

NWX-FDA OC

Moderator: Teresa Rubio
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Coordinator: Welcome and thank you for standing by. At this time participants will be on a listen-only mode until the question-and-answer portion. If at that time you would like to ask a question, press Star 1.

Today's conference is also being recorded. If you have any objections please disconnect at this time. And now I'd like to turn the call over to your host today - to Miss Teresa Rubio. Ma'am, you may begin.

Teresa Rubio: Thank you. I appreciate you joining today's Industry Stakeholder call. My name is Teresa Rubio. I'm a Health Programs Coordinator in FDA's Office of Health and Constituent Affairs and will be serving as the moderator for today's call. The purpose of today's call is to discuss FDA's sanitary transportation final rule under the FDA Food Safety Modernization Act.

I'm joined by Dr. Stephen Ostroff, incoming Deputy Commissioner for Food and Veterinary Medicine; Dr. Rebecca Buckner, Policy Advisor on the FDA Food Safety Modernization Act, to that FDA Deputy Commissioner for Food and Veterinary Medicine, who will discuss the final rule.

I'm also joined by Dr. Michael Kashtock, Division of Plant Products and Beverages, Office of Food Safety, Center for Food Safety and Applied Nutrition, who will answer technical questions about the rule.

This portion of the call will be in a listen-only mode. After the presentation we'll open the lines for questions. I will now turn the call over to Deputy Commissioner Stephen Ostroff.

Stephen Ostroff: Thank you Teresa. Let me say that I'm very pleased to have rejoined the Office of Food and Veterinary Medicine, because when I came to FDA in 2013, it was in the role of Chief Medical Officer in (FSDAN) and Senior Public Health Advisor in the OSDF.

So I came to FDA to work on food safety, and nothing made that opportunity more appealing than the promise of the Food Safety Modernization Act. It significantly improves food safety and reduce the incidence of food-borne illness in this country.

Therefore I'm really especially pleased to be joining you today as we announce the FSMA sanitary transportation final rule. This is the sixth of the seven major FSMA rules to be published in final form and continues to build on the idea that FSMA is designed to implement prevention strategies from the farm to the port.

This rule is critical to assuring that the many measures to reduce and prevent contamination built into the other FSMA rules overseeing the production of domestic and imported food are not placed in jeopardy by potential problems that can occur during transport.

The sanitary transportation rule will work in concert with previously issued produce safety, human and animal preventive controls, and import rules to systematically strengthen the food safety system and better protect public health.

I look forward to working with colleagues here at FDA, as well as with our partners in the states and this industry, for a successful implementation of all of the FSMA rules, including sanitary transportation. Let me now turn the call over to Dr. Rebecca Buckner.

Rebecca Buckner: Thank you Steve. As Dr. Ostroff mentioned, today's action is part of a larger effort to help prevent food safety problems throughout the food chain. The final rule is part of the implementation of the Sanitary Food Transportation Act of 2005 and the FDA Food Safety Modernization Act - or FSMA - which was enacted in 2011.

This new rule is focused on ensuring that individuals who transport human and animal food by motor and rail vehicle follow appropriate sanitary transportation practices and do not create food safety risks.

Practices that create such risk include failure to properly refrigerate food requiring temperature control for food safety, the inadequate cleaning of vehicles between loads and the failure to otherwise properly protect food during transportation.

These new requirements are flexible to allow the transportation industry to continue to use recognized best practices concerning cleaning, inspections, maintenance, loading and unloading of and operation of vehicles and transportation equipment.

With some exceptions this rule applies to shippers, receivers and carriers who transport food in the United States by motor or rail vehicle, whether or not the food enters interstate commerce. The rule also applies to loaders - which is a new category in the final rule - to include those who physically load food into vehicles.

Foreign exporters who ship food to the United States and arrange for the transfer of the intact container onto a motor or rail vehicle for transportation within the U.S. will also need to comply with the rule if that food will be consumed or distributed in the United States.

