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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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

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P R O C E E D I N G S

MR: : Well, maybe this will break the ice, here and get everybody--two questions here.

On a co-packer, who is responsible for registering. Is it the co-packer, or the company that's asking the co-packer to do that?

MS. FRASER: Well, it goes back to who owns the facility. So we're looking at, again, not the person but who has ownership rights; who is owning, operating, or is the agent in charge of the facility where the packing is occurring. And that's who has to register. And any one of those three entities can do the registration.

MR: : Okay. And then second question--and you kind of addressed it a little bit toward the end as far as labeling markings, where we wouldn't use the registration number. Is there any kind of labeling requirements, as far as--similar to like a "kosher" symbol where, yes, you are registered, and this mark indicates that?

MS. FRASER: No, there is none of that.

[Pause.]

MR. : Similar question. If you're a co-manufacturer of several brands--known brands--one registration will suffice for very brand that you manufacture for? Or it's got to be individual for different brands?

MS. FRASER: We're not looking for brands at all. So, again, it's looking at the facility. And one registration will suffice for the facility. If, as part of your facility you're saying, "Well, we do business as the ABC Company," because that's one brand you put, and then you also do business as the XYZ Company, then we would just ask that in the registration you list the trade names of the facility, not the brand names that you make.

[Pause.]

Anyone else?

MR: : Yes, if you own and operate a dairy farm but send your heifers off to a facility that raises heifers, is that still under exemption also?

MS. FRASER: Yes.

[Pause.]

MR. : If you own a dairy farm and you manufacture cheese on the dairy, are you exempt or not?

MS. FRASER: Depending on what you do with your cheese--that's like the orange juice example. So, if you're selling the cheese into commerce; you're selling it to a distributor or you're selling it to a retailer, then you have to register the manufacturing aspect of it. If you are selling it at a roadside stand, a farmer's market, and most of your--more than half of your customers are consumers, then you don't. So it's going to depend.

[Pause.]

MR. : Yes. On vessel coming into the United States--on prior notice--we're having a conflict on whose responsibility--the terminal or the agent dealing with the vessel, who would be responsible for calling that in?

MS. FRASER: We'll actually take prior notice after we do the session, but we don't

specify who has to give us prior notice. We just say we have to get it, and we leave it to you in the business context to figure out who's best position to provide it.

[Pause.]

MR. ROH: Everybody understands registration? You're all registered and ready to go? No problems?

[Pause.]

Okay. It looks like you did your job.

MS. FRASER: I earned half my keep so far.

MR. ROH: Okay. We're going to take a 10-minute break now. So please be back in 10 minutes and we'll continue with the demonstration.

[Taping stopped; taping resumed.]

MR. : If we've already registered, but by seeing this we see we've made an error, how can we go back in and correct it?

MS. SCHMIT: You can go right back to where the--the Home Page, here, we had a menu. You can update your facility information. If you registered by paper, you should have that PIN

number, because you didn't do it originally on-line, you can use the PIN number to link that--right here--link it to your account, so your account can access it. If you did it on line and it's already linked, just go into the "Update," and it will ask you which section needs updating.

Okay?

MR. : I think what I did is I set up two account numbers. If I want to cancel one--

MS. SCHMIT: Oh, account numbers? It doesn't really matter. You can have multiple accounts.

MR: : I can? Okay.

MS. SCHMIT: You can have multiple accounts, and it just depends on which account has access to the registration. Cancelling an account--if you really want one cancelled, call the Help Desk. But you might want to go in and look and see which registration numbers you have access to.

The account number I just created a moment

ago has access to this registration. If I had multiple registrations, I'm going in and saying--I just click the "Update Registration." It's showing me what I have access to. And you can go in and look and see what's there. Multiple accounts won't hurt anything, though.

MR: : If we've got our account number set up, then we need to have--even if the location is the same as the facility, we need to register the facility.

MS. SCHMIT: Registering the facility is a separate process than creating an account.

[Pause.]

