FSAM Proposed Rule on Preventive Controls for Animal Food (PCAF) Facilities Public Meeting

Friday,
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FDA-FSMA Proposed Rule
on Preventive Controls for Animal Food (PCAF) Facilities
Public Meeting

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I N D E X

I N D E X (continued)

KEYNOTE: "---" indicates inaudible in the transcript.
"*" indicates phonetic spelling in the transcript.

M O R N I N G S E S S I O N

(8:46 a.m.)

Greeting and Introductory Video

by Kari Barrett, Advisor for Strategic Communications and Public Engagement

FDA Office of Foods and Veterinary Medicine

MS. BARRETT: All right. I think we will go ahead and get started. Can everyone hear me? You may have noticed we are having a few technical difficulties, but we are going to work through them. And it is a small group, so if, during the course of the public meeting, you are having a hard time hearing or there is some issue, please see Aleta, who is right here in the white jacket. And we will make sure that solve it as best we can.

Again, temperature, hearing it. You know, we want you to get the most out of this and it to be a good experience. And I know that you have already had a little frustration with the cold weather and the security and everything.

So I just really appreciate you being here.

Let me introduce myself. My name is Kari Barrett. And I work at FDA in the Office of Food and Veterinary Medicine. I am on the Communications and Public Engagement Team. And really, what I focus a lot on is the public engagement aspect. And actually, I see a few familiar faces here today. And I am really pleased. I

have been doing a lot of the outreach work on FSMA, all of the proposals.

This is actually the eighth FSMA public meeting that we have had in this year. So we have been out on the road quite a bit. We have also been doing a lot of engagements. You may have seen on our website some of the farm tours and other engagements. So it has been a really busy year.

And we are really excited to have this particular proposal out, which is preventive controls for animal food. I know for some of you who deal with the human food and imports, it has been a busy time for you. You know, all these really significant rulemakings coming out at once. The logic behind that is that you can see them together and be able to comment on them as a package. But we also know that that is a lot of work for all of you to sort of see them in their whole and try to decipher that and what that means.

But I don't want to get ahead of myself. We will have Roberta Wagner talk about sort of the larger FSMA framework in just a few minutes. But before we begin with all of our speakers, let me just cover a few sort of housekeeping things.

First of all, again with the public meetings, the purpose is for us to share content with you to really walk

through the proposal in hopes of having you -- making sure your understanding of it is sufficient enough so that you can comment. And so during the course of today, if you have questions, if there is not clarity on the proposal, this is the opportunity to discuss that and to share that and really make sure everybody knows what it is that we have proposed so, again, that you can submit your comments, your data, your suggestions, your experience, and help the final rule become the rule that is practical for this industry. And I know Dan will really walk you through that. And he will also T up some questions for discussion today, too.

But, again, remember the proposal is just the best thinking of the agency to this point in the process. And there is a lot of process ahead. So your voice matters and your comments matter.

A couple of housekeeping items, we are doing this through Adobe Connect, so we do have people online, as well, today. And I want to thank them for their time and interest. We do put on our website the Power Points that you will see. So just know that they are available. They have already been posted to the web site.

We also did a live web casting on our first public meeting. This is actually the third one on animal food. And it is not quite up yet on the website, but it

will be, as well as transcripts for each public meeting. And they usually take about a month between the public meeting and actual posting. But all of this is available on our FDA-FSMA website.

And we do have a list serve where we give notice to people who have signed up of our FSMA actions. And I have been asking lately in public meetings who has already subscribed to the list serve. So if you have, could you just raise your hand?

All right. I am seeing more and more each time. That is encouraging. Because, honestly, it is our best way to reach you and to keep you informed. And I think people who do subscribe find it useful. We are not pushing stuff out all the time, but it is a great way just to keep connected.

We don't have much this morning in the way of handouts. You may have noticed that. We try not to over paper everybody. We know you don't like to carry it around. And there is often a lot of waste, so we have just have some really basic pieces of paper. We have the agenda. And I think there is sort of a cheat sheet of how to get some of the information we are going to talk about today and how to comment importantly. And again, the deadline right now -- I say right now, Dan -- is February 26. And again, Dan will speak about that deadline and how

firm that may be and some of the challenges around that.

Also, too, I just want to mention some very basics. If there are any media here, any media this morning? Could you raise your hand?

(Show of hands)

MS. BARRETT: Okay. And you have registered with our -- perfect. All right. Great.

Also, restrooms, they are out the door, kind of around back to the right. If you look at the back wall, there is a sheet, and it has code. I think it is 432. Did I --

(A chorus of "324")

MS. BARRETT: 324. Okay. 324. It is written on the sheet. Sorry, Aleta.

Also, exits you can see are clearly marked in the room should we need to leave unexpectedly. I have already mentioned to folks if you could silence your cell phones. If it always a little embarrassing when they go off when someone is speaking. So we really appreciate that.

And again, as mentioned, if, during the course of the day, you have any needs or there is an issue, please see Aleta. She is right here. She will be happy to help you. Also, we have some folks at the registration desk who can help, as well.

Now, before again bringing up the speakers, we do

have a video that I want to show. And it is about the FSMA framework. And it just quickly gives an overview of sort FSMA and the background and where we are headed. And what I would like to -- it is only a couple of minutes. But it is, I think, a very useful sort of basic summary of FSMA. And so with that, we will start that in a moment. But the important part about that, too, is it is available on our website. We are going to show two videos today. They are both posted on the website. So if you are speaking to audiences that are unfamiliar with FSMA, maybe this is someone who supplies you or others, you can feel free to download this -- it is on YouTube -- and share it. So we hope that it is helpful.

The other thing I will mention while we are doing this is we are also tweeting now. But let's go ahead and go through this.

(Video on Food Safety Modernization Act)

MS. BARRETT: All right. Let's hear it for captions. Right? I do apologize for that. I know that you couldn't hear it very well. Again, it is available, and I think it is just a very nice summary. So thanks for your patience on that. and we will get right back to the agenda.