Food that travels through the U.S. by motor or rail vehicle - for example, from Canada to Mexico - but is not consumed or distributed in this country is not subject to this rule. However, companies involved in the transportation of food intended for export are covered by the rule until the shipment reaches a port or U.S. border.

Finally, this rule does not apply to transportation activities conducted by farms, because the diversity of farms and their transportation operations make it difficult to develop regulations that would be broadly suitable.

FDA is instead considering establishing guidance on good farm transportation practices, and farms remain subject to the Federal Food, Drug, and Cosmetics Act provisions that prohibit the holding of food under unsanitary conditions.

The final rule takes into consideration more than 200 comments submitted to the docket and bills on current best practices within the transportation industry. There are a number of changes from the proposed rule.

One change is particularly important to rail carriers. Rail operators often do not own, prepare or operate equipment - such as refrigeration units - in the railcars they transport. Nor do they have the ability to ensure that certain requirements - such as temperature control and sanitary conditions - are met.

In the final rule the shipper or loader and not the rail carrier may assume the responsibility of ensuring that temperature control and sanitary conditions are suitable - for example, by inspecting a railcar.

By contrast motor carriers generally own their vehicles and are directly involved with sanitation during transportation operations. Shippers will continue to hold primary responsibility for establishing sanitary conditions of transport under this rule unless the carrier has entered into a written agreement with the shipper to assume this responsibility.

The final rule also clarifies that the intended use of the vehicle or equipment - for example, transporting animal feed versus human food - and the production stage of the food being transported - such as raw materials versus finished product - are relevant in determining the applicable sanitary transportation requirements.

Requirements for temperature control during transport have been replaced with a more flexible approach. The shipper and carrier can agree to temperature monitoring mechanism for food that require temperature control for safety.

Finally, if a person covered by the rule becomes aware of a possible failure of temperature control or any other condition that may render a food unsafe during transportation, that food must not be sold or distributed until a determination of safety is made.

Finally, with regard to implementation, FDA is committed to working with both industry and its state, local and tribal partners to ensure effective implementation of FSMA's new food safety laws.

Implementation of the sanitary transportation rule and all five FSMA rules will require partnership, education and training. The FDA and others are working on valuable tools to make compliance with the final rules easier, such as training forces and a technical assistance call center.

The agency will train its field staff on the new rule and - as required by the Sanitary Food Transportation Act of 2005 - will assist the Department of Transportation in developing procedures for DOT transportation safety inspections in order to identify suspected incidents of contamination or adulteration of food. This sums up the final rule. And I will now turn the call back over to Teresa.

Teresa Rubio: Thank you to all of our speakers. Now I would like to ask the operator to open the phone lines and provide instructions for our callers who may have questions. Please state your name and the name of your organization prior to asking your question. Operator?

Coordinator: Yes ma'am. Thank you. At this time, if you would like to ask a question, please press Star 1 and record your name. To withdraw your request you may press Star 2.

Again, at this time, if you would like to ask a question please press Star 1. One moment for questions. And our first question comes from Barbara Cantaneo. Please state your affiliation. Your line is open.

Barbara Cantaneo: Hi this is Barbara. I'm with Cryo Trans. I have two questions. The first question was with regard to the railroad system equipment, which is railroad-owned equipment.

You're saying that the shipper is responsible for making sure that the railcar is adequate, it's cleaned, the temperature is appropriate. What happens if it's not? How is this - who's responsible? What's the protocol to make sure that railcar is cleaned?

Michael Kashtock: Yes, this is Mike Kashtock.

When the cargo is loaded, the loader - who in some cases is going to be the shipper, in some cases is going to be a facility remote from the shipper - the loader has the basic responsibility to ensure that any conditions that the shipper has set for the transportation operation, whether it be cleaning, a certain type of cleaning or the presentation of a wash ticket, the precooling of the refrigeration compartment.

Whatever conditions the shipper has established, the loader will have to verify at the time of loading that the vehicle or the container has been made ready as specified by the shipper.