Anything else?

If you think of them later, I'll be around when the meeting's over. We have a couple computers set up--in 316. We'll try to somehow leave the door to the room open so it's obvious where we are. But we can show you more about some of the details here.

I just want to point out, one of the pages that's very useful--this page. There's a list of

all the step-by-step help for your account, because you need an account first to do it on-line, and that is separate. There's information on the prior notice help, which is going to get updated shortly, but also the food facility information. And, like I said, we just added the Spanish version of it. The registration's still in English, but we've got the directions in Spanish as well as English now, as well.

[Pause.]

Thank you.

MR. ROH: Thanks, Diane.

We're going to take just five minutes and switch computers here. So, get a glass of water or soda or anything that you need before we continue, and then we're going to go through prior notice.

And, like Diane says, she's got a couple computers set up in room 316. For those of you who want to register, if you're not yet registered, you can do it today here. Or, for those of you who may have made an error and you want to correct, we can try to do that as well.

[Taping stopped; taping resumed.]

MS. : Okay. The prior notice, that's mainly if you're importing, you need to file a prior notice, versus exporting. It's the consignee on your export in another country that would have to file the prior notice.

Would I have to file a prior notice for exporting?

MS. FRASER: Prior notice is only imports.

MS. : Imports. Thank you.

MR. ROH: Remember, it's only so that the United States officials can sort of verify the safety of the food. So it's only stuff that's coming into the country.

MR: : I have two questions. On the prior notice--say, on rail cars, for example, when they come over the border they're approved or denied by FDA. How does--like our terminal, when we receive the rail cars--how do we get confirmation of that? Just not--beside a broker? I mean, say, if I want to look to make sure that rail car's been approved by FDA to release or

accept in our facility, how can we--can we go on line and, say, punch up this rail car and it comes back to us and say it's approved or denied or hold? How can we verify that? Because I don't trust brokers.

[Laughter.]

MR. ROH: Right. When the rail cars are coming over the border in Canada, we have the right to stop them and review what's inside of them and sample them if we so choose. So you could, hopefully, be assured--you can always check with the local FDA office that is responsible for that particular border. But when things come over the border, say, from British Columbia, they go through, usually, the Blaine Port, or the Sweetgrass, Montana, Port, and they are not allowed to cross over into the United States unless they meet our requirements.

So, if they have an adequate prior notice, we'll let them in. If they don't we'll not.

Now, let me just say that there are certain times when they filed prior notice, the

train is very, very long; it's full of meat and bone-meal products, or whatever it happens to be. we may take a sample of it and allow the car to go to a final destination, because we don't want rail cars backed up in some location. And this recently happened in California.

The rail car made its way into the Valley somewhere, and it was supposed to be held--the product was supposed to be held until the sample analysis was complete. The product was not held. The officials in California were quite upset.

So there are certain things we can't control. We are working with the rail car companies, saying, "Okay, if we allow your rail car into the United States, you are to hold the product pending our approval." In most cases--in your case--if the product has come in, then you could assume that the prior notice was adequate, and we let it into the--

MS. FRASER: Umm--Mark, not exactly.

MR. ROH: From the field perspective--from our field perspective, it is--

MS. FRASER: Yes, that's an 801(a).

MR. ROH: --it's met the requirements.

Did you want to say something?

MS. FRASER: Yes, I think, generally on prior notice, you will not know before the food arrives whether FDA finds that to be--or to contain an article of food that causes us concern, out of the normal 801(a) import process that currently goes. I think that's something where--Mark is talking about is the traditional process.

Part of prior notice is for us to make assessments based on intelligence we have from CIA, FBI, our own alerts--whether food has been intentionally contaminated, accidentally contaminated; a natural contaminant that has grown on the field or whatever, that has concerned a concern. But we don't want to have--and let's the intentional terrorist situation, where we have knowledge that there's a food product coming in; we're going to want to sample it or hold when it arrives at the border. If we send notice back to whomever sent it that we're going to hold it, the

shipment may potentially get diverted.

