example you just gave, the cheesecake is an FDA-regulated product. They would have to register. They would be a mixed type facility.

MS. : Okay. So mixed facilities still do have to register?

MS. : Yes.

MS. : Okay.

MS. : The way I understand in the interim rule that if you attempt in case of an emergency, if you attempt to contact the U.S. agent and you couldn't contact them, you will still resource to the facility's phone number to contact them? Am I correct in that?

MS. : The question was if we tried a U.S. agent and we can't contact them, we'll try the facility. Let me answer it this way:

The obligation is to have a contact phone number 24 hours a day, seven days a week. That is the number we will call. If you don't give us a different -- if you are a foreign facility and you don't give us an alternative contact, we will use the U.S. agent. Depending on the emergency, if we can't contact them, we will try somebody else, another number. But that doesn't relieve you of the obligation to have an emergency contact that is available.

So, you know, I don't want to answer that in a way where people say, well, okay, if my agent is not available, they'll try somebody else. That's not -- we don't want to spend time and lose time calling multiple phone numbers.

MS. : I just want to make sure that we emphasize that in the facility phone number it is very important that the facility giving that phone number should understand that that could happen, and somebody on the other hand should be able to answer in English.

MS. : Well, not -- if you're giving us a different emergency contact at the facility, that would be helpful. If you are using your U.S. agent as the emergency contact, then the phone number you give us in the owner field does not have to be English-speaking because we are looking at the U.S. agent as your emergency. But so yes and no I guess is the answer, depending on what you are doing with your emergency contact.

MS. : Thank you.

MS. : You said that transloading --

MS. : Can you turn the mike down?

MS. : -- transloading facility must be registered?

MS. : Yes. The transportation hub or the unloading facility, yes, has to be registered.

MS. : Just like bringing food for export, so it's like a temporary --

MS. : If it's a holding facility, then it has to be registered, yes.

MS. : So even 50 minutes, you say, right?

MS. : Yes.

MS. : Okay. So there is no such a thing temporary food, then?

MS. : No.

MS. : Like an FDA exam -- I mean there is no facility so we bring it, our warehouse must be registered.

MS. : Correct.

MS. : Thank you.

MR. : Actually I will represent --

MS. : Can you move a little closer to -- thank you.

MR. : I will represent as U.S. agent for my father's foreign facilities, and my question is do I need to make a legal representative office as U.S. agent in here?

MS. : Do you have to make a --

MR. : Because I live here, yeah.

MS. : I'm sorry, do you have to make?

MR. : Legal representative office as a U.S. agent.

MS. : No, you don't -- all we're -- when you submit the form and you tell us the facility says

here is who the U.S. agent is, and they tell us the information is truthful and accurate, part of what they are telling us is the person they have designated resides or maintains a place of business here and is physically present here. They don't have to be a lawyer, they don't have to provide any authorization or legal documentation to us. They just have -- they are certifying as part of submitting that registration that they have met the requirement.

MR. : Because I'm not doing business in United States, so --

MS. : But do you live here?

MR. : Yeah, I live here.

MS. : Yeah, it's reside or maintain a place of business, so as long --

MR. : And I'm a representative as a U.S. agent for --

MS. : And that would be -- and if you're physically present here, as you are, you have met the obligation.

MR. : Okay. Thank you.

MS. : How much --

MR. : We've got three more.

MS. : We have about three more minutes, so we are not going to be able to hit all the questions, I don't think.

MR. : What's to prevent a foreign company from listing a U.S. agent without the knowledge of that U.S. agent?

MS. : We have had that happen. What happens after you submit a registration and tell us who the U.S. agent is, we send back a confirmation to the facility. The facility is considered registered at that point. We also send a notice to the U.S. agent at the address that the facility provided, to let them know you have been designated a U.S. agent by such and such a facility.

We have heard from several agents that that was news to them, and in which case we have gone back to the facility and said your registration has problems with it and you need to correct it, so they are initially registered, but we do take that into account and double-check that the agent knows they're the agent.

MR. : Thank you.

MS. : Good morning. Any of our facilities worldwide qualify as the requirement as a holding facility, and at any time any of those facilities could accept food for shipment to the United States. So it is our intention to register all of our facilities worldwide. What is our obligation with regard to cancel that registration, because we will be open for business throughout the world.