Barbara Cantaneo: So if I'm the - if I'm a shipper and I'm receiving a refrigerated railcar which is system-owned - which means it's owned by the railroad - because somebody said in their comments that the equipment's not owned by the railroad. That's not true. A lot of the equipment is owned by the railroads.

And so they may be loading poultry in one direction and produce in the other. And there's obviously a concern of cross-contamination. So if I'm the produce customer who is using that car right after they delivered a load of poultry, and

you're saying there's going to be some sort of cleaning ticket or something. How is that produce customer going to know that that car was cleaned before it got to them? And who's responsible for cleaning it, is my other question.

Michael Kashtock: Okay. The shipper establishes the necessity of a cleaning requirement. The shipper can establish an agreement with the provider of the equipment - in this case, whoever is providing the railcar - and that provider can accept the responsibility to clean that railcar.

If the provider of the railcar is doing nothing but providing the railcar, then the shipper either has to have another entity do the cleaning or may have onsite cleaning facilities.

But it's the shipper's responsibility to specify what kind of preparatory steps would be necessary for that railcar. In some cases the provider of the railcar may agree to do that. In other cases the shipper may work through a third party.

If the shipper needs some, kind of, evidence of cleanout - such as a wash ticket - then that should be written into the agreement. If the loading is being done at a remote site then the shipper would need to instruct the loader that the wash ticket would need to be presented at the loading facility.

So the shipper is really in the central position of establishing what these requirements are, determining who's going to address them, and then determining what validation measures - if you will - are conducted at the time of loading.

Barbara Cantaneo: So in the scenario of the poultry and the produce customers, right? So a poultry customer is loading it out. And then it goes, delivers, and then a

produce customer is going to load it back. I don't really understand who the shipper would be in that scenario.

Because they're both shippers, so is the poultry shipper responsible for making sure it gets cleaned upon delivery? Or is it the produce shipper who's responsible...

Michael Kashtock: Produce shipper.

Barbara Cantaneo:...for cleaning it before they load it? And then what if the produce customer says, "This came in with a bunch of bloody chicken stuff all over the floor. I'm not going to load this." Do they reject it? I mean, how does that - what's the protocol?

Michael Kashtock: Well, the shipper is the person who makes the arrangements for the shipping. So whoever making arrangements for the produce shipment, if they want to have a clean car, they have to take whatever steps are necessary to ensure that it is either delivered in pre-clean condition or that it is cleaned after delivery if it is not in pre-clean - if it is not delivered already clean.

But for every shipping operation, someone is the shipper. The poultry operation has one shipper. The produce operation has another shipper.

Barbara Cantaneo:Exactly.

Michael Kashtock: And those shippers obviously need to be cognizant of the possibility that there might have been prior cargo in the railcar that would require a cleaning.

We would encourage you - because we don't have time to get into a lot of depth - to submit questions through our Technical Assistance Network. Because this is the kind of question that has a lot of twists and turns to it.

But I would just say that to understand the key nature of the role of the shipper in this rule and what they're responsible for is key to really understanding what the answer to your question is.

Barbara Cantaneo: Okay. And so that whole scenario that we just talked about really applies on what's called system cars, which are the railroad-owned equipment. And then on - if a customer has a private car, a leased vehicle - which is what my company does.

I don't think that it would be an issue because they're going to load their own products and they're not going to have any other cross-contamination. Now when does this all go into effect? What's the actual effective date?

Michael Kashtock: For small businesses - and that is defined in the rule - it's two years. For anyone else it's one year from today.

Barbara Cantaneo: From today. April 5.

Woman: Also, tomorrow possibly.

Barbara Cantaneo: Okay. Thank you very much.

Teresa Rubio: Thank you. And Operator, we'll take the next question please.

Coordinator: Thank you. The next question comes from Erik Lieberman. Please state your organization.

Erik Lieberman: Hi this is Erik Lieberman with U.S. Food Imports LLC. And I have a question - I have a couple of questions. The first one - can you describe how this regulation applies to foreign shippers?