So, you will not know--you will know that prior notice has been filed by the submitter getting confirmation back. And you need to work with whoever is submitting prior notice on your behalf, whether it's your broker--you don't like--or whether it's the broker do like, or whether you did it yourself.

But you will get a confirmation prior notice has been filed. That's all you will know, is that prior notice has been filed. You will not know that, as a result of the filing, we may want to take action. If prior notice has not been filed, when the shipment arrives, then you're in the scenario that Mark was talking about. We will decide, at that time, with Customs, whether we will let it proceed to its destination; whether we will hold it at the border; whether we will make you export it or turn it around or whatever.

But it still will not be able to be delivered to the owner or the importer or the consignee, even under bond, once it arrives at

destination, until prior notice has been satisfied.

MR. : Okay. But, I mean we had that one incident here in the Valley not too long ago. so, how does that--how do we stop that? Like, at our facility, getting rail cars in 24 hours--so--okay. But still, we need to find out if the car's been released. I mean, there's no electronic way to say that--

MS. FRASER: That's where--you're in the field scenario, but that's more the 801(a) regular import. That's a prior notice scenario. And you have to keep distinct that the process that you current go through, that will not change. That is part of what you interact with the field offices for.

Prior notice is a heads-up to the government of what's coming in, so we can decide before the food arrives whether we want to do something out of the ordinary with respect to shipments we believe are high risk. We're not talking about every shipment. We're trying to target those high-risk shipments, and we will not

notify you that we are going to take steps out of the ordinary with respect to those shipments.

So, the other scenario--you're back to Mark's answer. Prior notice is a heads up--and even with respect to the ones that we flag as high risk initially, by the time the food arrives, we may have satisfied our concern and decided that that's still a shipment that can proceed as usual.

MR. : Okay.

Second question: on prior notice and, say, on vessels. They come into the port. You said certain vessels could be randomly picked for sampling? What kind of process is that? Or what type of a delay would that be to discharging that vessel?

MR. ROH: Well, again, like Leslye points out, there's two things going on. And one would be the prior notice portion of it.

If, for some reason, the prior notice center decides that there's something on this ship that needs to be looked at, it will be off-loaded onto the dock and looked at there. You won't get

it at your facility. you won't get it until it's been released by FDA. Okay?

The internal--if the prior notice center releases it, but--and because they've determined that there is no "safety concern" from a terrorist point of view--intentional contamination--that's the initial release. But if, for some reason, it happens to be coming from a country that has, you know, a history of filth in this particular product, or contamination in this particular product, the field organization may say, "Okay. Fine. The prior notice center released it. No problem. But we have a history of problems with this particular firm and this particular country," not from a terrorist perspective, but from a filth and contamination perspective. Then we may go out and look at that particular shipment, or look at a couple of lots, or do whatever, and take some samples.

Where, at that point it may be released to the firm; they could take it off the dock and put it somewhere, but they can't distribute it.

MR: : But that's like the ongoing process already in existence.

MR. ROH: Right. Right.

MR: : So there's ;nothing new in that regard.

MR. ROH: No, there's nothing new in that regard. No.

[Pause.]

MS. FRASER: I would like to clarify, you know, for--even with our experience to date--and we're not in full compliance, but people are filing prior notices, and they're not--you know, many of them we're missing registration numbers and some other data elements. But, generally speaking, we see most shipments proceeding as usual.

Now, let's talk August--full enforcement. Assuming prior notice has been filed, and all of the data fields are complete, most shipments will still proceed as they currently do. We get 25,000 lines a day, and most of those we don't see having significant health risks that would warrant a deviation from business as usual. That's not to

say that Mark's not going to have a problem with excess filth, but that's something we can handle under the normal process.

It's not to say that we don't have a problem with mislabeling or mis-branding, but that's something we would handle under the normal process.