MS. : As long as you really envision that at any given point those facilities, even if they are not holding food in that particular month but they may be next month, no duty to cancel.

MS. : Okay.

MS. : You're engaged in doing business and it may be that if you are handling all food products at all of those facilities at any given time you want to check the "most all" box instead of the individual box.

MS. : Right.

MS. : But the fact that you're registered for typical business operations, you know, even -- you know, your manufacturing line goes down for repairs, you don't need to cancel or update or do anything. I mean

we accept normal business ebbs and flows. But if you are truly taking a facility off line and it's not going to do business any longer, that's when we ask for the cancellation.

MS. : Okay. Thank you.

MS. : I don't know if this goes more to prior disclosure or to registration, but when you are talking about gray market purchasing overseas and it's -- and you don't know if the actual manufacturer is registered or how to get that number, the registration number for the prior disclosure even if they are registered, how do you deal with that situation?

MS. : That is more of a prior notice. And what I said, and Mary may have another answer, too. What I have said to traders -- I mean not even so much the gray market, but people tell me I'm a trader on the open market, I buy food and then I send it into the United States, and the manufacturer doesn't know I'm buying the food and I don't know whether they're registered, this is going to be a change in practice. Part of the purpose of prior notice and registration is our government wanted to make sure we knew what was coming into the country and who

was producing that food, and supplying it to American citizens.

And so what I say to traders is that you don't want to buy food if you don't know the manufacturer is registered and you don't have the registration number, because the food cannot come into the country and be delivered to the owner, the importer, or the consignee. That is a limitation imposed by the Bioterrorism Act. So it does require a change of business and it doesn't make sense to buy it just to have it held at the port.

Okay. And this will be -- I'm sorry, the gentleman will be the last question because Cindy is telling me it's time, and if we have time after prior notice, we'll come back to registration.

MR. : What is your understanding for foreign registration when a domestic importer purchased something that was made 100 years ago and there is no need to trace -- there is nobody, you know, there is nobody to trace. I have -- you know, I deal with wines, and those wines are fine, but how do we do this? Who do I -- what phantom do I go and --

MS. : Yeah, that actually I think is -
- that is one of the questions we did answer in the rule;
probably not as clearly as people can find it.

If the facility is out of business -- there's two
sets of the old wine question. There's the facility that
made the wine is no longer in business, and therefore I
can't have -- I don't have a registration number because
the facility doesn't exist. Then there will be, my
understanding is, a new affirmation of compliance where you
can say registration isn't required. Some day there will
be a new affirmation of compliance.

[Laughter.]

MS. : But basically for those kinds of
unique circumstances that are a little different, there is
a mechanism of once you file the prior notice, you get a
message back that prior notice is inadequate because you
haven't given us the registration number, that there is an
appeal mechanism where you can give us documentation and
other information.

MR. : Even though when we purchased
this, when the domestic importer purchased this, he has to
provide, in order to import it through U.S. Customs, and

BATF, he has to provide it with all the documentation from who he has purchased that from, and the documentations are issued by foreign governments which are already established entities.

MS. : Right, but the --

MR. : I mean the question that I had was why isn't it easier just to have those --

MS. : And that might be some of the information you have to give us because part of the requirement in the Bioterrorism Act says FDA must receive the prior notice and the other requirement is registration number is required. So we can't just issue a blanket waiver for not having a registration number or not knowing who the manufacturer is. We don't have a data field that we can just easily take that in.

MR. : This is not what I meant. I meant in terms of alcohol, for example, you have a specific way of doing business. Every shipping of business is regulated by government entity.

MS. : I understand, but that's not what -- the Bioterrorism Act does not say even if you give notice to another agency, you don't have to give notice to

FDA. So FDA still has to get the information separately. And I will note that for wine, BATF and Customs are not responsible for the health and safety aspects of the wine. They are responsible for the permitting, the labeling. But the quality of the wine, the wholesomeness, the safety of the wine is FDA's jurisdiction.