I know it doesn't apply to oceangoing or air transportation, but what happens when a container is sent to the United States on an oceangoing vessel and is not opened and repacked upon entry and placed on a truck for movement in interstate commerce? So how would this apply to the activities occurring outside of the United States?

Michael Kashtock: Okay. Someone has to have made shipping arrangements for that container to proceed by land in the U.S. after it arrives at the port. If those arrangements were made by a foreign individual, then that foreign individual is the shipper for the purposes of this rule.

If the foreign individual just directs the shipment of the container to the port at entry and then a domestic individual makes the arrangements for further transport of that container into the U.S., then the foreign shipper is not responsible under this rule as a shipper.

Erik Lieberman: Okay. Under FSMA, food that is not transported in compliance with the Sanitary Food Transportation Act is rendered adulterated by law. Can you discuss this?

How - what happens if a food is - say, for example, a product is received and a temperature monitoring device was turned off or didn't properly record the temperature. Is that food rendered adulterated by law under this regulation?

Michael Kashtock: No.

Woman: Not necessarily.

Erik Lieberman: No.

Michael Kashtock: No.

Erik Lieberman: Okay.

Michael Kashtock: What would happen in that case is - food that requires refrigeration for safety - there is a responsibility for the receiver to examine it upon arrival to determine whether there is any indication of temperature abuse.

If the receiver determines that there is indication that there might have been temperature abuse, a couple of things happen. The food is not to be further distributed from that point on.

The receiver has to ensure that a determination is made as to whether the food was indeed made unsafe because of the temperature abuse before the food can be further distributed.

In doing that, the carrier then is required to provide information upon request from the receiver that would establish that appropriate temperature control was indeed provided during the operation. So the carrier may have a device on the truck that records that information, and that information to be downloaded and presented to the receiver.

But the rule is designed so that any indication that there might have been significant temperature abuse of a food that requires temperature control for

safety then triggers a process whereby the question that gets answered is, "Was it made unsafe or not?"

If it was not made unsafe, then of course it could be further distributed. But the mere breakdown of a temperature control device in and of itself doesn't meant that the food is adulterated.

Because if the device broke down an hour before delivery and the temperature of the food itself indicates that it was not temperature abused, that in no way means that the food is adulterated. So no, if the temperature recording device breaks down, that in and of itself doesn't lead to that conclusion about the food.

Erik Lieberman: What if a shipper failed to specify in writing that carrier - the sanitary specifications for vehicles and transportation equipment? Would that render the food adulterated or not?

Michael Kashtock: Well, of course the shipper wouldn't be complying the requirements of the rule. The loader needs to know what the temperature requirements are that have been established by the shipper before the loading occurs. So if the loading is done at a remote site then the loader isn't doing what they're supposed to.

The receiver has, under this rule, the prerogative to ask for that information that the shipper has specified. So if the receiver asked for it and it wouldn't be available to the receiver, then the receiver is going to realize that there's been a breakdown in the system.

So the scenario you describe really causes the system to break down at multiple levels. And as an enforcement issue, we could certainly deal with the

fact that the shipper isn't doing what they're supposed to do. That would actually be a prohibited act.

Whether the food itself would be unsafe, again, gets back to - you know, the food is not unsafe unless it's been temperature abused to the point that it's made unsafe. So there's a couple of different layers to your questions.

Again, you know, we would say that a failure of someone to do what they're supposed to do doesn't mean that the food is unsafe. But the fact that they haven't done what they're supposed to do means that they could be accountable for not complying with the requirements of this regulation.

Erik Lieberman: Okay so - yes, my concern is that if there's a recordkeeping...

((Crosstalk))

Woman: (Unintelligible).

Erik Lieberman: ...(unintelligible) that I work with, for example. I represent a number of retailers. If there's a recordkeeping problem, do they have to reject that load because it's considered adulterated, even if the temperature has indeed been maintained? But if the carrier - if the shipper didn't (unintelligible) the necessary information to the carrier, would you still have to reject that load?