Perfect. Okay. Thanks again, everyone. We are getting to the content. And with our first speaker, I am

just really pleased that she could join us today. Sandra Schubert, who works with the State of California, is the Undersecretary for California Department of Food and Agriculture. And she was appointed by Governor Jerry Brown in May of 2011. And she spent two decades as a legal and political strategist for government and nonprofits on a variety of agriculture and public health and environmental resource issues. And she spent nearly 15 years in D.C. -- I am sure California is a relief after that -- and worked for the majority leader of the U.S. Senate and ranking committee member, so very aware of the political process on these really important issues. And she also has campaign experience and has taught at Georgetown University School of Law and lectured nationally.

And I am guessing many of you may know her. And I am just really pleased she could be here to welcome all of you to California and Sacramento today here.

Thank you.

Welcome and Opening Remarks

by Sandra Schubert, J.D. Undersecretary for California

Department of Food and Agriculture

MS. SCHUBERT: Okay. I am going to -- I have to hold this. Right? I am going to stand a little bit over to the side, because I am short enough. And you guys won't be able to see me over the podium. So can you guys hear?

Is this working?

So I want to start by thanking FDA and Kari and Roberta, and Dan, and the whole crew for coming to California again. I could start out by talking about our California AG industry. It is $44.7 billion, 800,000 jobs. It is the core of much of our -- it drives much of our economy in California. And when we talk about those 800,000 jobs, we are not talking about the ports, the truckers that ship it around, the restaurants, the food service industry that all uses it. So it is a huge driver in California.

And I don't need to tell you that. And we -- I think FDA and their collaboration and how the effort they put into reaching out to California for input on the FSMA roles shows that they recognize how we fit into this dynamic, not just as what we do in California, but for the country and how we help feed the world.

And as we go forward in helping feed the world, we have been -- Secretary Ross and the Governor have been doing some trade delegations, primarily to Asia, because we are sort of the entryway there. And with all of our ports and everything, it is a very key environment for us. And people look to California for food safety, not just throughout the country, but in other countries. And they want our products and stuff for food safety.

So FDA recognizes this. This is the fifth out of five rules. I don't have to tell you guys that. For the produce and preventative rule, they had multiple meetings in the state. Every single issue and rule they have put out, they have had public hearings in California to get your direct input. They have done a lot of outreach both to the state and to California agriculture.

And I just want to acknowledge I have looking through rules, not as much as CDFA staff. And in a second I am going to make at least one of them stand up, and he is going to love me for that. But I have spent a lot of time. They are long. They are hundreds of pages. They are complex. And I know we all have other things to do. But it is a unique opportunity, the fact that we are being reached out to and we are being looked to because we are leaders on food safety in a variety of areas to give this type of feedback.

So I just want to encourage everybody, in spite of everything else that is going on here, to really step up yet again, take the time to read another regulation, which I know how much everybody hates that, and really go through it. And not just give FDA input, but give CDFA input on what you think needs to happen with the regulation, where we need clarification. I know a couple things we have talked about is we want a little more clarification on the

difference between low and high risk. We think that is really important, that we make sure that we are accommodating different risk levels. It is important for us and you to give input, both to FDA and us, so we can formulate it in our comments on what you see those lines and barriers being. Things like that are really critical.

I know that we, in California, we are working on a model plan for the California feed industry. It is important to help give us input on that. We will be sharing that with FDA for the FSMA process how we think this should be happening.

So I don't want to take a lot of time, because I am not the meat person. I am actually here to listen and learn about the details. But I do want to call out Rick Jensen. And I am going to make Rick stand up. He runs our Inspection Services Division.

Rick?

And anybody else from Inspections please stand up.

He overseas these efforts --

Come on, you guys. Get up. I am not joking. Natalie, I see you guys. Up. Up. Up.

(Participants standing)

MS. SCHUBERT: Okay. So I want you to know how important this is to CDFA. And these are the folks that

work on this every day. And this is Rick's team, who is working on this issue and all the other issues that are part of FSMA. So we are dedicated to this. They need your feedback. FDA needs your feedback. I really want to thank you guys for being here yet again to come to California. I know it is a lot for you guys. And we appreciate you asking us for input. And hopefully -- we like the back and forth we have had. We think we are getting really good process on clarification in going through these rules. So we look forward to the process. And I really want to thank you guys again.

MS. BARRETT: All right.

MS. SCHUBERT: And Rick and his staff, thank you, guys.

MS. BARRETT: Well, thank you so much, Sandra. And thank you, Rick. And thanks for the whole team coming. That is really great seeing you all here. And, you know, coming out here is so important for the FSMA framework. So we are really pleased to be here. And we will continue to come to California as we have additional proposals that come out.

Now at this time we are going to start diving in more specifically into FSMA. And we have Roberta Wagner, who is here today. Roberta is our Deputy Director for Regulatory Affairs at FDA Center for Food Safety and

Applied Nutrition. And Roberta has really -- actually, Roberta has had many roles at FDA and actually has a really great perspective because of that. She has been in the food center. She has also worked in our Office of Regulatory Affairs with the field staff. But she has been very instrumental on FSMA both in the development process, as well as she is playing a key leadership role as we go through implementation. And so this morning she is going to talk about the overall FSMA framework.

Roberta?

FSMA Framework

By Roberta Wagner, Deputy Director for Regulatory Affairs, FDA Center for Food Safety and Applied Nutrition

MS. WAGNER: Okay. Good morning. I am Roberta Wagner. And I have been with FDA for 28 years now. And 20 of those years I was in the field. So I worked with the field investigators. I actually started as a chemist in a laboratory in the Baltimore district, analyzed pesticide samples. I was a pesticide and industrial chemical specialist out in the lab. Then 10 years in the investigations and compliance branches out in Baltimore district, as well. That's the accent people ask, "What is that accent?" It's a Baltimore accent.