MR. : I a little bit disagree with you because it is -- in order to be able to import the actual wines, you have to provide a certificate of conformity and origin, and it's delivered by --

MS. : I'm not disagreeing with that. I'm just saying that there is no -- that does not supplant what is a separate obligation under the Bioterrorism Act for the information that FDA must receive. And so we could talk about that off line, but that is a different obligation and this is a new requirement that is imposed by this law in terms of what we have to get. And we do have an issue with how do we handle wine that has been produced many years before that we still have to wrestle with what is the best way of doing that.

So I invite you to submit comments on that as part of the record.

MR. : I did it three times, and I didn't hear anything back.

MS. : Well, as I said, you are not going to get an individual answer. That's part of the comments we need you to send to the docket in terms of the things we are looking at between now and December 24th, where you think we have not answered those kinds of questions. That's what we would look at for issuing another rule.

MR. : We have ongoing shipments and --

MS. : Okay, but we will -- right. I understand.

MR. : Thank you for the first half of this session. We are going to break for 10 minutes.

[Recess.]

MR. : If you will step up to the microphone, and again I ask that you speak up and directly into the mike so those in the front and back can hear the question.

MS. : My question is about in-bond products that have arrived in the U.S. prior to December 12th.

MS. : Can you move closer to the mike, please.

MS. : Sure. The in-bond products that are in the U.S. prior to December 12th, and down the line comes February, our customer wants a portion of it to be tax-spate (phon.). We've already missed the window, the timeframe for a PN because they arrived before the rule was in place, so how can somebody go about clearing those?

MR. : Right. I think that in the initial phases, for that stuff that's in that gray area at implementation, we are going to have to look at each and every case and make a determination there. I think both agencies are committed to making this reasonable to implement, especially at the beginning. We understand, though, there will be some growing pains and I think we will all learn some important lessons through this.

MS. : And if the food arrives before December 12th, prior notice is not required.

MS. : Exactly. So what if it's arrived and it's in-bond and down the line comes next year, after December 12th, we need to -- a portion of it to be tax spate.

MS. : Well, tax is a Customs issue.
That's a different issue.

MS. : Okay. Thank you.

MR. : Hello. My question deals with imports. If I am a company that makes foods and nonfoods and I bring in a raw material like lactose for use in an OTC drug product, how is FDA going to know that this is intended for a drug product as opposed to a food product and not hold it up needlessly when it comes into the U.S.? Same with saccharin or a lot of these other common raw materials that are both in drugs and in foods. How do we make sure that the ones that are not intended for foods --

MS. : The product code will be different.

MR. : It will be?

MS. : Uh-huh. There are different product codes for drug ingredients than there are for food ingredients. So you'll use a different product code.

MR. : And my understanding is that the current system doesn't cover that. Is this going to be something new? Because right now there's an HTS code, for example, would not --

MS. : That's the HTS code. I'm talking about the FDA product code.

MR. : Okay.

MS. : So you may have one HTS code with, you know, a whole bunch of different FDA product codes. What we key in on is the product code and for the HTS codes, the tariff schedule codes, we have identified which tariff codes require or may require prior notice. Right now we have flagged them as what is an FDA-regulated product and which might be a regulated product. For those of you who are brokers, those are FDA FD 1s and 2s. We now have the FD 3s and 4s, and that relates to prior notice. So the harmonized schedule code will be flagged so you will know what requires prior notice, and the FDA product codes we are planning to put on a Web site which FDA product codes require prior notice and which don't. Not which don't, just which do.

MR. : And then that would still -- would you still be allowed to use that through the ABS or the Customs systems in terms of it breaking out? You wouldn't have to go through the FDA prior notice system to get to those?

MS. : Right.

MR. : Okay.

MS. : What we hope to do with the FDA product codes is put it as a tutorial and what is the FDA product code billed and then on a separate Web site just a list.

MS. : My question is to Leslye. It's regarding U.S. agent. Presumably we would receive a few e-mails to our surprise that we are appointed a U.S. agent. At this point we could reply to FDA as disagreeing. My question comes to you in the future down the line if we did accept it as a U.S. agent representing a foreign manufacturer, in the future if we do decide we do not want to represent them anymore, is there any way other than communicating with them? We have no way of communicating with FDA to release this burden. So is there something, once we accept, we start -- because we cannot go in the registration to change that. Or is there any way that we could going back to --

MS. : You could send us an e-mail to the same fww.ferls (phon.), the address that was at the

beginning of my presentation. You can send us an e-mail and let us know.