Michael Kashtock: Yes, I would encourage you to read the discussion in the rule of this issue. We've anticipated that we would get these kinds of questions, because some of what we put in the proposal led some to conclude that food is going to be deemed to be adulterated for deviations from the rules requirements that are really insignificant.

We tried to address that in the text of the preamble. I would encourage you to look at that. And then, again, get back to us through the TAN - the Technical Advisory - or Assistance Network - if what we have in the preamble discussion doesn't adequately answer your question.

Erik Lieberman: Thank you.

Teresa Rubio: Thank you so much. And we do have several other questions in the queue, so Operator, we'll take the next question please.

Coordinator: Yes, ma'am. Before we take that question, a friendly reminder. Since we do have so many people in queue, be considerate. We ask that you may ask your question with one follow-up. Thank you. The next person (sic) is from Steve Austin. Please state your affiliation.

Steve Austin: Hello. I'm with a company called Red Gold and we transport finished canned tomato products. My question is, are shelf-stable packed foods exempt from this rule unless they require refrigeration?

And then the second part of my question is, incoming ingredient products that are not shelf-stable packaged - those would fall under the rule. Am I correct in that? Thank you.

Michael Kashtock: Shelf-stable packaged food products are exempt. You asked if they - are they exempt if they require refrigeration. If they require refrigeration for safety, no they're not exempt. If they require refrigeration just to maintain desirable quality level, yes they would be exempt. And the last part of your question again was?

Steve Austin: Products that are - say ingredients that are not packaged in shelf-stable packaging. Those would fall under the rule, I believe. Would they not?

Michael Kashtock: If they're fully packaged - and we have a definition in the rule that I'd ask you to look at - you know, fully enclosed by a container. If they're fully enclosed by a container and they don't require refrigeration for safety, they are not subject to the rule.

If they are in some kind of a container that doesn't fully physically enclose the food and - you know, to separate it from its environment, then it - those kinds of foods would be subject to the rule.

Steve Austin: Thank you.

Teresa Rubio: Thank you very much. And we'll take the next question please.

Coordinator: Thank you. The next question comes from Chuck Snow. Please state your affiliation.

Chuck Snow: Chuck Snow. Traffic.

Teresa Rubio: You can proceed with your question please.

Chuck Snow: My first - well I had - it's, kind of, a double discussion. First of all, how many cases of contamination have there been in the last ten years through faulty equipment or whatever? Has it gotten into the food chain through rail and truck? I'm just very curious why these rules were put into effect.

Michael Kashtock: We have, in the final rule, referenced - if you look at the references at the conclusion of the preamble discussion - pretty much all of the incidents that

we are aware of, either because they've been brought to FDA's attention directly - through our Reportable Food Registry, for instance - or they have appeared in media accounts.

I can't give you a numerical answer, but I can tell you that if you, you know, look at the references at the conclusion of the preamble discussion, you'll pretty much see what we are aware of. And that should be able to give you an idea.

Chuck Snow: Okay. Next thing I just want to bring to your attention. If we're going to ahead with this - now I understand it's two years for large companies and one year for small, we're - is that for the shipper or the carrier when you're talking the two- and one-year increments?

Michael Kashtock: Well it's the other way around. It's one year for large, two years for small. The definition of "small" is in the rule. It's a little bit different for carriers than it is for shippers, loaders and receivers, because the way that the Small Business Administration defines small business - what a small business is - is different for the carrier industry than it is for the shipper industry.

But, you know, we take the small business definitions for shippers, carriers, loaders and receivers. They are what they are, and if a business is a small business, they get two years. If it's not a small business - whether it's a shipper, carrier, receiver or loader - they get one year.

Chuck Snow: All right.

Teresa Rubio: Thank you very much and...

Chuck Snow: Thank you.

Teresa Rubio: ...we'll take the next - unless there was another...

Woman: (Unintelligible).

Teresa Rubio: ...we'll take the next question please, Operator.

