

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

[TRANSCRIPT PREPARED FROM A TAPE RECORDING.]

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P R O C E E D I N G S

[In progress.]

MS. : So, yes, we would just mail it back.

MS. : Okay, one more. And what about pharmaceuticals? Those are still directed by --

MS. : Pharmaceuticals are still done by Cedar. They have nothing to do with this.

MS. : Okay. Well, I have one that's a combination prior notice and registration. We have a facility that is -- the jurisdiction is exclusively for USDA, but the chicken is going to be consumed for -- by humans, so how do you --

MS. : If the facility itself is completely under USDA jurisdiction, if the facility itself is completely under USDA jurisdiction, they don't have to register.

MS. : Okay, but when you do the prior notice for importation, you need a registration number, so what do you -- are you going to have a generic number?

MS. : We'll get to that in prior notice. If it's an exempt facility, it doesn't need a registration notice.

MS. : Okay.

MR. : My name is Jack Webster. I work for a company that manufactures nonedible sausage casings that are regulated by the FDA as food packaging material, and therefore should be exempt. We have some concerns that when importing these products into the U.S., the agents may not be able or may not understand the differentiation between nonedible casings and edible casings.

MS. : I don't think I understand the difference. Debbie, are you on that?

MS. : Okay, explain to me how if it's around the sausage it's not edible.

MR. : Our casings are made out of cellulose which is essentially the same thing as cellophane.

MS. : Okay.

MR. : And our product is stuffed and then cooked and then removed, so prepackaged hot dogs that you would buy at a supermarket have been cooked in these

kind of casings. In fact, those used to be called skinless wieners. It's a way of -- is there a differentiation?

MS. : Well, this may be something we may have to take back, but -- go ahead.

MS. : There's only one product code for casings, be they edible, be they nonedible.

Technically under the regulation, the interim final as it is currently written, they would be -- they are not food. So they would not be -- they would not be subject to filing prior notice.

MS. : I will tell you that is certainly a good one to send in a comment on.

MS. : Yes. Did you comment previously? Did your company send in comments previously?

MR. : No.

MS. : Yeah, technically it doesn't -- if it's not a food, under the current one.

MS. : If we have your name and phone number, we'll try and get you a better answer on that. But right now we only have one product code that covers all casings, so it wouldn't -- we wouldn't differentiate between what was edible and what wasn't edible.

MS. : But let me explain, though. If you are not required to register and -- you know, I mean this is a good example of something that we are going to put in our frequently asked questions, and it would be put out, you know, we would definitely train the people that are going to be bringing these in, so if you are worried about that people would know whether they're edible versus nonedible, that's something we certainly would put in our training to make sure.

MR. : Our concern is that the import inspectors wouldn't understand that.

MS. : And that's who we would make sure would understand that.

MR. : Are they separated? Is there a different harmonized tariff code for edible and nonedible that you are aware of?

MR. : I don't think there is. I'm the regulatory manager and I normally don't get into the Customs issues like this.

MR. : Okay.

MR. : There are essentially four different kinds of casings. There are collagen casings,

which are edible. There are the old intestines, natural casings. And then there's cellulose casings, which are not edible, and then there's plastic casings, which are not edible.

MS. : Okay.

MS. : Okay, can you hear me? I'm Nancy Linde and I'm here on behalf of NSF, International, as well as a subsidiary company called the Toxicology Group, and altogether NSF has many businesses. We are in approximately 80 countries, and I have three questions for you.

My first is a lot of our clients send us things that technically are foods, like clove oil would be one example. And the purpose of sending it to NSF is to have the product tested for purity or contaminants. Sometimes the clove oil would be a food additive, but other times it wouldn't be, it would be for use in cosmetics or candles. And then also people send us dietary supplements that are - - obviously meet the definition of food according to 21 CFR, but they don't have an intention of selling the product as a food or as a dietary supplement within the

United States. We are just testing it for purity so that they can sell it elsewhere.

An example of that would be somebody sending us something to test for aflatoxins that would be imported into Japan.

So my question is if these samples are coming to us, they are not intended for consumption, are they thereby excluded?

MS. : Well, that's a prior notice question.

MS. : Yeah, that's actually a prior notice question.

MS. : And the answer to that is no, they are not excluded. If they are foods and if there is a possibility that they may be used as foods, they are included in the prior notice, right.

MS. : But for registration, it depends on if they are intended for food or animal consumption.

MS. : Well, for purposes of sending to NSF, we are never going to consume any of these.

MS. : That's for registration, though.
For prior notice, as she indicated, that would be a
different issue.

MS. : All right.

MS. : Samples are not excluded,
unfortunately.

MS. : Okay. I read that about the
quality control samples.

My next question would be on behalf of NSF, we do
a third-party certification, and that involves audits like
GMP audits overseas. Part of the audit process, we always
collect samples and bring them back for testing, and I
don't know, would NSF have to register in that case? Or
would it be just the facility?

MS. : No, it's not a registration
question. It would be a prior notice question.

MS. : It would be purely prior notice.
If you are not holding it for, you know, manufacturing,
process, packing, for human or animal consumption, then you
would not qualify for registration.

MS. : Okay. But those facilities are
going to have to register?

MS. : Those facilities, because they are obviously creating, and not just creating samples, they are creating it for human or animal consumption.

MS. : Okay. I guess that eliminates my third question.

MS. : Okay.

MR. : Brian Daugherty representing Bulk Mac Transport (phon.). We are a bulk carrier that operates a lot of rail siding and transfer facilities. Railcars come in, we pull them with trucks and deliver them, which sounds like it has to be registered, but I have another issue. I've got a lot of customers that are registered in my facilities. Can these be registered on multiple people?

MS. : What do you mean they are registering your facilities?

MR. : I have a particular customer that panicked because of this whole registration. They went around and registered all of my facilities.

MS. : Well, they have to be the owner.

MR. : Well, they're not.

MS. : Operator, or agent in charge of that facility to actually register.

MR. : The owner is the railroad, the operator is typically the truck line or the railroad, but there actually are shippers that have gone out and registered facilities that they don't own or operate.

MS. : That they don't own or operate.

MR. : Right. Can there be difficulties --

MS. : Well, I would suggest -- well, what happens is if it's a duplicate registration, what happens on the actual electronic system, it's going to show up as a duplicate, and basically ask have you registered before. Two things you should do:

One, if you're aware of that, you should get them to cancel the registration, and you need to register if, you know, you are the owner or operator of the facility and get that clear. I mean, you know, they're supposed to be attesting that they are the owner-operator. I mean obviously people are panicking, you know, we're not going to be running out and enforcing all this against people that are doing this in a sheer panic, but he should cancel

those registrations. You should register them. You know, you as the owner or operator should register them, unless you want to -- I mean what is he putting underneath the -- you know, the contact and the owner? Are they putting themselves as the owner, or are --

MR. : They're putting themselves as the owner, they're putting themselves as the contact. Some of these facilities aren't even operational. They haven't been focused on for two or three years.