MS. : Thank you.

MS. : My question involves fresh produce being imported from Mexico. Say you're bringing in some garlic, so you have to do like your two-hour prior notice to take it across the border. Then it goes to say a plant up in Los Angeles where they just peel it, so in a sense it's like just husking it. So does that come under the farm rule where that facility that peels it does not have to be registered, or should they be registered?

MS. : A facility that's peeling it is not a farm or even if it is, it's not -- unless they happen to own that farm in Mexico, peeling still was not one of the listed manufacturing activities they can do. So they would be a manufacturer processor, would be required to register.

MS. : Okay. So like, for example, lettuce, if you are removing outer shells and putting them into a case in the field, that's fine. But if you're moving that truckload someplace else and then processing

it, then that processing plant does have to have registration?

MS. : Correct.

MS. : Okay.

MR. : Hi. I work for a broker, and we have received a list of tariff numbers flagged FDA 3, FDA 4, but on reviewing them we noticed that there are some that are in our opinion that are not flagged that should be flagged. Specifically processed foods. Is there going to be another list of tariff numbers issued?

MS. : My understanding is that the listing that you received is not complete.

MR. : Okay.

MS. : We sent over, I believe, 2800 HTS codes and only 800 of them have been posted to date.

MR. : Okay. So there will be a further posting?

MS. : You're going to be getting -- yeah, it's an ongoing process. We discovered this yesterday, and I just got an e-mail last night that we were getting calls from folks that they weren't all up yet.

MR. : Okay.

MS. : So it's obviously -- it's a matter of programming.

MR. : Thank you.

MR. : Mine is a registration issue. If the owner of a facility is not the business operating the facility, is the owner, therefore the landlord, also required to register?

MS. : We need one registration from the facility, and any one of those three can fulfill that obligation. If none of them fulfill it, each of them are separately liable for violating the act. So any one of them can register, and as long as somebody does, no one else has to register.

MR. : Okay. Thank you.

MS. : I just want to clarify. Prior notice on air shipments is no earlier than wheels up; is that correct?

MS. : No earlier than four hours before the food arrives for prior notice purposes. Wheels up is the Customs advance manifest rule, proposed rule, and we have to wait to see what the final rule says.

MS. : Okay. So we could do PN before the airline confirms it's on board?

MS. : I'm sorry, you're not speaking into --

MS. : We could do the prior notices before the airline confirms it's on board; right?

MS. : Absolutely. And, in fact, we hope you do, and that alleviates the four hours for close-by shipments, if wheels up is less time.

MR. : This is a registration question. Would an organizer of a trade show in the food business have to register under this law, if there's samples of food being given out on the floor of the trade show?

MS. : If those samples are for consumption, then yes. If the samples are for testing in the lab, then no. Registration is tied to consumption.

MR. : If the trade show is produced at say the LA Convention Center, would the organizer of the show register, or would the convention facility register?

MS. : Ultimately the person with the interest in the food should be the one that looks to register first. So, again, it can go to any one of those

parties if I look at owner-operator or agent in charge. The best person, I think, in that instance to register is the organizer of the trade show, because you are the one that knows what you're doing with the food.

MR. : Thank you.

MR. : Okay, my question is regarding about supermarkets are not -- don't require to be registered, right? Supermarkets?

MS. : Supermarkets that meet the retail definition do not have to register, so that generally will be most supermarkets. But it's a case-by-case basis.

MR. : How about if the supermarket who imports the stuff in has to take it to their distribution warehouse? Do they have to register?

MS. : The -- look at it facility by facility. The warehouse will have to register. The retail store itself likely is exempt if its primary function is sales to consumers.

MR. : Okay.

MS. : If you look at something like a Costco, grocery warehouse, again that's a facility-by-

facility exemption, so as long as they're selling more to consumers than they're selling to businesses, the facility is exempt. If they are selling more to businesses than to consumers, the facility would have to register. So it may vary from facility to facility whether you meet an exemption.

MR. : Okay. Can I ask one more question?

MS. : One per person, please.

[Laughter.]

MR. : This is a registration question. Is the exemptions for registration U.S.-specific?