I am from the East Coast. And I have to say it was 60 degrees when I left yesterday in Baltimore, and I

don't know what happened out here.

(Laughter)

So with that said, I am now in the Center for Food Safety and Applied Nutrition. And I have been in the center off and on for the other eight years in my career in FDA. I was the Director of the Office of Compliance there. My background really is as a regulator. So I am glad to see the inspection force out there.

But with that said, I should say relative to FSMA implementation, I am the lead on the Imports Group. So that group is under me. And I am an advisor on the FSMA operations team, which I will explain to you a little bit more later today.

(Slide)

What I have been asked to do today is not talk about the rule that we are here to discuss, but basically to summarize and review a little bit about FSMA. It has been out for tour going on two-and-a-half, three years now. And so I think folks might have forgotten some of the background there. So what I plan on doing is basically reviewing the guiding principles behind FSMA. And I will talk a little bit about each of the rules, proposed rules, that have already issued and talk about two other rules that we will be issuing shortly, as well.

(Slide)

Just starting with why is FSMA important, you just saw the video clip. We continue to have way too many food-borne illnesses. And I would even say food and feet contamination events I would put into that, as well. You just saw the slide. About 48 million people, 1 in 6 Americans get sick, 128,000 hospitalized, and 3,000 die each year because they food. So just think about that. That is a huge significant public health burden. And we believe most of it is preventable.

In addition to food-borne outbreaks and food/feed contamination events and the associated food recalls -- so every time we have one of those contamination events, food-borne outbreaks, we have a lot of recalls typically. We get costly disruptions in the marketplace, as you all are aware. And ultimately, there can be some loss in the public confidence in the food and feed safety system. And this is why FSMA is important. This is why FSMA is timely. This is why we need it now.

What FSMA does, it provides for FDA for the very first time a legislative mandate to require comprehensive prevention-based controls across the entire food and feed supply chain. That is a first. The legislation transforms FDA's approach to food and feed safety from a system that is far too often responding to problems to one that prevents these problems before they occur. That is what

these preventive control rules are about.

We live in a nation that increasingly relies on getting our food and feed and food-and-feed components from overseas. We are in a global economy now, a global world. An estimated 15 percent of the food consumed in the United States comes from abroad. And really, it is about 60 percent of the fruits and vegetables consumed in the U.S. and 80 percent of the seafood that originates from countries overseas relative to the food that is consumed in the U.S. So most of our seafood and a lot of our fruits and vegetables originate from overseas.

What FSMA does, it provides us in the import arena in particular significant enhancements so we can oversee imported foods and feeds. You know, it does put a lot of onus on the importer to assure that they are bringing safe food into the country.

FSMA recognizes the need for a global approach to food and feed safety. It emphasizes that domestically produced foods and feeds and foreign produced foods and feeds intended for export into this country, they need to meet the same standards. They need to be, you know, in the import arena, they need to be producing food that is just as protective as we are in the domestic arena so we create a level playing field. So that is all encompassed in FSMA.

(Slide)

There are some key FSMA principles. I will say that. And these are listed on this slide. FSMA calls for new accountability for all those involved in food and feed supply chains, even if that supply chain begins halfway around the world. The legislation emphasizes the primary responsibility of the food and feed industry in producing safe human and animal food.

FSMA requires comprehensive, as I already mentioned, prevention-based controls from farm to table. And we are doing this through the establishment of standards. That is what these regulations are. We are establishing standards for preventive controls across the food and feed supply chain. We are doing it through rule making, and we are doing it through a very open rule-making process.

I mean, Kari mentioned already, and I think every single one of us is going to mention today, please submit your comments through the dockets. These rules are by no means final. We want your comments. We have actually posed a lot of questions to you, particularly in areas where we really don't know what the right solution is. So please send your comments in through the dockets. You can truly shape, one person in this audience can truly shape, certain components of these regulations. And don't think you can't. So please do that.

The legislature requires that established standards be science and risk based, targeted and practical, and flexible. We recognize that the food and feed production industry is very diverse. We cannot have a one-size-fits-all here. We recognize that. We believe we have created the rules in such a way hat it allows for flexibility.

FSMA recognizes the preventive control standards, improved food safety only to the extent the producers and processors comply with them. So we can put out all the rules we want. If the industry is not complying, we are not going to be in a better place. So as you read through FSMA, you know, the legislation definitely highlights that inspections are an important means of holding industry accountable for the production of safe food. It establishes an inspection frequency mandate in the domestic arena. And it also basically says we should be doing certain numbers of inspections in the foreign arena. And there is a reason for that. In FSMA they recognize the oversight that is needed to make sure that the industry is complying with our rules.

The law also provides FDA with new enforcement tools. And you saw some of those on the video clip earlier today. We have new enforcement authorities. They are designed to achieve higher rates of industry compliance

with the standards that we are proposing, and also so that we can better respond when things go wrong and contain problems.

Lastly, the legislation recognizes the importance of strengthening existing collaborations with foreign and domestic food safety partners to achieve our public health goals. We certainly cannot do this alone. And when I say public health partners, we include industry, consumer groups, states, other feds, even our international regulatory partners, in that mix.

(Slide)

And I guess I should also have mentioned on the last slide that -- well, I will move on.

Section 103, and this is getting technical here, of FSMA mandates, hazard analysis, and risk-based preventive controls for human and animal food facilities require to register with FDA under the Bioterrorism Act of 2002. If you notice -- and I just want to give you a few key points about the prevent control roles for the human food and the animal food pieces. We chose to create separate rules, one for human food and one for animal food. And we did that for a reason, and that reason is we know and recognize there are differences in hazards associated with human and animal food production. So that is why we have two rules.