MS. : Okay. Well, it's basically a false statement.

MR. : Because really they're rail sidings is what they are.

MS. : Yeah.

MR. : They're not real facilities.

MS. : Yeah. I would strongly suggest that you -- you know, I mean it sounds as if that individual needs to cancel those particular registrations that they are not the owner or operator or agent in charge of, and then the person who really is needs to register them if they are operational, if they qualify under the regs on that.

The problem is that what can happen is let's say you go in and you're going to create your own new account, so you will have your own password, so you will be able to get in, create your own account. When you start registering it, it's going to bring up and say, you know, this seems to be registered, have you registered before, and it will, you know, show you the address, if it's the exact same address.

If you put no, it will let you continue to register. It will just mean we end up having duplicates on the system. If they are the same, it's going to show two different owners, and that will create confusion in terms of contacting, you know, an emergency contact in emergency situations. But we also -- if you are aware of that, you really need to get the person to not do that.

MR. : I just found out accidentally.

MS. : Yeah.

MR. : It's confusion. I'll still be able to register the ones that I am responsible for?

MS. : Yes.

MR. : But there could be another party, then?

MS. : Yeah. It will just show that there is a duplicate, and you just put -- when it comes up and it says are you sure you haven't registered before, if you say no, it may say again, are you sure, just put no again, and then see what happens. And if you can't get through that, you need to go ahead and call the hotline. But it should let you register again. It will just be a duplicate registration.

MR. : Okay.

MS. : Okay. They will do -- let me explain. After this electronic registration and you get your receipt and confirmation, when you are initially registering, it does some immediate verification checks electronically, but subsequent to the receipt of confirmation, the electronic system will then do additional checks, and if there is a question, you will be getting by mail, as I recall -- yes, by mail -- you will be getting a thing saying, you know, this doesn't seem right, are you sure you're the owner. And somebody is supposed to respond back.

I would suggest you tell the individual that registered incorrectly that he may be getting a letter from

us and they may really not want to be doing that, that they may want to go in and cancel it. And they can go in and cancel it.

MR. : I've been talking to them, but they're not willing to cancel.

MS. : They're not willing to cancel. Well, you could explain to them it's a prohibited act to -- which means that it's illegal. That means that he could be subject to civil and criminal penalties if they register and they're not supposed to -- you know, they're not supposed to do that.

So it will show up when we come out to inspect, and those type of things. So we still have more time.

Some questions, sir?

MR. : Thank you. I'm in the fresh fruit and vegetable industry, and my company is housed under one roof in one building. My company processes and repacks fresh fruits and vegetables for the retail arena, and for the food service arena. We have two subsidiaries that pack for each of these categories. We have ABC that packs for the food service and DEF, if you will, for the retail. But they pack for the parent company, which is our

name brand. In registration, do I need to register all three, the parent company and the two subsidiaries?

MS. : Okay, let me make it clear.

MR. : I'll stop.

MS. : It's the facility that is registered, not the company, so if your facility is under one location, it's just that facility. It doesn't matter if it does it for 16 companies. If you are one building, if you are -- or if you're a couple of buildings on the same real estate section, that's just one facility.

MR. : That's great, and that's the right answer.

[Laughter.]

MR. : Jeff Aleman, General Wine Company. We import alcoholic beverages from all over the world. This relates somewhat to that question. All of our product comes into Detroit and is stored and packaged there for distribution throughout Michigan. We have three other facilities throughout Michigan that service cross docks. So my product comes into Detroit, we package it, and we send it on our trucks to these cross docking facilities and they are broken down and delivered to our accounts.

Do these other facilities need to be registered?
Or are they considered like a -- almost like a transport
vehicle facility?

MS. : Under the reg I would tell you
that they have to register. They are not a carrier, they
are storage or holding or whatever you want to call them,
but they don't seem to me --

MR. : The product is not stored or
held there, it is immediately transferred onto our trucks.

MS. : It's --

MR. : It's cross dock facilities.

MS. : It's just purely a docking
facility?

MR. : Yeah. It comes from Detroit.
It's delivered to --

MS. : Can you tell me how long you
keep it there at all?

MR. : It's transferred to trucks.

MS. : That's what I'm asking. Is it
there for any period of time?

MR. : Just the period of time to
unload it from a semi and put it onto smaller --

MS. : To another semi.

MR. : -- trucks.

MS. : It's really not a carrier. I mean that still sounds to me under the reg that it is. I mean this may be something we need to take back, but from my understanding, it's not a carrier facility, so it definitely would be a registration.

MR. : It's still considered holding, I guess, because it's there for minutes, hours.

MS. : Right.

MR. : Exactly.

MR. : Okay.

MR. : Keith Klawinsky from Valley Research. How guarded should we be of our registration number? Should we supply that to domestic customers?

MS. : Well, it's totally up to you. I mean we have in the codification, we have specifically said that registration is for no other purposes than for FDA, you know, to have a list. Under the statute we are required to keep it confidential. You can do whatever you want with it. I mean you could publish it to the world. It depends on what you want.

Your registration number will not get them into your computer records. You have to have a password. So you're not -- you know, that's not a problem. The only thing I would argue that could potentially, when we are talking about prior notice, is I mean some nefarious individual could certainly, you know, take your registration number and try and use it on a prior notice, but if the details aren't going to match up, you know, between the kind of product that they're trying to import and your registration number, because we will have that information, then it should show up that it's probably not their number.

So I would suggest that you sort of have to make that business decision yourself about how much you want to share it. There was some talk, I know, when we first were talking about this, that people said, oh, well, everyone is going to then want to know if you're an FDA-registered facility because they won't want to do business with you. You know, that's going to be a business practice. We'll see what happens over the future.

But we clearly make it, you know, a point of it in the codification that it is not -- you know, as far as

FDA is concerned, it is not a stamp of approval, it's not anything. It's merely a registration.

MR. : Okay. Thank you.

MR. : Good morning. My name is Tom Ward from Trans Overseas. We operate a bonded warehouse right here in Romulus, and we unload consolidated containers that may or may not have food products in them. We registered last Thursday. It was very simple. It took 10 minutes and we got the registration number back in 20 seconds online.

MS. : This is a paid political announcement.

[Laughter.]

MR. : My question is just with our status, where people might not consider us in the loop as far as registering, I suspect there's way more than 400,000 companies that are going to need to register. I've been communicating with my customers, encouraging them to register early, and so far I only know of two of them that have, and I'm wondering if you have any kind of contingencies for after Thanksgiving when suddenly there's

going to be thousands upon thousands that are going to try to register at the same time.