MS. : No. They are not U.S.-specific. The six exemptions apply to U.S. and foreign, and then the foreign facility exemption only applies abroad.

MR. : Okay.

MS. : This is a registration question. If I have a manufacturer that is manufacturing the product, it's chocolate, but then the chocolate is being packed out at a facility, then, you know, put into a warehouse before it's shipped out, does each step have to be registered?

MS. : Yes.

MS. : Okay. Thanks.

MS. : Let's say that the -- your grandmother in a foreign country buy all kinds of candies, chocolates, and all that and pack it via airmail to your grandson here, and I understand that there is no registration required, but prior notice still required; right?

MS. : That's right.

MS. : Well, no, not exactly.

MS. : Well, it's pretty much right.

MS. : Okay.

MS. : What we wrote into the rule very late one night, if I remember correctly, is that if it's a personal shipment, if it's an individual to an individual, and you don't know the exact manufacturer and you certainly don't know the registration number --

MS. : Right.

MS. : -- you can give us the name of the firm that's listed on the label. So if it's a whole variety of candies, Grandma is going to have to give us --

MS. : So that was my main question because if she doesn't -- she just ship it out, and they could be held in -- denied, refused --

MS. : Well, they could be refused and held until prior notice is covered.

MS. : Yeah. But she doesn't remember what she bought. I'm sorry.

MS. : No, you don't have to be sorry for that. We were -- like I said, we were able to deal with that fruitcake. But we had a little bit harder time with this because an exemption for -- we couldn't figure out how to exactly narrow down that kind of exemption so it would take care of your grandmother and not encompass a whole bunch of other stuff that we didn't want to encompass.

MS. : Okay.

MS. : So that's one of those things that I would encourage some sort of thought process, instead of saying just don't exempt it. Give us an idea of maybe a better way, but what we came up with, very late one night, was that if it was a personal shipment that you could then give us the name on the label, because FDA label

requirements require the name and address of the manufacturer, packer or distributor. When you're giving us comments, look at what the Bioterrorism Act requires because we only have authority and as much or little discretion as Congress gave us, and that's why we can do the homemade food because we didn't think Grandma was a manufacturer. But if Grandma is buying manufactured candy, legally we can't say that it's not required. That's why there is that quirky distinction.

MS. : Thank you very much.

MR. : I have a question. Does this prior notice has to be exactly 48 hours in advance, or we can notify --

MS. : No, it has to be no more than five days in advance, and no less than two hours for trucks, four hours for air or rail, and eight hours for sea.

MR. : So, for instance, the products coming from China --

MS. : Talk into the mike, please, because we're recording it, so we need you to talk into the microphone.

MR. : Oh. I'm sorry about that.

So if the product, a shipment coming from China and takes like let's say 21 days, once the product was shipped, we can't notify, got to wait until like five days?

MS. : You're supposed to wait until the five days, right.

MS. : Yes. And that's a limitation again in the Bioterrorism Act. Congress said you cannot give us prior notice more than five days before arrival.

MR. : And can I ask one more question?

MS. : No.

[Laughter.]

MR. : I'll be back.

MS. : Go to the end of the line.

MR. : We're going to be tough but fair.

MR. : Good afternoon. This is a registration question. Storing our products in a cold storage warehouse, which is independent from our company, and does it mean that they have to issue as a -- or recognize us as a U.S. agent, register us as a U.S. agent?

MS. : I'm sorry, I can't -- you're not talking into the microphone.

MR. : I'm talking into the microphone. We're storing our products in an independent cold storage warehouse, where we import regularly. Does that mean that they have to recognize us as a U.S. agent, the cold storage warehouse?

MS. : The foreign facility can choose who they want to be the U.S. agent. It can be you, if you agree, or it can be anybody else.

MR. : No, no, I'm talking about domestic cold storage warehouse.

MS. : Domestic doesn't have a U.S. agent requirement. Only foreign facilities.

MR. : Only foreign.

MS. : Only foreign facilities.

MR. : Okay.

MS. : And again that was something Congress put into the statute. It's because we don't have authority to go overseas and just walk into or communicate directly in that sense, as we can with domestic, and so they wanted to have someone U.S.-based that we could

communicate with directly. We don't need that for a domestic facility.

MR. : Okay. Thank you.