I also want to emphasize that we chose -- and this was an FDA decision -- to modernize current good manufacturing practices for human food facilities and proposed for the first time -- and Dan will talk more about this current good manufacturing practices for animal food facilities through the preventive control rule-making process. FSMA, if you read FSMA, you are not going to see it mentioned that we are going to do rule making around GMPs. FDA chose to do it this way. So I just want to make that clear. And again, that supported two different rules, one for the animal and one for the human food.

With that said, the preventive controls for animal food rule aligns very closely to the proposed rule for preventive controls for human food. Both proposals are based on HACCP principles, Hazard Analysis and Critical Control Point principles. And for those of you that have been around the food and feed industry for while, you know that the industry actually pioneered the HACCP principles. And they have been required by FDA in certain areas for years in juice and seafood.

Both rules have built-in flexibility, as I have already mentioned, to account for diversity in food and feed production operations. The rule permits firms to establish preventive controls that fit their products and their operations as long as the controls minimize the

hazards or prevent food safety hazards that are reasonably likely to occur. So we have tried to build that into the rules.

Both proposed rules are based on the premise that required changes to current food and feed production practices need to make a substantive difference relative to food safety and the protection of human and animal health. In other words, we don't change for the sake of change. If there are best practices out there, you know, we want to build upon those. If we are asking for change, it is because it will improve food safety and/or protect human and animal health.

And again, why there are similarities in the two preventive control proposed rules, there are some distinct differences. And Dan will explain some of those in a few moments.

(Slide)

Key implementation challenges. And we are talking about implementation challenges relative to the major preventive control rules under FSMA. We recognize that there will be challenges to industry's implementation of the standards proposed in these preventive control proposed rules. But there are also going to be challenges to the regulators responsible for assuring compliance with these rules.

Some key implementation challenges are outlined on the slide. You know, for example we are challenged in that we need to recognize and accommodate the complexity and diversity of the food and feed system. We sit in Washington. We make rules. And we don't know all the diversities out there. Again, the reason we have to do stakeholder outreach, and we continue to stakeholder outreach.

We need to recognize past progress in the area of food safety, as I mentioned, and build upon it, not start from scratch. We are not starting from scratch here. You know, many people have adopted HACCP principles and good agricultural practices. We need to recognize that and build upon it.

We are challenged in that we need to provide sufficient industry outreach and technical assistance as firms and facilities move to achieve compliance with the new preventive control rules. We recognize that we are going to have to put out a lot of industry guidance so that this -- especially for the smaller and medium-sized players. You know, the big players out there, they pretty much know what they are going to have to do. But we need to help, and we recognize we need to help, the smaller and the medium-sized players.

Lastly, we are challenged in that we need to

develop and implement new approaches to inspections and compliance that are public health focused and preventive focused, as opposed to regulatory and enforcement focused. So we really are going to be taking a hard look at our inspectional approaches, and we are going to try to transform to something that is more public health and preventive focused, as opposed to -- if you have experienced an FDA inspection, you know we are out there. We are inspecting against a set of regulations. We are gathering evidence. We are almost out there in enforcement mode regardless of whether a firm has a good track record or not. So we will be rethinking that.

FDA intends to change our current approach to achieving industry compliance to one of partnership with all food safety players. As I mentioned before, the food safety players are the states, other feds, international partners, industry, trade associations, and consumer organizations. So we are looking to everyone to help us implement this rule appropriately.

(Slide)

So now I am going to spend the last couple minutes just going over some of the other proposed rules that have been issued in addition to the one that we are here to talk about today, the preventive controls for human food rule. And I will also quickly mention two other rules

that we will be issuing very shortly. I am just going to start with a recap of what is out there and kind of the timing around that. And then I will give you a few key points relative to the other four major proposed rules that I consider part of the preventive control package under FSMA.

So as most of you are aware, in January of 2013, FDA announced the release of the proposed rule for preventive controls for human food facilities and the proposed rule that includes standards for produce safety. Then in July 2013, we released two import-focused rules, one for foreign supplier verification programs for importers. I will be referring to that as FSVP from this point forward. And then we also issued the proposed rule titled accreditation of third-party auditors and certification bodies.

The latter two rules will help assure that the standards in the preventive control rules issued under FSMA are being met for imported products. So we do expect that the preventive control rules for human food and animal will be applied in the international arena, as well.

In late October 2013, we issued the proposed rule for preventive controls for animal food. And lastly, I just want to mention that we will be issuing early next year the proposed rule for safe food transport and then

also a proposed rule to deal with intentional adulteration. And for those of you that are not aware, intentional adulteration can include things such as a bioterrorism threat or economically motivated adulteration or substitution.

(Slide)

So a few key points relative to the produce safety rule. You know, FSMA directs FDA to set science-based standards for the safe production and harvesting of fruits and vegetables to minimize the risk of serious adverse health consequences or death. The proposed regulation, we do need to mention that it really will apply to 20 percent of the farm that produce about 80 percent of the fruits and vegetables in this country. So as you read through that rule, you will see a lot of exemptions in there. And it really is targeting the biggest players in this country. And those biggest players are about 20 percent of the farms in this country. And like the slide says, they produce about 80 percent of fruits and vegetables in this country. That rule also applies to farms in the foreign arena, produce produced in the foreign arena that is intended for export to the United States.

FDA's proposed standards associated with identified routes of microbial contamination of produce

through this rule making, including standards for agricultural water, biological soil amendments of animal origin and animals in the growing area, and also standards for equipment, tools, and buildings, and employee health and hygiene.

And I have to say we continue to do outreach to the grower community. Even after the rule was published and during the comment period, we continued to hear issues and concerns. And some of them are extremely legitimate. And FDA plans on addressing all of those.