Coordinator: Yes ma'am. The next question is from Steve McQueary. Please state your affiliation.

Steve McQueary: Brown Line LLC, an LTL refrigerated seafood transporter.

Teresa Rubio: You may proceed with your question.

Steve McQueary: All right. From a temperature recording standard, who's going to be responsible for maintaining the records? And what type of devices or requirements will we be looking at? And who will determine those?

Michael Kashtock: Okay. When you say "records" I'm assuming you mean records of temperature control during the shipment - during the operation itself.

Steve McQueary: Correct.

Michael Kashtock: Okay. We are not requiring in the rule that those records be maintained for FDA examination. What we are requiring is that the shipper and the carrier - when the shipper has determined that temperature control is necessary, that the shipper and the carrier can agree upon how that is going to be done and how that is going to be monitored and how that is going to be recorded.

That agreement has to be in a written document form. We - FDA - can examine that agreement if we want to understand how temperature control is being done upon the agreement of the shipper and the carrier.

So that agreement is a required record that has to be maintained by the shipper under this rule. And if the carrier enters into this agreement, there are also some records that we would require that the carrier keep. But I just want to emphasize that the in-transit temperature control records are not records that we are requiring to be kept for examination by FDA.

Steve McQueary: Okay well that's - as an LTL carrier, our concern would be - I may have 20 shippers on one truck and they may all have a different requirement for temperature monitoring. And we just wondered if there's going to be any type of a standard to protect us from, you know, having to use 20 different devices.

Michael Kashtock: Well we're not requiring that you use any given type of device. If you have 20 different shippers, I mean, you're probably already establishing some kind of an understanding between them and you as to what you're going to do that would be satisfactory to them. And you can continue to do that.

We're not going to tell you that you have to do it any differently than you're already doing it. I think the one change under this rule is that it'll be some more transparency in terms of when the shipper is instructing you - what he wants you to do - in many cases, that is going to be a required record that FDA can go to the shipper and examine that record if we feel that it's necessary to do that.

But the way that you're operating right now really doesn't - I mean, I don't think it's going to be affected by this rule, because you're already operating in

some way where you're in agreement with the shipper as to how you're going to transport his food.

Steve McQueary: Okay. Well my only concern is, we saw through the utilization of HASP that some companies put some stringent temperature requirements. And an LTL carrier, if they open the doors of their trailer to even to get a shipment off it, they're already out of compliance.

And I'm just hopeful we don't continue to go down this road through the requirement allowing the shippers to set all their standards that may or may not be feasible.

Michael Kashtock: We do have a portion of the final rule discussion that does speak about issues for LTL carriers. And again, I would encourage you to look at that and follow up to our TAN - said this numerous times - if you have any other further questions.

Steve McQueary: Thank you.

Teresa Rubio: Thank you so much. And we'll move on to the next question please. Operator?

Coordinator: Yes ma'am. Thank you. The next question comes from (Frank Bada). Please state your affiliation. Please check your mute button. Your line is open.

Man: (Unintelligible) question.

Teresa Rubio: Operator, we can take the next question.

Coordinator: Yes ma'am. The next question, then, comes from Jon Samson. Please state your affiliation.

Jon Samson: Yes good morning. This is Jon Samson with the American Trucking Associations. I wanted to first start with a comment and thank Dr. Kashtock and FDA. I believe, from the proposed rule to where we see the final rule - at least the initial look of it - that the increased flexibility of the industry is definitely there. And so we appreciate that.

I guess you've answered the recordkeeping requirement for temperatures with Steve's last question. But to expand upon that a little bit, we did have continued concern about, you know, the roomful of records, whether that be for temperature recording, training, the sanitizing of - in the three previous loads of sanitizing of trailers.

I just wanted to - and I'm sure it's laid out in there quite well - but have you expand a little bit more just on the recordkeeping requirements in general, what's going to come underneath those, if there's really going to be any 12 month of recordkeeping requirements.

And then on the training side, whether that's going to be left up to industry or there's more specifics within the rule as it relates to training.