If it's something that we think poses a significant threat, we have concern about diversion, we have concern about cross-contamination, then those are the ones that would be flagged and pulled aside for being handled differently. And how long that delay is going to be is going to be a function of the source of the contamination, the nature of the contamination, how fast we can get information back and satisfy our concern, or figure out: this is a serious problem and you're not going to get the shipment ever, because it's a significant health threat.

So, you know, I think the point Mark made in the presentation that most of this is business as usual--once we get the information sooner. If

you don't get us the information ahead of time so that we can perform the function Congress has told us to make assessments about food before it arrives, then you're going to be caught up in potential holds of the food because you haven't satisfied the prerequisites for getting it in. That's a different issue.

So, you know, if everybody is doing what they need to do, most of the shipments are going to proceed the way they currently do.

MR. ROH: Although if we were to answer this gentleman's concern about the rail cars--if the rail cars are coming to his facility in Fresno from Canada, he could almost assume that since they've made it to Fresno, we've approved it.

MS. FRASER: Rail cars are a little harder.

MR. ROH: Yes, rail cars ar--

MS. FRASER: You can't assume--they probably have been approved, but it's a little difficult to pull off a rail car at the border, even if you--you know, that may be something where

we would meet the rail car at your facility, possibly, as opposed to hold the whole train at the border and say we need to get this one rail car. It's a little different than trucks.

MR. : [Off mike.] The rail cars are a big part of our--

MR. ROH: I know. And that is something that we are working on. Unfortunately, some of these transport organizations, we haven't worked with them directly so much in the past. We've worked with the product--like, say, you took the product out of the rail car, and you put it in your own silo or whatever you did with it. We worked with you and we worked with the product. And the rail car just went on its merry way.

We're working closely--we're trying to develop relationships with some of these shipping entities now--the railroads, for one--saying, "We can't do that anymore." If something comes in and we don't want to stack up rail cars on the Canadian side of the border or in Blaine, because there's no place to put them, we have to let the rail

companies move the car to where there's track-- available track--that they can actually store. And in some of these oddball situations, in most cases, if it makes it to your facility, we've let it go.

But in some of the cases, we need to ask the rail car company: "Okay. We let you move this car to here because you've got track to store it, but it's still under our control. You can't do anything with it."

MR. : [Off mike.] Well, that's the whole purpose of asking how can we--in other words, the elevator--determine that this car has been released, or is red-tagged, or something.

Because as I say, we've got train movement 24/7.

MR. ROH: Right.

MR. : [Off mike.] And there could be a lapse of information from, you know, from Canada all the way down. And meanwhile, here comes a train, here comes a red-tagged car. The facility is not aware of that red-tagged car, and we don't.

MR. ROH: But, from a field perspective, I can say we're working with the rail car companies from headquarters' perspective.

MS. FRASER: I think you're going to have to work with the broker. Because we only can deal with--that's who we know, is who has filed the prior notice. And that's where the message--both from a prior notice, the carrier will find out when the carrier arrives what's happening with that particular shipment for prior notice purposes. For entry purposes, you will be dealing with--Customs would be dealing through the broker.

But for prior notice purposes, it's the carrier that will find out, upon arrival, whether business will--whether there will be a deviation from current practice. To the extent that you have suggestions on how that should be handled differently, or separately, that's something that I suggest you provide to us in writing when the comment period opens so we can look at it.

MR: : [Off mike.] I think I know something about what he's talking about.

MR. ROH: You need a mike.

MR. : That particular instance: a rail car was sampled as part of the BSE sampling program, up on the Canadian border, by Seattle District. And the rail car--the information was there in the system--in other words, I think the customs broker who was working with the company that was importing the product from Canada--this happened to be, I think, cannola meal--should have communicated that that rail car was still on hold pending sample results by RDA, by Seattle District.

That information never got to those folks. So these poor people at the grain terminal comingled that product--they off-load these rail cars as quickly as they come in, I'm sure. They comingled that product with other products. That caused a big problem for everybody down here in California, because products had already been loaded on trucks, and was headed for dairies. And we had to get that--or, actually, California Department of Food and Ag has to get that product back.