(Slide)

So key points for FSVP, this is your foreign supplier verification program for importers. It is the foundation of our modern oversight of imported food and feed. Under the proposed FSVP regulation, importers would be required and held accountable for performing certain risk-based activities to verify that the food and feed they are importing into the U.S. meets U.S. standards or that it is produced, you know, put another way, it is produced in a manner that provides the same level of public health protection as that required for domestically produced food and feed. So we are creating a level playing field here between imported and domestic food.

The proposed rule for FSVP is predicated on a reliance on private sector supply chain management. The

requirements are risk based. They will vary depending on the food and feed product, the hazards associated with various food and feed products, who is to control the hazard, and where the hazard will be controlled. So there are different requirements, if the hazard is going to be controlled by the foreign supplier in the foreign arena versus if it is going to be controlled in the United States by the U.S. importer, which can be the manufacturer, as well, or the U.S. consignee.

So if you read the rule carefully, it really distinguishes requirements between whether the hazards are controlled in the foreign arena or in the United States by the importer, which could be manufacturer or the consignee.

And then there is also -- it is risk based in that there can be differences based on the category of importer. And what I mean by that is that very small importers will have perhaps different requirements than larger. That is what the proposed rule suggests.

FSVP obviously is part of a larger FDA importer oversight tool kit. And then one thing I want to mention is that FDA intends to align the supplier verification provisions in the FSVP rule with supplier verification provisions in the final rules for preventive controls for human and animal food. If they end up in the rules -- and that is an area that we have asked for suggestions and

comments -- we really want to make sure that we are not creating a system where folks that importers under FSVP, and these importers are also food manufacturers, that they have to meet two sets of requirements that duplicate one another. So we do have that in the back of our minds as we move forward.

(Slide)

Okay. The accredited third party rule -- and I have to say this: this rule has -- folks are really misinterpreting what we are trying to do through this rule. So hopefully I can clarify a few things here. And there are a few points relative to this rule. Under FSMA, FDA is required to establish a voluntary program for accrediting third-party auditors to conduct food safety auditors of foreign facilities and their food.

Under FDA's voluntary program, the way this works is FDA recognizes accreditation bodies based on a set of criteria. Those recognized accreditation bodies will then accredit third party auditors or certifying bodies. And then the third party auditors audit and issue certifications for foreign food facilities and/or foreign food that is deemed in compliance with U.S. standards. And they have to be in compliance with U.S. standards. It is very clear on that.

With that said, under FSMA, very limited

application of when you would use or have to use an accredited third-party auditor. Specifically, facility certifications will be required by importers that participate in the voluntary qualified importer program, VQIP. That program has yet to be established. And basically that is going to be a program that will provide expedited review and entry of food for the best of the best importers. So these are importers with phenomenal track records and importers that are going to be very transparent or have to be very transparent with FDA relative to what they know about foreign suppliers.

So that is one place that we would have -- if somebody wants to be part of VQIP, they will have to have facility certifications for the imports they are bringing into the country. The other place is FSMA gave FDA discretionary authority -- and I want to emphasize the word discretionary here -- to require mandatory certification of imported food that poses a safety risk based on specific criteria that are laid out in the legislation. And it is a list, quite the list. So those are the only two circumstances or purposes for certifications under FSMA. It is in the foreign arena, it is for VQIP, it is for mandatory certification. That is it. So hopefully that clarifies that a little bit.

(Slide)

So this is my last side. You know, again, we want to emphasize that written comments are crucial to the proposed rules. I don't want you to think that we already have what the final rules will look like in mind, because we don't. We continue to receive and review the comments. And the final rules will reflect the comments that we have gotten. And we have gotten a lot of comments on our proposed rules so far.

We are committed to continuing stakeholder engagement. You know, I am thrilled that you are here today. This is a stakeholder engagement, in my opinion. Ask questions, as Kari mentioned. This is all part of the process.

And I will just close by saying that at the end of today I will be talking a little bit about what FDA has been doing relative to implementation of FSMA. I mean, you obviously know we are doing rule making, and we are starting down the road of guidance development, but there are other things that we are doing already, looking at what these rules might look like and how we would operationalize that, what kind of inspection, what will be our inspection strategy, what will be our compliance strategy.

You know, in things like the produce arena, our compliance strategy might look very different than what it could potentially look like in the preventive control

arena. For example, there might be a very extensive period of time where we are doing education and outreach and technical assistance. And then we might move into pre-assessments or something like that. It will be a long time before we are moving into enforcement. But with that said, obviously if we run into outbreak situations, that is a whole different beast. So thank you for your attention. And I will turn it back to Kari.

(Applause)

MS. BARRETT: As Roberta -- well, a couple things. To Roberta's point about one voice here can make a difference, it certainly can. So again, your comments are so important. The other is to have a dialogue. Roberta will be on our panel, listening to public comment. She will also be on the panel for Q&A. So there is an opportunity for a dialogue then. And as she mentioned, when we get into implementation at the end of the day, we will also do some additional Q&A, if people have any questions. So there will be a number of opportunities for that.

Before I introduce Dan McChesney, I have a housekeeping note that if someone has a Nissan, their key might be at security. During the break or if it is your car, you might want to see them prior to the break.

Okay. So I would like to welcome Dan McChesney

up to the podium. Dan is really going to get to the meat of what this proposed rule on animal food preventive control is all about. He is our Director, Office of Surveillance and Compliance for the FDA Center for Veterinary Medicine. And as mentioned, he will give an overview of the proposed rule.

I also have to mention we have a change in our agenda. And Dan is willing to step in and also talk about the economic analysis. Unfortunately, John Lienesch, who was to speak on that, was unable to join us. So really, I want to say thank you, Dan, for covering that piece, as well.

So Dan, if you will come up. Thank you.

Proposed Rule on Preventive Controls for Animal Food Facilities Overview

By Dan McChesney, Ph.D., Director, Office of Surveillance and Compliance, FDA Center for Veterinary Medicine

DR. McCHESNEY: Thank you, Kari.