MS. : Well, let me give you an idea. The system that we designed is actually capable of handling an enormous number of registrations at a time. It has got more capability than the FCC do-not-call list that just registered. And as you recall, I think they did something like a million in a week for the do-not-call list. It is a very robust, you know, IT system.

I would urge you to help us all you can, to encourage people to get in there and register now. We're all taking vacation as of December 12th, so nobody will be available.

[Laughter.]

MR. : So your goal is no matter what, they can still register by December 12th, even if they are all doing it on the 10th and the 11th?

MS. : Well, I'm not going to tell you that if 400,000 people, you know, try to register on the 11th, it won't be a problem. That's certainly something that, you know, could happen. I mean there's no way to do that.

Obviously you are supposed to register by the 12th. If, you know, someone -- I would never encourage anyone not to register because if for some reason we had some major incident right afterwards, you know, it could be -- the only way we're going to find out if you're not registered, obviously, is through inspections or through someone else turning you in. But --

MR. : Well, you still have to declare a registration number for prior notice, so I don't know how you would do that.

MS. : That's -- I just was going to say in terms of imports, it's much more critical because it will be required with respect to the imports. For domestic facilities, it's likely to only show up in your dealings with other businesses or in your dealings, you know, with us, as an agency.

This is not to say don't register because obviously everyone needs to be registered by December 12th. And I -- you know, I won't say it won't crash, but the likelihood is just not there that it will.

MR. : I appreciate it.

MR. : My name is Irwin Groskind, and I represent Maury's Seafood, International (phon.). The question that I have is that periodically through the year we use an outside frozen cold storage facility to store part of our product. Does that need to be part of the registration process?

MS. : That facility should register, so whoever owns that needs to register.

MR. : Thank you.

MS. : Do we have any more questions?

MR. : Morning. Mike Skrjanc with AGA Gas (phon.). We supply a multitude of gases used in the packaging and in some cases used actually in the consumption such as CO2 and the beverage rate. Nitrous oxide, used for whipped cream as a propellant. Nitrogen, liquid nitrogen used for fast food freezing of beef, chicken, things like that. Do we need to register our facilities?

MS. : As I recall, this came up and the things that are used in the food clearly need to be registered as facilities. I'm not -- the freezing one I don't know, and I'm going to have to defer --

MS. : We're going to have to get you an answer on that one.

MS. : -- but I do know the -- you know, for the whipped cream, those type of things, you absolutely would have to --

MR. : So the nitrous oxide and the CO2 for sure.

MS. : For sure. The other one --

MR. : So the other ones, just depending on their usage?

MS. : Depending on their usage. If it's considered a food additive, it would be, but I would have to get someone -- I would take that back and hopefully put that on a frequently asked questions response. I apologize. That one I'm not quite clear on.

MS. : If you would just see Kelly with your name and phone number, we'll get you an answer.

MR. : Yes, I will. Thank you.

MS. : Any more questions? One more.

MR. : My name is Lloyd Hancock, and I'm a food distributor. Our company does not have the Internet available. We do have an IT person that does our

program. My question is would the IT person have the capabilities of going into the Internet and printing off those particular sheets that need to be filled out for the management to fill out and give back to her?

MS. : No, but let me encourage you to -- you can't print them out. You have to actually order them to get a mailed form, but I would encourage you just to go to the library or Kinko's and just do it that way. It will take just 10 or 15 minutes as I indicated, and you can do it on a computer that's not your own. So, you know, if you have a home computer, you can do it. I would suggest that you try and do it that way. Otherwise, you have to actually request the forms, because they are not the electronic menus printed out. That's not the form. So you actually have to request the form from FDA, get it, then fill it out, mail it back in, get back a confirmation. I would highly recommend you try and get access, you know, through a library, if you don't want to, you know, pay Kinko's or -- I don't mean to promote Kinko's, but any one of these services, you know, even here, the Marriott has a business center. I would suggest that you may want to try and do that.

MR. : Well, my concern is that the owners of the company that would be making those decisions do not have the capabilities of being computer savvy. As a result of it, they're going to have to provide the necessary answers to be able to put into the computer. That's my concern.

MS. : Okay, you said you have an IT person?

MR. : We have an IT person, yes, but that IT person is not on staff all the time.

MS. : Oh. Well, that's obviously a situation that you're going to have to decide with your IT person in terms of their confidentiality agreement, or whatever, yes, they would have to provide the information. If you -- you are worried about what information needs to be required. Well, that's in the reg itself. Everything that's required, you don't need to go to the electronic system to find out what's required. That's in the actual reg, the regulation itself. You can get the regulation again at a library or mail in for a copy of the entire regulation.

I think actually some of the handouts have almost everything that's required to be in there, if you don't have the actual regulation itself.

MR. : Okay, thank you.

MS. : Okay, if there are no more questions, we're going to take a short 15-minute break till 10:15, and then we will do the prior notice, and then we'll have questions on that.

[Recess.]

MS. : If you would be so kind as to come to the microphone, and ask your question, and we will make our responses. If we can't answer it, we'll table it.

Don't be shy. There's a lot of information out there on prior notice.

MR. : Yes, Tom Moore, Trans Overseas again. I have one question. [Inaudible.] I would assume in meetings like this that it was up to me to do the prior notice for those containers before they arrive at the coastal port, but even listening here, it almost sounds like that responsibility might be on the inbound carrier, which would be the steamship line.

MR. : It's really not up to us to determine who has the responsibility. We're just saying to everyone, someone has to file the prior notice. Because that's a business decision.

MR. : But if it's quoting an entry number, would it be the inbound entry number, or the entry number back here in the States?

MR. : It's the entry number at the port of first arrival, so for the case of an inbound, you should -- it should quote the inbound number, so that we can match the two up correctly. Because we are not going to allow it to move from the port of first arrival on its Customs entry number. We are going to move it based on the inbound number. Then the entry number will be taken care of when it arrives here in this port.

MR. : So that will be up to us to determine between ourselves and the carrier who is going to be submitting that number?

MR. : Exactly. And there may be cases, because of what we talked about with the IT movements, where the carrier may file -- may begin the

process against the IT movement and be unable to have all the information.

MR. : Yeah, that's going to be the case, yeah.

MR. : And the -- a second prior notice will have to be filed and satisfied here when it makes arrival, when it makes entry.

MR. : A second one?

MR. : Well, an update to it. It will have to be -- it has to be completed.

MR. : Are we still allowed to move from the port without a complete prior notice?

MR. : No.

MS. : Nancy Linde again. I'd like to pose the question to you from the Customs perspective, like the other gentleman asked a question, and I did. His was gases that are sometimes foods and sometimes industrial use, like carbon dioxide may be a coolant. And I asked about clove oil, which might be a food or flavor and may also be for use in a cosmetic. How is that going to be treated? You know, it's one thing whether or not it's required to have prior notice, but also, you know, would it

be sufficient for those things like the carbon dioxide where it's industrial use only to simply put on a bill of lading that this is for industrial use and not for food?