MR. : Okay. This is my second question. We have importers that bring in samples that they don't know and we don't know until the day it came in, so like in situations like let's say it arrived like let's say during a holiday or during the weekend, based on the presentation you gave us about the prior notice, then this shipment is supposed to be going to jail, is that what's --

[Laughter.]

MR. : -- you know, you stated? I mean what's the -- what can we do? I mean what are we supposed to do for that case? Like the manufacturer or the producer sent out some samples for testing, and the importer there, they import like big quantities, but they're just getting some samples, and they have no idea. They didn't tell us, they didn't notify us, and the next thing you know, hey, a Monday morning, hey, we got a shipment for you to clear. What do we do?

MR. : I mean I don't think that's going to change a lot from the way it is. It isn't going

to be released from the carrier's control until such time that prior notice is received. If it goes on without -- it won't be released until prior notice is received for that. So I mean if it comes in on a weekend and it isn't going to be processed, it isn't going to be processed, anyway.

MR. : Right. So in other words --

MR. : It just won't be released until prior notice.

MR. : -- we still have to do the prior notice even though it's here?

MS. : Right.

MR. : Monday morning, you're not going to get it released until two or four hours after you submit, depending on the mode of transport, until you submit the prior notice.

MS. : I think it also gets to the potential thought process of change of business process. I mean if you want to have immediate access to the product when it hits the United States, then you need to make arrangements with whoever is shipping it to know that it's coming and to see that prior notice is filed.

MR. : Okay. So but then still like if it's on -- if it came in on a Sunday, then we come to work on Monday and say, hey, here it is, then --

MS. : Then you need to file the prior notice at that point before you can get the food.

MR. : I see.

MR. : Right. And that's no different. You didn't come in until Monday, anyway.

MR. : I see.

MR. : That isn't really going to change.

MR. : Okay. Thank you.

MR. : We'll have about 10 minutes left, so if you can please keep your questions brief.

MR. : This question is in regards to registration. I'm in the grocery business and all we do with our distribution centers is distribute food to our different stores. Are we required to register those distribution centers?

MS. : You are holding food at the distribution centers; yes.

MR. : Okay. Thank you.

MS. : This is in regards to registration and prior notice. If I'm going to be the agent for a foreign manufacturer, and I import most of the goods in about nine ports in the U.S., and I have multiple brokers and I'm going to hold the registration number as well as I guess give the prior notice through ABI, am I going to have to give it to each broker, or assign one broker and then they would notify all the other brokers?

[Laughter.]

MS. : Because I have about 200 containers coming into the U.S.

MS. : It depends on how you want to set up your business practice. Whoever is filing the prior notice for each of those products coming in, or each of those articles of food coming in is going to need the registration number to put into -- if it's a manufactured product, to put into the prior notice. So depending on who is filing your entries and who is filing your prior notices, if you're using the ABI system, they will need all the information.

MS. : So, in other words, I can give to each broker, because they are regional in the U.S., you

know, in the different like 10 ports, I can say here's the -- here's my prior notice and here's my registration number, and they -- each broker can file it, or not just one broker?

MR. : I would suggest that you let each broker file prior notice for the shipment that's arriving within the port that he's licensed.

MS. : Okay.

MR. : And he's going to need to know the registration numbers and you will have to find a way to communicate that to him. But, you know, as for particular entry, the shipment information, he will be filing his ABI entry and he can get the prior notice directly as your agent, as the importer's agent.

MS. : Okay. Thank you.

MR. : This is an entry question regarding mystery shipments that we were talking about before. A shipment arrives into the United States with no prior notice, and then the presentation says it goes -- it immediately goes into constructive GO. What is constructive GO?

MR. : Well, it's -- there's actually -
- when it arrives and there's no prior notice satisfied,
the port director makes a decision on what to do. Is he
going to allow it to stay within the port? Can it stay --
and if it's within the carrier's facility, still under the
carrier's control, and that could be considered
constructive GO. Or if it's at a land border port, and we
don't know when the prior notice will ever come, it might -
- the decision might be made to send it back.

MR. : So there's no rule that would be
consistent from coast to coast? Every port is going to
make up their own rules?