So, it's something that should never really have happened, but I think everybody learned from that--as a result of that. And, for your information, I think Cannamera, ADM, and one other company who brings a lot of product in that you guys handle, is now on some kind of certification system whereby we're no longer sampling those rail cars at the border. So, hopefully, the process will run smoother for you guys now.

[Pause.]

MR. : I've got a question concerning the prior notice of foreign exporters. If a product moves from one country to another, and then is processed or packaged in that country, and then comes to the U.S., the person that submits the prior notice, do they also have to quantify or qualify--whatever the word is--where that product originally came from, and what manufacturer, before it's allowed to come into the U.S.?

MS. FRASER: Whoever is submitting the prior notice--in your example, it would be the second country is the country that we're interested

in; the manufacturer, because that's who's handled it or put it into its final form. That would be the country of production.

The country of origin--and that was part of the explanation Mark was giving--might have been, in fact, the first country for Customs' purposes, but for our purposes the country of production would be where it was put into the form we're getting it in the U.S. And we would need that manufacturer's registration number as part of the prior notice.

You'd also need the shipper's registration number as part of the prior notice, if the shipper was required to register.

MR. : Country of origin? Or--

MS. FRASER: Country of origin is not required in the prior notice. Customs will ask for it. But for prior notice, we would ask for country of production, not country of origin.

MR: : Okay, I have one more question--and you may or may not want to answer it here right now.

MS. FRASER: [Laughs.].

MR: : But I'm having difficulty with the transportation companies. We get a lot of ocean containers coming in, and then they're put on rail and they're brought to the railhead in Oakland. And I'm getting them with broken seals. I'm getting containers with no seals on them.

And my question is--what's really frustrating is--how can the FDA, or U.S. Customs somehow monitor who breaks these seals and why, so that when I receive the container and the seal number doesn't match the seal that was put on in the foreign country, who broke the seal and why? And get a document explaining that.

I just received a container yesterday that had no seal on it at all, and no explanation why it was not sealed. But the shipper had the seal number that was originally put on there and provided it to me.

So, somewhere in transport that container was opened, but nobody is telling me who opened it, or documented who opened it. How could FDA monitor

that? Or USDA? Or Customs--whoever's the authority there--and provide us, as a consignee, with the information we need of why that container was opened?

MS. FRASER: Well, this is an easy one for me not to answer, because it's well outside my area of expertise. This is really the field and Customs and Border Protection. So I will turn that to Mark.

MR. ROH: This is a Customs issue. No one is supposed to break those seals without Customs' approval. I'm not particularly familiar, at this second with the paperwork that Customs fills out when they break the seal, because FDA--if FDA wants to look inside the container, only Customs can open it for us. We can't do that.

So, they have to maintain--and I'm sorry I don't know the forms or the information--but they have to maintain some documentation that they've broken that seal.

Now, if they're not submitting that to you, that would be my first telephone call, would

be to Customs. "This is the container number. Why and when was the seal broken?" And if they can't answer that, I would make a complaint. Because that is an integrity issue of the particular shipment; particularly if it's a food, or if it's an edible--or if it's a drug. I mean, whatever's in there. That's an integrity issue, and Customs is responsible for the integrity of the seal until it's released to you.

[Pause.]

MR: : In regards to the seals, not just from incoming loads, but let's say internal from state to state, our company seals every container. Does FDA reseal the container if they have to check the load? What procedures do they have?

MR. ROH: No, we don't have--we'll sometimes put a sticker on it that says "Examined by FDA," the initials. But we don't have the official seals. Again, that's Customs.

We don't break a seal, and we don't official reseal. We don't have the authority to do

that.

VOICE: Domestic shipments.

MR. ROH: Oh, domestic shipment--I'm
sorry.

MR. : Yes, for
domestic--internal.

MR. ROH: For--what would be the scenario?