MS. : I'll answer for Jim. We're working together collaboratively, so it's either going to meet the intents of both agencies or it's not going to meet them. So they won't be dealing with it any differently. And as -- I think I found you the page in the CFR, and we'll give you the page that we've got that we think answers some of your questions, and if it doesn't, then I'll go back and get further definition from some of our policy folks.

But they won't be acting independently.

MS. : Right.

MS. : One of the things that wasn't covered in detail, and it doesn't usually -- it isn't usually covered in detail -- was in addition to all of the electronic reviews and screenings that are going to be done first on the ACS side and then through FDA's system of OASIS, we're going to have a staff of 24/7 reviewers, human beings, and when the systems, for all intents and purposes, burp something out, you know, this is after prior notice

has been indicated as satisfied, and this is where the review comes into place, if we see something in that, the human beings see something in that particular submission that would indicate to us that, A, it needs to be held, or B, it's a quirk of that industry as in, you know, we know your firm, we know the fact that you bring clove oil in, we know it's not for food use, we know it's for something else. This is a mental database that will be built up over time, and one of the reasons why we are going to be exercising some enforcement discretion during the first few months after the 12-12 date, so that we can have some experience using the systems, have some experience with the kinds of things the system is going to burp out at us, and need further review of. And hopefully some of these issues will be solved then.

But it is very much a joint effort. Our folks who are going to be doing the targeting are actually going to be colocated with the CBP folks who do targeting in a centralized facility in Virginia. So we will be talking like on a moment-to-moment basis. So whatever decision will be made will be joint.

MS. : I think you're suggesting if you show up at the border, and you have not declared -- you have not sent a prior notice because you're saying it's not food for human consumption, the question is whether Customs would stop you and say, oh, of course it is food, it's clove oil.

MS. : Right.

MS. : Is that what you're asking?

MS. : And technically what would happen is the Customs person would get back to the FDA person and say what is this. Help us figure this out. So it will be one decision per two agencies.

MS. : Every other time clove oil has come in it's always been a food, we might be a little suspicious that you hadn't filed prior notice, but it would be a human decision at that point.

MR. : And part of the query process of this set up at the very beginning is, as I said, on the entry side, the tariff numbers are determined -- determine which products may be subject to it. So you won't even past the -- if clove oil is listed as being -- if the tariff number of the clove oil comes in under is listed as

being a food product, we're going to require the prior notice.

MS. : Okay. Thank you.

MR. : Hi, my name is Robert, and I work for a company that manufactures fibers, and my questions are kind of related to what you just spoke about. One of the raw materials that we use, we sell to technical and industrial but also some like pet food applications is cellulose, which comes from wood pulp.

I also have a company in Europe, a parent company, where we might import goods, import raw materials, the pulp, or the pulp ground down into a powder.

We have had final rulings from Customs that the raw material, of course, and the product that's milled to a powder still falls under chapter 47 of the HS code, which is the duty-free for pulp and paper. Let's just 50-50 is business that actually goes into food and actually goes into industrial. What do I have to do for shipments coming from Europe that's the pulp, that's the powder, and also if I buy pulp from say Canada or from somewhere else? Is that considered something that I give prior notice to?

MS. : If it's intended as a component of food, yes. And, you know, unfortunately I can't -- there is no -- I think the term is de minimis -- there is no de minimis. There is no -- if it's at all potentially going to be used in food, it's a component of food and therefore you have to do prior notice for it.

MR. : Even though the HS code -- I'm sure it will not pop up as hey, we'd better look at this.

MR. : Well, again, there's like 2,000 impacted HDS codes, and I don't know them all, to be honest with you.

MR. : I can't imagine that chapter 47 --

MR. : Most of them are in the first -- well, there are some in chapter 47. They're scattered throughout the tariff because there are items that are in the chemical chapters, in any of the natural substance chapters. There's a lot of mineral chapters. There's a lot of them that are scattered around because they are food -- they have a use as food. The scientists have determined which one of those, based on FDA product codes, might be. We have loaded them already in the system, and if the

system spits out that your particular item in chapter 47 is subject as a foodstuff, we won't even let you get past the first step because prior notice will be required.

MR. : Okay.

MR. : If it's not, and you know that the food is subject for food, you're subject to potential penalties from FDA because you didn't file prior notice and you were supposed to.

MR. : If I'm not setting up the import, if I'm buying from a vendor, do they have to set up the prior notice?

MR. : Well, somebody will be subject to it.

MS. : Right.

MR. : And that facility obviously has to be registered. So a pulp company, for example, who sells a few hundred tons to me out of the half a million tons a year, they have to be registered as a food facility then?

MS. : Yeah. Jarilyn?

MS. : Yeah.

MS. : Yeah.

MS. : Yes.

MR. : For some of these specifics, you should best talk to your Customs broker because they already have the lists in the databases. They already know which ones are subject to FDA requirements. That's already been loaded into the database.

MR. : And I know it's not, because there's no FDA code builder for the HS code. We'll have to submit it.

MR. : Well, that doesn't mean that there's -- just because there's no code builder for this doesn't mean that it's not covered, it's not a covered tariff. There are some that we have heard that don't have FDA codes, but that are still potentially covered tariffs because of a broad description.

MR. : But, Jarilyn, you are saying that any pulp company that I might buy raw material from, I have to get them registered if they are not in this country?

MS. : If they know that it's intended for human food or consumption, yes, they need to register as a facility.

MR. : I honestly don't think they know because it's such a small part of the business. I mean we are talking literally tenths and tenths of a percentage of their whole business.

MS. : To be honest with you, I don't know what to tell you other than that's the way this -- both the statute and the reg read. It says, you know, intended for. They would have to register as a facility and you may want to tell them that they need to register.

MR. : I mean there's hundreds of potential vendors which I want to keep open to keep my prices down.

MS. : Yeah.

MR. : I'm going to need 10 people working for me to do all this work. But I guess that's what --

MS. : But you wouldn't register. The facility itself would have to register.

MR. : Correct, but to get somebody who's selling tenths and tenths of a percentage of their product to me, they're not going to want to.

MS. : I appreciate that. I think our problem is that this is what Congress told us to do, and sort of we are sort of in a -- we are in a no-win situation in terms of being able to change that type of thing.

MR. : And just what happens if obviously a container that's coming in of wood pulp, with the pulp and paper industry being so big as Customs ports, that's not going to be probably flagged as, hey, that's food. What happens if I do nothing, it comes in? I mean I am subject to criminal penalty for not knowingly doing prior notices?