Welcome. It is nice to see and say I recognize a number of faces in the audience, and a couple comments going towards that. The first public meeting was held in the metropolitan Washington, D.C., area. And I would say those of us that were in the Washington, D.C., area recognized it was sort of all the normal players that were there. All the associations were there and a variety of people that we deal with on a really regular basis.

Then we went to Chicago, and we got more towards people who were going to be implementing the rule and affected by the rule. And I think as I look around here today, you know, I think we are moving even more towards that. I think we are seeing a lot of folks in the audience here who are really going to be impacted by this rule. And I think that is really a good thing.

The other thing, when Sandra mentioned that the California Department of Agriculture is here -- and there is quite a contingent of them back there -- FDA has had a long, fairly strong, very strong relationship with them, surely on the animal feed side, which I am experienced with, and California has a very strong program on the animal feed side. And having said that, just to give you some overall feeling for it, of all the inspections that FDA does related to animal feed products, FDA does about 30 percent of them and the states do about 70 percent of them.

So this rule is going to have a big impact on states that are doing inspections. And so we realize that. And we will talk a little bit about training towards the end here, but we realize that there is going to be a big training component here. And we are relying heavily on our states to surely do the preventive control for animal feed, but I would say also probably for the other rules, for the

human food preventive controls.

With that, we will go ahead and start here.

(Slide)

The official name of this -- oh, a different start here. Let me see. Let me go back one.

We left out one slide. And the reason -- I am not sure why we left it off. But we normally talk about this as being the animal feed preventive control rule. And the reason we talk about that is simply because this is the official title of the rule. And if we had to say that, we would be here many more hours.

Now having said that, if in fact you went to look at the comment on the preventive control rule for animal food, you would not find that. This is what you would find. So when you go, we are looking for comments on this rule, and this is what it will be listed under, its official title.

Some of the requirements, it has already been touched on a little bit here, but this rule establishes good manufacturing practices for the entire animal feed industry. And it is the first time it has done that. In the past -- or currently, we have good manufacturing practices for medicated feeds. And those good manufacturing practices largely focus on how you incorporate and deal with the drug part of the feed, not

the feed itself.

So this is establishing good manufacturing practices for animal feed for the first time across all segments of the animal feed industry. And when we talk about animal feed, we are talking about both pet food and food for food animals. It also establishes hazard analysis and risk-based preventive controls. And we will talk more about that. So those are the two major parts of the rule.

(Slide)

Who is covered? It is pretty straightforward. If you manufacture, process, pack, or hold animal food, and you have to register under the Bioterrorism Act, which is Section 415 of the Food and Drug Cosmetic Act, you are subject to this rule, or if any part of your business that does that is subject to this rule. So there are a few circumstances where you might have, such as a fertilizer operation, which would not be subject to the rule, but if you are selling something into the animal feed side, such as phosphates, that portion would be. So there are some little nuances like that.

It applies to both domestic and imported food, as has already been touched on. As we go to a globalization of our food supply, it becomes more and more important that we look at imported products.

The last one, some exemptions and modifications

requirements are being proposed. The legislation allows specifically in the legislation that there be differences between the human preventive control rules and the animal feed preventive control rules, recognizing that there are surely differences in the animal feed industry and the human food industry.

Now, having said that, these rules cannot be wildly different, because we still have to have one inspection enforcement doing them. So we cannot have hugely diverse rules, but we surely can tailor the rules to the animal feed industry. And we will talk about some dollar exemptions that really relate to the size of the two industries.

(Slide)

Human versus animal preventive controls. I put this slide up here originally because human preventive controls came out a long time ahead of animal preventive controls. And we could, because of some administrative procedures acts and legal requirements, we could not talk about a rule that had not come out. So I used to talk about the human preventive control rule and say it is really a whole lot -- the animal one is going to be a whole lot like it.

But it does go here to point out how they are alike, and they are very, very similar. The animal

preventive control rule establishes good manufacturing practices. The human prevent control rule, as you heard, had modified some of the current ones. There are not a lot of changes, but there are some sort of modernizations of them. All the modernizations that we have seen on the human good manufacturing practice side are incorporated into the animal good manufacturing practices.

Food allergens are a stated hazard on the human preventive control rule. Food allergens we do not consider a hazard in the animal preventive control rule. Not because we don't have food allergens in animals, but what we see in animals are usually skin irritations, things like that. We don't see the anaphylaxis-type reactions. So they are not in there.

What we have put in animal preventive control -- and it is probably not characterized, based on questions we have gotten, the fifth bullet here does not characterize what our concern is correctly, but it surely brings up a talking point. It says animal plan control does include nutrition and balances. And when we talk about nutrition and balances, we are not trying to be the animal nutritionist here and say, oh, for poultry this is what the diet has to look like. We are simply saying that if, in fact, the feed says it includes X, it needs to include X, and it needs to include it at that amount.

That becomes critically important for animal feed, because the animals are eating complete diets. So if you have a pet, your pet is eating the same thing day in and day out. Or if you have cattle or swine or chickens, they are eating the same diet day in and day out. So it is very important that if it says there is salt in the poultry diet, the salt is in there and it is in there at the correct amount, or if it says there is calcium in there, calcium needs to be in there in the correct amount.

On the human side of the house, you know, if you don't get something in one of your food groups, you are always going to eat something else that it is going to be in there. So, you know, you can have your green beans and you can have your protein source and you can have your potato chips and your ice cream. You know, animals really don't get that option. So their individual diets actually become much more important than our diets, because they have less ability to choose.

And we will talk about different definitions for very small businesses. And again, it is based on the way the industries are structured.

(Slide)

I put up the current good new manufacturing practices here just to give people a flavor of what is in there. It covers all the same areas that are covered under

human GMPs. It also covers all the same areas under GMPs that have been out there under the AAFCO GMP requirements. It is similar to the PSA 2200, I think it is PSA, which is an industry/academia good manufacturing practices for the feed industry. It is also the same area that is covered by the CODEX documents on animal feed. So there is nothing new here. What is new might be the stringency in what is in here.