MR. : Let's say we're shipping a
truckload of product across the States; let's say
from here to New York. Our loaders seal the truck
and write down the seal number on the consignment
paper. And when it arrives to the destination, the
seal's been broken.

You know, we assume that somewhere in
between, that happened. What--could it have been
maybe FDA would stop the truck in the middle of the
road and checked it?

MR. ROH: No. No. If you're the
manufacturer here, and you're shipping something to
New York, our concern is with your manufacturing
facility here. We're not going to get involved
with your shipment from here to New York--unless

there's an issue with it. But--in my years, I have no experience with doing that.

If your shipment--if your seal on the truck is being broken from your manufacturing facility to your consignee in New York, it's not the FDA.

MR. : Thank you.

[Pause.]

MR. ROH: More prior notice questions? How about registration questions, while we have Leslye here today?

No prior notice questions? So all your questions are answered. That's good news.

MS. FRASER: Well, and I will say that--that's good--because I need to catch a plane right after this. So if you have questions, it's better to ask them now, because I won't be able to hang around very long afterwards.

MR. ROH: Did we have a question in the back?

MR. : Yes. What if--say we're ordering a product from a broker, but that product

has already been imported into the States, and as a broker, we come in contact with them--

[End Tape Said A.]

MS. FRASER: --because otherwise the food cannot be delivered to the owner, importer or consignee--whether it has problems--whether we have concerns with it or not. The Bioterrorism Act says prior notice is a prerequisite for the food even getting to its destination.

MR. ROH: Okay. Good.

I'd like to remind you that--oh, do you have a question?

MR: : In the event we have a facility operating, and a second group comes into the facility to set up, do they also have to register?

MS. FRASER: If it's a different owner--

MR: : It is.

MS. FRASER: --then yes.

MR: : They would have to register.

MS. FRASER: Yes.

MR: : Thank you very much.

[Pause.]

MS. : Earlier, I heard live animals do not require, or they do require prior notice?

MR. HACKMAN: Live animals imported to the United States for the purposes of food require prior notice. For example--I'll give you a very clear distinction.

A racehorse that may be coming into hte country from a foreign country for the purpose of racing, that animal--it's initial intention is not for food. So that animal would be exempt. But if it's a dairy animal, swine animal--whatever other animal--if it's intent is for food, prior notice is required.

MS. FRASER: Unless--at the time of importation--

MR. HACKMAN: It's under the exclusive--

MS. FRASER: --it's under USDA's exclusive jurisdiction. And you would know that because you're getting approval and a sticker and all of

that--a seal--not a seal, but a stamp of approval to import it.

But if it's not under USDA's exclusive jurisdiction, then it's ours, and prior notice is required.

MS. : Okay. And then, a registration question with regard to slaughterhouses--meatpacking? That is under USDA's exclusive--

MS. FRASER: Correct.

MS. : So that's exempt.

MS. FRASER: Correct.

MS. : And dairy farms? Also exempt?

MS. FRASER: Because they're farms.

MS. : Right.

MS. FRASER: If they meet the definition of farm, and are not doing any other covered activity, then they are exempt.

So, you know, dairy farms doing something within the farm definition only is exempt. But if you have a milk pasteurization plant at the dairy

farm, then, depending on what you do with the milk, that plant may have to register.

MS. : Okay. Thank you.

[Pause.]

MS. : Do product samples also have to have prior notice?

MS. FRASER: Yes.

MS. : Okay. And--whether it's sent by mail or any--any quantity, basically, that's for human consumption needs to be--thank you.

MS. FRASER: Actually, any sample--whether it's for consumption or not--needs prior notice. If the sample is for testing only, and no consumption, then registration is not required. But if the sample is also going to be consumed by one or more persons or animals in the United States, then registration of the facility that made the sample would also be required.

So, registration is tied to consumption. prior notice is tied to any food.

[Pause.]

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MR. ROH: Questions?

[No response.]

MR. ROH: Okay. Well, I would like to remind you that Diane is going to take group--

[Taping of session concluded.]

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