MS. : Customs could effect civil money penalties. We could take civil or criminal action if you knowingly -- certainly criminal if you knowingly bring product in, you know it's destined for food use and you don't file prior notice.

MR. : And if it's, like I said, about 50-50, or whatever the percentage, even if it's only 5 percent going into the food, if I can't segregate ahead of time, I have to, for all shipments?

MS. : Yeah, unfortunately there is no de minimis there. There's no minimal value, if any of it is going for food, it has to be filed.

MR. : Okay. Thank you.

MS. : I'm Debbie from Wilson, International again. I know this has been answered, but I just wanted to clarify it. If the trucker -- if they did the prior notification and they indicated they're going through Port Huron, but they come into Detroit or vice versa, even though FDA is approved, what about Customs? If we've entered -- if we have issued an entry number, is it going to be a problem for Customs purposes, or are you going to accept that number?

MR. : Well, currently now if you file an entry in Port Huron and you show up in Detroit, you're going to have to cancel your Port Huron entry and file one in Detroit because we don't have cross processing. We're working to effect cross processing within related ports, but it's a ways above.

MS. : That won't come till February.

MR. : Yes.

MS. : Okay. So then what happens if they do show up in Port Huron, the time clock has already started for that two-hour prior arrival or prior notice? Can we have the truck directed back to Detroit because that timeframe is still within that window. Does that prior notification, is that nonexistent, or do we have to start from scratch again? Can we still use the prior notification and just change the entry number and the port?

MR. : That's prior notice question.

MS. : Well, the prior notice gives you -- the way prior notice under the interim final is crafted is you have the ability to identify your anticipated port of arrival. And as Jarilyn mentioned, we're talking weather and stuff like that.

MS. : Right.

MS. : That would cause you to send it some place different. From a prior notice perspective, the only time that FDA is probably going to get really freaked about this, if you say you are going -- you know, if you're going in through Port Huron -- geography is not what I'm strong in, but for argument's sake, you're coming in through Blaine (phon.) and you show up in the Ambassador

Bridge. I mean, you know, that's the kind of thing that's going to flag FDA.

From the standpoint of how the entry plays out, that I can't -- I can't speak to how the entry plays out. Prior notice will be -- we are going to stop you from a prior notice perspective if you show up at a different port than what you said you were going to from an entry perspective. That's going to be a Customs answer.

MR. : And that's, again, only if your entry is filed in one port and you show up in the other, obviously it's no good.

MS. : But so we cancel the entry. I've got that part down. So then we can still use the prior notice, so then that's not going to be a problem.

MS. : Yeah, I don't see -- I mean, I don't know from a reconciliation --

MS. : The only difference is that that prior notice is going to have the wrong entry number on it, and there will be nothing corresponding.

MR. : Because you cancelled, then you'd have to file a new prior notice.

MR. : I think you would have to file a new prior notice.

MS. : No, no, wait. Let's go back a minute.

If the prior notice confirmation came in, it was all -- you know, the prior notice was adequate, if we are saying that there is not an adequate prior notice because the anticipated port of arrival turns out to be a different port, then the prior notice is probably satisfied. I think it's only Customs that might be --

-MR. : But if we can't link it up, we're not going to release it.

MS. : You're saying if you can't link it up.

MS. : Yeah, it's a technical --

MR. : It becomes a technical issue because -- well, the brokers -- I know Debbie understands this issue, because -- but the -- because of each port, the way the Customs law was written, each port is its own entity, and brokers are only licensed to operate in certain ports. And the entry is filed and it's port-specific. Therefore, if an entry is filed in Detroit, it can't be

processed in Port Huron currently. Each broker's license is specific to and issued by the port director for that port.

Therefore, they can't -- we run into a problem of them having the ability. So what we have to do then is cancel the entry and file a new entry number for Detroit. When they do that, we lose the link between the prior notice and the entry. The entry will then say, we can't process because there's no prior notice.

MS. : Now the other thing I was thinking, too, was with the congestion at each one of the ports, and I think we touched base on this once before, but there was a meeting up in Mississauga for the carriers, and the carriers were told that no truck would be refused or sent back. If we don't have the facilities in this area to put them into a warehouse or somewhere to hold until the prior notice takes effect, we definitely can't have trucks circling -- there's no space at the bridge. If they send them back to Windsor, there's no space in Windsor because they'll congest the area up in there.

So what are we going -- I mean when we send our notifications to our carriers and our vendors, we want to

ensure that we are giving them the same information that they are getting from anyone from FDA and for U.S. Customs. What do we do in this case? I mean it's obvious that if there's no place for them to be held, they have no choice but to go back to Canada until the prior notice is accepted.

So do you see a lot of IEs? I mean do you anticipate that, or what do you have in place for that?

MR. : Primarily again we have left it -- we've had to leave it to the ports because they are the only ones who can make that determination. I see in Washington. I really can't make a determination whether Detroit has enough --

MS. : But you worked at the ports, so you have an idea.

MR. : So the ports have to make a lot of those decisions, and they are going to be publishing or sending out information as to, you know, the secure facility is this, this, and this, this is where the merchandise will go.

You're right, we can't force -- they were correct when they said we can't force someone to leave, because of

a technical problem. However, in most cases it becomes the most -- it becomes the most suitable option for them to take it back and wait for the timeliness.

Now communication is going to be the key to this thing, and people like you and the importers and the carriers are going to have to develop new levels of communication on these issues because of the timeliness questions.

MS. : Right. Okay. Thank you.

MR. : I'm Dave Wankowski from Kraft Foods. I've got a couple of questions on prior notice, one being on competitor samples. In other words, if we want to bring in a competitor's sample from a particular nation into the States here and we are required to not only list the shipper's registration number, but also the manufacturer's registration number, how does one get that number, first of all, from that manufacturer? If it's a competitor, it may not be, of course, available.

And then secondly, it may not even be in existence because if that manufacturer's not currently exporting goods into the U.S., they wouldn't need to register.

MS. : Unfortunately I don't know the answer for a registration question like that, but we'll take it down. Jarilyn, you don't -- we've had this issue come up in a number of contexts. We've had it come up in -- with respect to companies who --

MS. : Who go out of business.

MS. : -- who go out of business or people who bring in very old wine, vintage wine for which, you know, the manufacturer hasn't been in existence for years and years and years. And the current guidance, the last guidance that I read on those kinds of situations were such that they would come in and they would be refused, and I put that in quotes, and that they would be held pending an explanation by the submitter of the prior notice as to why a registration number wasn't provided.

Personally, and I think pretty much everybody who has heard this explanation thinks that this is not a tenable explanation, so that we have to come up with something better.

MS. : In the preamble, the only exception for not giving the registration number is when it's international mail and it's an individual mailing

something that they bought from someone, and they are able to put just the manufacturer's name and the address.

MS. : As they would get it off the label.