So we are going to spend a few minutes just highlighting a couple of things that are in this area, because it is not my intention here to walk through and say this is what you have to have for GMPs, but to sort of give you a flavor of what is in them and where you might want to comment.

(Slide)

Personnel deals with good hygiene practice. If an employee is sick, should they be handling finished product or, you know, product that in the original heat kill step might do something. What is that? It also includes things like training.

This, I think, is going to be an area where we are looking for comment, because the starting place on the animal feed rule for good manufacturing practices are the human GMPs. And you might say, well, they are too stringent for animal feed practices. I think one of the

major areas we are looking for comments is in the hygiene area. What is appropriate? Is it the same thing that is appropriate or should there be lesser standards? And we will talk a little bit more about that in a few minutes here.

Plants and grounds, you know, concludes that proper cleaning, maintenance, and pest control. We will just pick on pest control, because we -- I have always -- I have done that in the last two. And this is very much like presenting a college lecture, which I used to do. And you are teaching the same class over and over, so you like to keep using the same examples so you don't confuse the students. Or sometimes you just have one example.

The one I always pick on here is pest control. You know, you need to control pests. If you have a feed mill, no matter where it is, you need to keep the grounds cleared back from the facility. You need to make sure pests don't get in. and pests can be, you know, mice and rats or they could be deer or birds or you name it. And my comment in the past has always been, if you have a feed mill and you are out somewhere, I will just say here in the central valley and you have a feed mill, there are a lot of animals outside looking in at you, looking like you are running a restaurant. You know, if I can get into that feed mill, I don't have to go forage for my food. It is

just there. All I have to do is just chew through a bag or something. So it is really important to keep pests out. You know, the same on the human side. But there is a -- you know, just an example, that when we talk about things like that, it is sort of the obvious.

(Slide)

Sanitary operations. You need to keep the surfaces clean. Proper use and storage of toxic chemicals. You know, you don't store your pesticides next to some feed ingredient. Water supply, sanitary facilities control. You need an appropriate water supply, plumbing, hand washing facility, just normal, good hygiene practices.

(Slide)

Process controls. This is how you make the product. Adequate sanitary -- there are some sanitary principles that are not included under GMPs that you need to address in these rules that are not laid out here. You have to label things correctly. Do you make them correctly? You know, are you doing something that prevents contamination or controls it? Equipment, do you have equipment dedicated to the dirty side of the facility, to the clean side of the facility, or do you take your front loader and use it on both sides? You should not be doing that, obviously. And warehouse and distribution, do you store it correctly? Do you keep it dry? Things like that.

So just sort of basic things.

(Slide)

And they cover this in a whole variety -- now, the slides we have had on GMPs, this in my view is probably the most important slide, because here is where it says we realize there is a spectrum of animal food producers, production facilities, and hazards and risks that can vary greatly. So we can look at a pet food manufacturer over here, who in many ways is the same as a human food manufacturer. They make a product. The product comes into the home. It is handled in the home. If there is contamination with that product, and contamination is low on those products, but if there is and it is handled in the house, it can contaminate work surfaces, utensils. And if they are not cleaned properly, you can end up with sick individuals. And we have numerous cases of that over the years. And we are getting better at detecting that.

So that is a concern on the pet food side. So you might say, well, they need GMPs that are very similar to the human side. On the other side of the house you could be running a feed mill, making cattle or dairy feed. You make the feed. It goes into a large truck. It goes to the farm, and it is spread on the ground in front of the animals. You might say, well, I need some different -- some of the GMPS that would be appropriate for pet food may

not be appropriate there. And that is sort of our dilemma. You know, how do we -- what is the right balance there? And that is where we are looking for your help on that for reasons of, one, should they be different; if they are different, how should they be different, and how should we kind of marry those things up so we don't have GMPs, completely different GMPs for everybody, for multiple people.

And so it is really -- that is what this is really asking about. What is appropriate? You know, we said we would start up with the human food GMPs. To be quite honest, we started there because we had a few months, we had like four months to write this. People were writing it on like Christmas Eve because they had to get it out. It came out two years later. So if we were writing that -- if we realized we had two years to write this, as opposed to two months, we very likely would have written it very differently. You know, I think Roberta could attest to that. All the rules that we heard today, we probably would have written them differently, if we knew we had all the time we ultimately had. But we didn't. And so realize there needs to be changes in this. So surely on the GMP side, we are asking for your comments. Basically, did we start in the right place? And if not, how do we need to modify that and what modification? So we would really ask

you to look at these closely and focus a lot of comments on GMPs.

The goal here today is to highlight probably six or seven areas for questions. And having said that, I think we asked for comments in about 60 areas, on about 60 things. But what we are talking about today are probably the major things we really need your help on.

(Slide)

Now we are going to move to the preventive control part of the rule. We put this slide up here, and we could probably just talk on this slide and not use any other slides that follow. But we are starting off here at the top. So you have to first identify your hazard, whatever hazards are associated with your product.

When we talk about hazard identification here, it is a little bit different, it is very different actually, on the animal side than it is on the human side, because when you are identifying your hazard, you have potential endpoints. You have the endpoint of human health, especially if you are a pet food, but you could also have a pet food with an endpoint of animal health. The class example, two examples there, are Salmonella in pet food is largely -- is not much of an issue for the animal. Animals, dogs and cats, rarely get ill, violently ill, from Salmonella, but people do.

On the other hand, if you don't put thiamine in cat food or you leave vitamin D out of other pet foods, you can end up with a really ill animal very quickly. So two different endpoints there, human health, animal health. On the food animal side, it is largely an animal health issue. So I guess the point is when you are looking at hazards, you are going to have to consider hazards both in two areas: Does it impact animal health and also does it impact human health? And consider hazards in both of those areas.