Michael Kashtock: So I'll start with training first. First of all, carriers' responsibilities under this rule are predicated upon entering into an agreement with the shipper to assume some responsibility for sanitary conditions management or maintenance during transportation operation.

So when a carrier agrees to do that, that is when requirements such as training and recordkeeping are triggered. For training, we are going to have a carrier training requirement.

It is going to be a requirement that - training to establish awareness of potential problems that can occur in transportation and what is necessary in the way of response - that carrier personnel undergo this training.

We envision that this can be done in a one-hour online module that FDA will create and post and make available. We do not envision the necessity to travel to some central location for a half a day or a day worth of training. This is going to be something that can be done at the worksite - if there's a computer there - in an hour.

And again, going back to - you know, there are some relationships in the carrier/shipper environment where the shipper does everything and the carrier has no contractual responsibilities. In those situations - and I don't know if they apply as much to trucking as they do to rail - the carrier would not have a training requirement. I just want to make sure you're aware of that.

As far as records, again, record requirements do not come into play unless the carrier has agreed to accept responsibilities for sanitary transportation maintenance of some sort during the operation.

We are not, in the final rule, requiring that electronic records be Part 11 compliant. I don't know if that was a concern to you, but we get a lot of comments stating that the burden of electronic records - having to comply with Part 11 - was disproportionate to the public health need underlying the regulations. And we agree with that.

We are allowing for offsite storage of records that - as long as they can be retrieved within 24 months. That is for most of the records, but not all of them. But if you look at the specifics of the records requirements, you'll see that onsite storage is now no longer required for all records.

The other - the last thing that I would say is that what records we would require of a carrier would be records about what agreements they've reached with shippers, how they interact with shippers - if it becomes necessary to do so - if a question arises about whether proper temperature control was maintained.

So when I say "interact" I mean the procedures that a carrier would follow if he has to interact with a shipper. And of course, training records. So these are records that essentially are created one time. You have one SOP, perhaps, as to how you would interact with a shipper if a question arises about temperature control.

Training is done once unless the responsibilities of the individual significantly change or the business significantly changes. We're not requiring the maintenance of records that are generated during each and every operation.

And that's the, you know, "the roomful of records" concept that - you know, your trucks are running six days a week so you have this pile of records that are getting bigger and bigger by the week of conditions that were recorded during the operation. We are not requiring that kind of recordkeeping in this rule. The recordkeeping that we are requiring...

Man: (Unintelligible).

Michael Kashtock: ...really relates to how you do certain things, and generally those things get recorded once. And then of course, if we need to examine those records, we would come and ask for (unintelligible).

Teresa Rubio: Thank you.

Jon Samson: Okay.

Teresa Rubio: Thank you very much. And Operator, we'll take our final question please.

Coordinator: Yes. The final question comes from Peter Johnson. Please state your affiliation.

Peter Johnson: Yes I'm with the Brewers Association. My question relates to brewers' spent grain as animal feed. Can you address how the final rule applies where the loaders are typically brewery personnel loading the spent grain into a farm-owned vehicle?

Michael Kashtock: Well, if it's a human food byproduct that's going to be transported to, you know, where there are farm animals and fed directly to them, that is one of the new food types that we have - that are not subject to the final rule.

Human food byproducts that are transported to be fed directly to animals - and I think that's what you're talking about. So the whole transportation operation is exempt. From the shipper to the loader to the carrier to the receiver.

Man: (Unintelligible).

Teresa Rubio: Thank you very much. And I'd like to note that we're hosting a webinar on April 25 at 11:00 am Eastern Time covering this final rule. More information about this Webinar is available on the FSMA Web page at www.fda.gov/fsma.

We also look forward to continuing discussing implementation issues on a range of topics with stakeholders - including the development of guidance documents as necessary - and training to help industry implement these rules.

This concludes today's stakeholder call. Thank you for your participation, and have a great day.

Coordinator: Thank you. And this does conclude today's conference. All parties may disconnect.

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