MR. : It's based on a number of
factors at the port. Those are the three options that the
port directors have, is either they can hold it there until
such time that -- at the port, physically within the land
border port, usually when we're talking about ports like
this, or it can be held at the carrier's facility if it's
at a seaport or airport until such time that we deem that,
you know, prior notice needed to be satisfied, or it can be
exported.

MR. : So we don't know.

MR. : The port can be directed to the secure facility, which at that point that's when it kind of falls under the GO procedures.

MR. : Is there any intent to have a standard rule?

MS. : That is the standard rule. It leaves flexibility for the port director to decide based on conditions at the port, volume of the shipments, security of the article, what is the most appropriate. So it's not a rigid rule. It is a flexible one that is based on what makes the most sense.

MR. : Thank you.

MR. : My question is about registration. Does FDA provide any kind of verification to registration number, like say if an importer wanted to verify --

MS. : No.

MR. : -- you know, the supplier has registered with FDA?

MS. : No.

MR. : How can he be sure that, you know, the registration given is indeed, you know, genuine?

MS. : We do not and cannot under the Bioterrorism Act inform members of the public whether a facility is registered or disclose registration numbers. That is between responsible parties. However you arrange that with your business -- people with whom you do business, they can give you a copy of the confirmation, they can fill out whatever other information you would get. It may be similar to them saying they are giving you safe, wholesome products that have been made in compliance with any applicable laws. It's whatever you want to arrange, but we cannot give that to you.

MR. : Okay. Thank you.

MR. : Keith -- he's busy talking to somebody. This question is for Keith. This question is for Keith.

Are we to understand that one shipment that has one entry, but multiple food brand items, requires multiple PNs on one entry? And also would the 3461 reflect PN numbers?

MS. : You said multiple brands?

MR. : Multiple food brands.

MS. : Multiple brands. Brands are not one of the items of information required by prior notice. So if there are five different brands, but it's still the same manufacturer, the same product, the same size, say it was that tuna example, and you have five different brands of six-ounce cans of tuna from the same manufacturer, then you just have one prior notice. Brand name was removed.

MR. : Or multiple food items.
Imported multiple food items.

MS. : Multiple items, yes.

MR. : Sorry? Multiple food items may be of different brands, but imported under one entry.
Would that have separate PNs?

MS. : Are they different foods?

MR. : Different foods in one container, mixed.

MR. : Each one would have to have a separate PN.

MR. : Separate PN for one entry?

MR. : For one entry, that's correct.

MR. : And would that 3461 reflect all the PN numbers? The 3461 that's printed out, we have now

in the new system that you are talking about, are there PN numbers mentioned on the 3461?

MS. : Not unless the manufacturer or the shipper puts them on that form.

MR. : But you say it goes through ABI.

MR. : Right, but the prior notice information will -- the confirmation number will be sent to CBP's database, the ACS system, and we will know what PNs are required and which have been met and which haven't been in our system. So when the entry is presented, we will know whether it may be entered or it hasn't met the requirements of prior notice.

MR. : And for customers who are entering it through the ABI system? The customers who entered through the ABI system, they would have to input the information about the PN on the ABI so that Customs would be able to see that information and then approve that. So is that -- that's what my question is for importers who are 80 percent on ABI, they have multiple shipments coming in of different food items, and the prior notice, the software vendors are working on the prior notice information to go to ABI so that Customs can see

through that and then send us the approval, would that apply in this case, too, for multiple items?

MR. : Yes, it's -- if I'm understanding the question correctly, the -- each FDA food item or product code has to be -- a PN has to be submitted for each one of those items, and the ABI, the vendors are building their system to be able to accommodate that. I mean actually that's there now for the FDA 1s and 2s, so we accept multiple FDA product codes for a particular line item on an entry.

MR. : Okay. Thank you.

MR. : We have about three minutes left.

MS. : I have a question for Leslye. In case of a real emergency communication, if FDA has communicated the situation to the U.S. agent and the U.S. agent communicated it to the facility, is there a standard expected maximum time for the response, or it's on a case-to-case basis?

MS. : Typically, I mean you're really getting into -- possibly it sounds like you're getting into the recordkeeping access, which is -- which we're not

talking about here at all. The communication for registration purposes which, you know, we would not necessarily use your U.S. agent for recordkeeping issues or access -- communication for prior notice -- I mean for registration purposes could simply be we have received information from our intelligence community that bottling plants are targeted for attack in certain areas, and we're passing that information on. There's no response necessary, per se. It's to let you know.