MS. : But the codification or the preamble don't speak to the type of thing you're talking about, when it's a business-business transaction. And that may be something we have to bring back.

MS. : We'll bring that back. If you have a business card, you could leave that with us.

MR. : Yes. The second question is, is there any idea of the time for processing the prior notice numbers? There's been a lot of talk out there it could be anywhere from immediate to up to two hours, and we went even as far as it heard that if you haven't heard back within two hours, to refile another notice again.

MS. : No, you shouldn't do that. That's a for sure --

MR. : So any time --

MS. : We were saying 15 minutes.

MS. : The normal process, the entry process we have now, between CBP and OASIS.

MR. : Fifteen minutes.

MR. : But, remember, that if you file and then try to cross within 15 minutes, there's no guarantee that it's timely.

MR. : Correct.

MR. : So the timeliness is still based on the timeframes.

MS. : And if you don't get a response, that may very well mean that your prior notice -- that you do not have a prior notice that's confirmed, and therefore you may be refused at the border.

MR. : If you don't receive -- I mean if you're waiting for a response back, thinking you have all the information accurate, there's got to be a time when you draw a line in the sand and say, well, I haven't heard anything back, maybe I should notify somebody. So I think maybe that would be -- so that 15 minutes, is that the placeholder that we should use?

MS. : I think we should probably include that in our FAQs. But 15 is about what we're saying. But as far as knowing what the status is, what we are going to give you is a message that says it's received,

with a confirmation number. It doesn't mean it's satisfied.

MR. : Right. Understood.

MS. : So there wouldn't be -- it wouldn't be an issue of whether there was data missing or that kind of thing.

MR. : It would just be received, but just that initial --

MS. : Correct.

MR. : Okay.

TAPE CHANGE TO SIDE 2

. . . country. Are we to understand that definition to be correct?

MS. : I think something like shelling and husking is okay. It's any further processing. The one question that's in the preamble, I believe, is the difference between whether coffee is caffeinated or, you know, whether it's in its natural state, as caffeinated, or it's decaffeinated. Decaffeinated coffee has been processed, whereas my interpretation and this is just --

MS. : Yeah, I think in the preamble there's several examples that are given with respect to that. I don't think nuts are used, but there's some other examples with respect to preparing, you know, preparing foods from a farm, and some of them do, I think, talk about husking and shelling and stuff. So that certainly seems to be analogous to the nut example.

MR. : So that would keep it in its natural -- still maintain natural state, or out of its natural state?

MS. : I would say it would keep it as natural state, but it wouldn't -- you couldn't do anything more to it than that.

MR. : So then you need to supply grower, if known.

MS. : Yes.

MR. : Okay.

MS. : I just want to add to this. I just reviewed a list of products that will be added to, a list that will be on the Web. Jarilyn mentioned there would be some -- a reference there for those things that

are considered nonprocessed, and I don't recall nuts being on it. So we will double-check on that.

MR. : That would be a great example to use.

Last quick question. It was my understanding that if the initial prior notice is rejected for whatever reason, and if it's initially submitted through the ABI system, if it's rejected, then it needs to be resubmitted through the PN system. If that's the case, and if I read the slides correctly, if it needs to be resubmitted through the PN system, then that number must accompany the product coming in, what the slide said, it listed examples of where prior notice must be accompanied with the goods coming into the country.

MS. : Right.

MR. : Now if initially submitted through the ABI system, it would be in the entry system and Customs and FDA could see it. But if it's rejected for whatever reason, it takes away that electronic viewing that accompanied the product there, or the paperwork, from my understanding. Is that correct?

MS. : I'm sorry, I was writing when you started your question. Can you --

MR. : Okay. From what I understood today in today's discussion, if the initial prior notice filed through the ABI system is rejected --

MS. : It's refused.

MR. : Refused.

MS. : Yeah.

MR. : For any reason.

MS. : The end product.

MR. : Right. Then if we need to refile that prior notice, it needs to be refiled through the PN system. It cannot be refiled back through the ABI system. And if that's the case, from what I have seen in the slides, if it needs to be refiled under that PN system, then that number, then the PN number needs to accompany the goods versus if it's -- versus being electronically viewed through the ABI system as initially.

MR. : We have an override for the entry.

MR. : Is that right? I mean it just seems like your work is going to be a cluster, if you will.

MS. : Yeah, we have -- we will have a link with CBP on those prior notices that are filed in on the Web. We will actually be transmitting a certain level of data to them which will include the confirmation number, the bill of lading, entry identifier, so they will actually have that confirmation number in their system as well.

MR. : Okay. So it will not have to accompany the goods if it's initially refused?

MS. : That's a disconnect in the reg then. Under PNSI, the --

MS. : That's something I would have to go back and check because I'm not --

MS. : -- the PN confirmation must accompany the goods, and in this case because it's a -- it's required to be filed under PNSI given a refusal under the ABI ACS, it's a disconnect.

MS. : Yeah, that's something we'll have to take back and check on, and obviously feel free to submit a comment to the docket on that.

MS. : Just to make sure that we know what you're talking about, because at one point you said rejected and one point you said refused.

MS. : Well, I put refused.

MS. : Okay. Because rejected -- if it's rejected back through ACS, you can resubmit it.

MR. : Right. I meant refused.

MS. : So it's actually at the border?

MR. : Correct.

MS. : Okay. Well, then, we do need to --

MS. : And then again, if it's at the border -- see, that also provides you with an -- if it's at the border, it's physically there, so then you do have the ability potentially to attach the PN confirmation to it. It could accompany it at that point.

MR. : Or if it's just coming into the port or something like that, obviously having the accessibility through the electronic version is much more user-friendly, obviously.

MS. : Exactly. Uh-huh.

MS. : Well, right now the problem is that PNSI is not directly linked to ABI ACS. Part of what we are working on over the next few months is to enhance the interface between the two -- between all of the Customs

systems and the FDA systems such that we will be able to present a plan to the White House as to how we're going to reduce our timeframes to make them consistent with what are in the -- I guess, is the advanced manifest rule still proposed?

MR. : It's still proposed.

MS. : It's still proposed. It hasn't gone final yet. And we're going to be working on doing this. Of course, if ACE was up, it would be far, far easier.

MR. : The last thought came to my mind, for samples coming into the U.S., how is one to distinguish between a sample coming in and an item coming from a person who bakes a cake in Italy and sends it into the U.S.? Is that person going to need to write on the -- I think somebody else asked the question, too -- the invoice or something that it's a baked good versus a sample or something else, so that FDA will be able to distinguish between the two requiring a notice?

MS. : Well, one of the things we're looking at now, and this is a relatively recent exemption, the personally baked good that's going to another person,

is the kind of return address that you're going to have on the parcel that you would see in the international mail. And if it's coming from a firm, it's obviously not a home-baked good or you would think it wouldn't be a home-baked good.