It could be we have a concern about shipments we have heard from -- you know, that this exporter had been infiltrated or something. So it's more that kind of a communication, not an access kind of question.

MS. : Thank you.

MS. : Last question, this is about the prior notice. Travelers, they buy a food at the gift shop or a duty-free shop, and bring it in. How you do the prior notice?

MS. : Who is going to -- is this for their personal use?

MS. : For their personal use.

MS. : Then there is no prior notice required.

MS. : Oh, no --

MS. : You're bringing it back with you? You're bringing it on your person?

MS. : Right. Oh, as long as it's not by mail or anything, just baggage?

MS. : If you're bringing it in for your personal use, prior notice is not required. If you're bringing it in for business reasons, we have a challenge because prior notice is required.

MR. : The key is it has to be accompanied.

MS. : Personal use could be the gift.

MS. : Yes.

MS. : Okay.

MS. : It could be you, personal use is you, your family, or your friends.

MS. : Right.

MS. : Leslye calls this the friends and family rule.

MS. : Right.

[Laughter.]

MS. : And the key to that is the food accompanies the individual.

MS. : Okay.

MS. : It's -- you know, you get it at a duty-free shop, you're bringing it on the plane, it's for your personal use.

MS. : And you can even buy it at a non-duty-free shop. Again, if it's for your personal use, no prior notice is required.

MS. : As long as it's hand-carried?

MS. : As long as you hand-carry it, yes.

MS. : All right. Thank you very much.

MS. : Grandma will be coming with the candy.

[Laughter.]

MS. : I think we've figured out how to get that candy in.

[Laughter.]

MR. : My question is is the agent liable for prior notice, the failure of prior notice at all? Is it related at all?

MS. : Again, keep separate the U.S. agent and registration has nothing to do with prior notice unless you have designated your broker and they are doing both. We don't hold liable per se -- I mean your failure to provide prior notice within the United States is a prohibited act, but the bigger consequence is the food is not going to be delivered to the owner, the importer, or the consignee until you file prior notice. So that's really I think a more significant liability than civil or criminal penalties. But it's whoever files or whoever is responsible for filing the prior notice or getting it to us.

MR. : Okay. Thank you.

MR. : If there are multiple registered facilities, but one import entry, would all facilities need to be shown on the prior notice?

MS. : The prior notice requires the registration number for the manufacturer of the particular product you are bringing in, and the shipper. Those other

facilities may be required to be registered, but they are not required on the prior notice.

MR. : The manufacturer and shipper
both?

MS. : Are required.

MR. : Right. Thank you.

MR. : Last question.

MR. : You said earlier that prior
notice can be sent no earlier than five days prior to
arrival.

MS. : Except for mail.

MR. : Right. With entries filed via
ABI specifically on ocean where we can actually transmit to
ABI 10 days out, where ABI will hold off on selectivity, is
there a mechanism set in place where we can transmit prior
notice information along with our ABI entry and then
Customs hold off sending prior notice to FDA, or how would
that work?

MS. : If you can do it, we're happy.
If that can be accommodated through the Customs system and
the information, yeah, you submit it with whatever you
submit to Customs, and if Customs doesn't -- isn't going to

run it through selectivity, if they bounce it to us the same time they do that, then everything is fine.

I'm sure that's what Congress was getting at. You know, five days came out of somewhere, and the only place I can think it came out of is what the current Customs process is. So if that can be done -- and, Keith, I can't see you, so just tell me you're nodding.

MR. : I think I don't know why it can't be done, personally.

MS. : It makes sense to us.

MR. : It makes sense to do.

MS. : The question becomes the IT considerations.

MR. : Right.

MS. : That's the question. And certainly it's something we would -- we wouldn't object to as long as the IT systems can make it happen.

MS. : Just to add one additional note and that is that you won't get a PN confirmation number any sooner than five days before.

MR. : Okay. Thank you.

Just let me take a moment to introduce somebody
that I did not do earlier. We recently named our director
of Import Operation. I would just like to --

[Applause.]

[Whereupon, the proceedings were concluded.]

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