So there's going to be a lot of discretion that will be exercised in this arena until such time as we get some of these situations straightened out.

MR. : Most of these will be done at the time that the information is reviewed, and based on -- again, if we find an invoice in the guy's pocket stating that it's a commercial sample and he's declared he got it from Aunt Edna, well, now, he's also subject to Customs penalties because he didn't tell us the truth.

So I mean this is -- a lot of this is, if you want to call it the honor system, with tight checks.

MS. : It's a work in progress.

MR. : People are required, when they arrive, to tell us the truth, whether it's when they file information upon arrival in the United States, you're required to declare all your merchandise. It's not -- that's not negotiable. That's a requirement of the law.

One of the oldest laws on the books in the United States. You're required to declare everything you bring in with you, and you are required to truthfully declare it.

So we are working from that premise forward and saying that if it's personal, you declare it as personal. If it's commercial, you declare it as commercial. Smuggling is something else. When people don't tell us the truth, we call that smuggling, and then we deal with that in an appropriate way.

So I mean that's -- it's kind of a vague answer to your question, but it's really the only one we have, unfortunately.

MR. : Well, using discretion on your enforcement, for instance, if we registered (inaudible) Kraft Foods, Inc., versus Kraft Foods, Inc., is that something that you would apply discretionary enforcement to?

MS. : Oh, certainly.

MS. : Let me explain. The IT system that we have developed will actually registration a lot of those type of things, and they will pull up what's similar, so then they will look further to see if the address

matches, they'll look further to see if the owner matches. It will be doing a lot of verification before you even get your registration confirmation number for registration.

So the system is accommodating those type of things, and it will come back and say to you did you mean Kraft, you know, no comma Inc., as opposed to Kraft, Inc. I mean it actually will do those type of things in responding to you while you are filling the registration out.

MS. : And beyond that, once registration is filled out, a similar kind of system is also built into prior notice, so that if there's -- if there's a transposition of letters in a name, there's name comparisons done. We've -- traditionally anybody who deals with us knows that forever we have had problems with foreign firm names being, you know, 300 digits long and there's three or four of them that are transposed, and in our system those are different firms.

Well, this new system that we're hoping to have in place in time -- and I think it's been -- the firms' master list is done. I don't know how up it is, but it's a really very nice system. It will actually go -- it goes

off postal system databases, and it will tell you whether or not there is a street and a city by that name, whether there are cities in that country by that name, and that's part of the preliminary validation that the data will be going through.

MR. : Okay. Thank you very much.

MR. : Keith Klawinski with Valley Research. If we were to export a product, shipment to one of our customers, and they for some reason don't need the product any more and decide to return it to us, they would need prior notification filed?

MS. : If it's a food --

MR. : And so therefore they would need to register their facility?

MS. : No. No.

MR. : No? Oh, okay.

MS. : Not necessarily. Not necessarily. It depends upon what it is.

MR. : Okay.

MS. : I mean I would assume that if you were shipping a product out to them, the product would

have been manufactured in the United States, so that's the manufacturer.

MR. : Okay.

MS. : People sending it back to you would not have to register, because they didn't manufacture it.

MR. : Unless they were a holder of food.

MS. : Well, unless --

MR. : They'd have to register as a shipper or as a warehouse or whatever.

MS. : But not as a manufacturer.

MR. : Not as a manufacturer.

MR. : Okay. So they wouldn't be considered the holder of that product for two months before they decided they didn't want that product?

MS. : Well, if they hold food, they have to register then. It depends upon what --

MS. : Well, it depends on what their business is. If they are holding food -- I mean if you are just sending it to, you know, a company that doesn't hold food as their business, they're just -- you just happened

to send them something that is food, that doesn't mean they have to register. That has to be their facility that does that as the normal course of business.

MR. : Okay. Thank you.

MR. : Jack Webster from TPAC again.

Is there any downside to registering a foreign facility that doesn't need to be registered?

MS. : No real downside. It just clutters our database a little bit, but there wouldn't really be a downside. If you think there's any chance at all that it's going to be subject to it, it's probably better to register it than not.

MR. : And what about prior noticing a shipment that doesn't need to be prior noticed? And this is based on the concerns I raised before where I think that the FDA and Customs are going to think it's going to be -- need to be prior noticed.

MS. : Well, if the tariff code doesn't allow it, you won't be able to.

MR. : Well, that was my next question. As I said, I'm really not familiar with the tariff code.

The tariff codes are what's going to determine whether something has to be prior noticed?

MS. : Correct.

MR. : On the ABI side, they will be. So you will be using the tariff codes to file the -- through ABI, and then ABI will tell you that that is not a tariff code that required prior notice.

MR. : So in a situation, if there's only one --

MR. : I don't know if you have something similar in the --

MS. : We won't be using the tariff code, but if -- you can't file it if you don't have an FDA product code that's related to food. Unlike through ACS, ABI ACS, you can use any product, any FDA product code when you transmit. On the Web we are limiting our set of product codes just to foods. So you wouldn't be able to save and transmit the prior notice.

MR. : So this is information we're going to get off the Web. As I said, right now all I've done is read the regulation, and I can see, as I explained before, that we should be exempted from this, but I don't

know anything about these code numbers or anything, and I'm not sure where they're going to be leading us.

MS. : And again, the product you were talking about was? Oh, the casings.

MR. : Nonedible casings.

MS. : But you filed through ABI ACS right now when you --

MR. : I don't know.

MS. : Well, I guess my suggestion would be that you go back and talk to your broker and see what -- see how they bring in -- what they do with the HSC codes.

MR. : Okay. And just one last -- I tried to educate you a little bit about casings before. Let me throw in one further one, and that is we do make a couple products which would normally be considered food contact materials, but because they have a technical effect on food, they are supposedly -- they are -- they don't qualify for that, so that would be another -- it's our understanding that those would have to be registered and prior noticed, but they fall again in a -- I don't know how the category -- they're nonedible food that has technical -

- or nonedible food packaging that has a technical effect on food.

MS. : As in they become in some measure they become a component of the food?

MR. : Not the casings, but specifically I would be talking about nonedible casing that has a color additive included in it so that it colors the meat product that stays with the meat, and then the casing is removed. [Laughter.]

MR. : We're learning all sorts of stuff.

MS. : Stuff I never wanted to know. We're writing it down. I really am going to enjoy this enforcement discretion period is all I can say.

MR. : I just have one more question. It sounded like you said that for prior notice, it's actually if when my broker files with the ABI system, the harmonized tariff code will be the determining -- whether it needs a prior notice or not?

MR. : From the Customs side.

MS. : So if you file through ABI ACS, the first part you are going to hit is ABI ACS, and at that point in time they should tell you.

MR. : Right. When you file by the tariff, there's determinants in the tariff, in our tariff file, that say all of the product codes under this tariff are covered or some of the product codes under this, and then it will drop to the product code level and look to see if that product code is required or not. And then it will accept it, pass it on to FDA.

MR. : So if my particular HS code right now -- how do I find that out? Who do I ask if --

MR. : The person who files your Customs entries, because this is done --

MR. : They'll know today whether it's --

MR. : This is done at the time of your Customs entry. If not, they will be able to figure it out pretty quickly.

MS. : But we are also putting those on the FDA Web site, hopefully, like I said, within about the next week or two, all the HTs.

MS. : I don't want to create a false sense of security for you here, you know. It may not be there now, but if we find out that there are HTS codes that are not there, for which there are product codes that are foods, it will be amended as time goes on. So while, you know, your broker -- if you file through ABI ACS, your broker is going to be your best gauge of what your next step in the process is.

MR. : Brokers have the ability to access the ABI files and look up the tariff file in the ABI, and there are two codes that identify that the brokers can use that identify which tariffs are subject and which aren't.

MR. : And I'm pretty sure that the HS code that I'm using is not something that is going to be enforced, so Customs right away will say, even if I try to do prior notice, forget it. But you say the FDA code will be the next step that you --

MS. : It won't even get to the FDA code, if it can't be -- it's a sequential process. First it goes into ABI ACS. Then if it passes muster with them, they do their verifications, validations, and all their

checks, and then they send it to FDA, and it goes into the OASIS system, and that's where the product code comes in; correct? MR. : But just so you know, we're not going to go back and talk to the scientists and have them check on cellulose.

[Laughter.]

MR. : Well, I've got final rulings. I mean if you can change your --

MR. : Well, no, it won't change the tariff code. They're just going to determine that some of them are subject and we'll have to add them based on their determination that the product -- there is a product code or should be a product code for that. Because they may add product codes as this goes on. I'm sure we will. I'm sure there will be all kinds of things added to this before it's done.

MS. : Yeah, and something that we have under discussion still is right now there's the ability, if there are tariff codes without FDA indicators on them, the filer software is supposed to allow them to transmit data to FDA anyway. And the same issue has been brought up on this. If it is a product that does not have a PN FDA flag

on it, are we going to say that you have to transmit that, anyway? That's something we're still working out.

MR. : But as of right now, if my codes that I use are not prior -- on the prior notice list, I don't have to worry about anything I talked about the last time I was up?

[Laughter.]

MS. : You want to check on December 11th.

MR. : I'm checking for updates.

MS. : Well, and I would say, too, we probably need to get a legal call on this because the answer may be that you might have to file through the Web. So I think it's something we need to get an answer for.

MS. : But it's also -- this is all part of, you know, the enforcement discretion issue, too, and obviously this is -- you know, it's going to depend on what happens. I mean if this is so confusing now and it's still confusing on December 11th, that might impact what we do on, you know, with respect to enforcement discretion.

MS. : And one of the things that we had some confusion with and we talked to the couriers about

a week and a half ago is they wanted to know, given the fact that we were in a state of flux, and it's an interim final rule, and comments are still being accepted, what would be changed between now and 12-12. Nothing. Nothing will be changed between now and 12-12. The comments that we get in between now and the December 24th will be considered certainly after the rule is implemented. And even though it's an interim final, as Jarilyn described, it has all full force and effect of a final regulation. It's just that we're accepting comments on it for an extended period of time. So comment, feel free, everybody who has any issues that they think we have not adequately addressed or need to further consider, comment.

MR. : Last question. I'm sorry, I know it's late. One thing I was going to mention, first of all, there's not too many brokers in the room that I recognize, so I'm trying to take advantage.

One of my customers was at a meeting in New Jersey last week similar to this. I don't know who ran it, but they were told specifically -- they asked a question and the people got back to them later that prior notice

wasn't going to have to be done until arrival at the port of entry instead of the port of arrival, which --

MS. : That is incorrect.

MR. : -- I'd love to find out more about that because they are set that they researched it all out and that's the way it's supposed to be.

MS. : I would appreciate -- you have my name and --

MR. : Yeah. I saw the clarity again today. Because I was thinking maybe that was one of the changes that was coming up that I was going to hear today, but it's obviously not changed.

MR. : In every case it must be submitted at the port of arrival.

MR. : Yes, I saw that clearly.

The other thing I was going to ask briefly -- I know it's getting late -- right now as a broker we are required to provide that the product code information and required to report to the sequence of the measurements of the product, you know, how many cases and how many pieces in a case and how many grams to a piece and all that. Is the prior notice in your almost infamous tuna example going

to be the same type of sequencing? I know there's got to be four separate prior notices on the tuna, but is it going to be the same level of detail in the packaging?

MS. : Yeah. Uh-huh.

MR. : So I'm going to have to do it, the same way with Customs, plus on the prior notice? Because from my understanding of the satellite broadcast, my former requirement hasn't gone away. But I still have to do the product code screens and transmit those?

MS. : I'm not following the question.

MR. : Right now --

MS. : Do you transmit quantity now, too, for FDA?

MR. : I transmit quantity now.

MS. : At a Customs level or at an FDA level?

MR. : Well, I transmit at the Customs level. Well, I have to transmit the FDA product codes through Customs and sequence out all of the quantities.

MR. : So you're already doing that.

MS. : And that's not your requirement?

MR. : No, that's FDA's.

MR. : That's FDA's requirement. And if I don't put the base unit as the last unit, I get a reject, and I have to resequence it.

MS. : Right.

MR. : So that hasn't gone away?

MS. : No.

MR. : But now in addition to that, the prior notice is going to have the same level of detail to it?

MS. : No, you're sending it at the same time. Just because you are able to send it now doesn't mean that it's not a prior notice data element.

MR. : We're working hot and heavy on the screens right now. So all they are going to be doing is adding screens that covers the other information that's not currently provided?

MS. : Right. Yes.

MR. : I get the impression that that's a separate thing where the prior notice has got its own --

MS. : No, we're taking advantage of every situation where the data is already part of the transaction, which is why --

MR. : Because my goal now is to determine how much manpower I need for the transmitting part. Okay, thank you.

MS. : Okay. All right. Thank you. We certainly want to thank our panelists, Jarilyn, Jim, Debbie, Kelly, for being here today. This is the first of the domestic outreach meetings that are being held around the country. I think there are five more that will be conducted, and hopefully you know a little bit more about what you need to know to be in compliance with the Bioterrorism Act. Locally we have Tony (inaudible), and Tony will give out his telephone number. Hopefully you won't mind. 313-393-8176. And Tony is available as a resource to field questions as we move towards the 12th of December.

So thank you for attending, thank you for your time and attention, and we do appreciate your coming out today.

[Whereupon, the conference concluded.]

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