Once you have identified the hazards, you have to come up with preventive controls. Once you have your preventive controls, you have to monitor to make sure you are actually doing them. What happens when they don't work? You need to take corrective action. All the stuff you have in place, if you put something in place and you don't verify that it is actually working and it is the appropriate thing, it is pretty useless. So there needs to be verification.

Recordkeeping. This rule is incredibly heavy on records, probably the most burdensome part of it and the thing I think most folks will have problems with. And then once you do all that, you sort of start the cycle again. You go back to your hazard analysis.

(Slide)

Who is responsible for developing this plan? Well, it says a qualified individual. And what are they supposed to do? Prepare a written food safety plan, validate that they are working, review of records, reanalysis of the food plan. Well, who can do this? The qualified individual has to be one qualified either by training and/or experience. It can be a person within your organization, with the firm. It can be someone outside of that that you hire as a consultant to come in and develop a plan. They just have to some relationship, but they don't have to be an onsite person.

(Slide)

Preventive controls. The legislation talked about preventive controls in three areas. The first two were probably pretty obvious. You want to talk about process controls and sanitation controls. Because, as we have said before, there are some sanitation issues that are not controlled by GMPs, and rightly so for preventive controls. Process controls, that is where you identify your hazards. How a recall plan got to be a preventive control no one quite understands, but that is how Congress put it in the rule. And so we will just go with what Congress said. They call that a preventive control, and it is. Independent of what they call it, you still need a recall plan.

(Slide)

Preventive controls. We have sort of mentioned this already. What do you need to do? Well, you need to do a hazard analysis. You have to develop preventive controls for those hazards that are reasonably likely to occur. And we will talk a little bit more about that terminology in a minute here. You have to have a written plan. And you have to have a recall plan for animal food for which a hazard is reasonably likely to occur.

(Slide)

Hazard analysis. I mean, this is just sort of basic HACCP. You have to identify a known or reasonably foreseeable hazard for each food type to determine whether a hazard is reasonably likely to occur. Naturally occurring hazards may either be, you know, be unintentionally added, either natural or -- and you may control hazards that may occur naturally or may be unintentionally introduced. And you must consider all types of biological hazards.

The first bullet up there -- and we will talk a little bit more on the other side about this -- has given rise to some comments on the human food side. And so when you look at this, I would encourage you to read the human food comments that I believe are submitted by GMA. And it goes to the basis of reasonably foreseeable and reasonably

likely to occur. And FDA's view is that that is a pretty broad way we can interpret that.

There are some other views that are relayed out in comments that, by saying this, we are actually making a lot more things, requiring a lot more recordkeeping than may be required. So is a way to read this that says everything you control under with GMPs, you may have to have lots of records and verification that it is working.

And it is also not the wording that has been used traditionally in some HACCP plans. So there is a concern surely in the human food industry that some HACCP plans, as currently structured within that industry, would not fit under preventive controls. And I believe -- and so we actually had a meeting on that with the folks who made those comments to try to understand that. And we are working on getting that and understanding that.

It is a lot of nuances. I think FDA's view is we have put this as a pretty broad overarching type of preventive control that HACCP fits in. Another way to read it is we are requiring something different. So when you give comments on this, I would ask you to go read those comments that GMA and other parts of the human food industry have put it around this issue, because this is one issue that, one, is going to have to be resolved, and it cannot come out two separately -- we cannot come out one

way for human preventive controls and another way for animal preventive controls. We have to have the same approach and the same wording in this area. So we are really looking for comments both on -- you know, the human rules closed, but ours is open. We are looking for your comments on those.

(Slide)

Obviously, the other part of hazard analysis that you have to do is what is the severity of the illness or injury that occurs. I don't think this is controversial. It is just basic HACCP or basic hazard analysis.

(Slide)

It was mentioned in a question, where should -- hazard analysis of intentional hazards. We asked for questions in there. Should we -- should this rule cover economic -- hazards introduced for economic reasons. The classical example there would be melamine here a few years ago put in to make a protein content. You know, should you be required to know the control for those hazards that are economically introduced? And if so, when should you be required to do that?

Now, admittedly, it is pretty hard to know about a hazard that you have not been exposed to before. So I think if anybody said, well, melamine is going to be used in wheat gluten before it was, I don't know that anybody

would have come up with that. Once we found out that that is a common thing, you know, now it is a hazard that people have to reasonably -- it is likely to occur or potentially likely to occur, that needs to be controlled for. So we are looking for comments on that. And we fully realize that controlling something you don't know that people are going to do is a difficult thing. But having said that, you know, I think nowadays if you look back and say I am buying a product on protein content. How might one alter the protein content of that. I think you need to have some reasonable, say, thought process in that. Or if you are buying something on fat content, how might they make fat content look different?

So we are looking for information and your thoughts on that. And this is all flushed out in the preamble. It gives you a little more background on this. But basically the question is, should economically -- should economic adulteration be considered under this rule is sort of the bottom line question.

(Slide)

Preventive control elements. We have already mentioned these. Once you do your hazard plan, your analysis, you have to do monitoring corrective action, verification. And you have to keep records.

(Slide)

Monitoring. We have already talked about that. You have to have written monitoring procedures. How often are you monitoring? What are you doing? And you have to have records that do that.

(Slide)

Corrective action. You have to have a corrective action plan: When I find the problem, this is what I am going to do. It needs to be written down. You have to assure the affected food is evaluated for safety. And once you determine food is adulterated, you have to prevent it from entering commerce, or somehow being treated before it reenters commerce. Remember, this is -- we are looking at this piece here, if this is an animal food being recalled. But one could also look at this as a human food that people are going to say, well, something is wrong there. But lots of things that don't quite make it for human food become eligible for animal feed. And an example there might be Salmonella in a product. So if that product has Salmonella on the human side, it could actually be diverted to animal feed, if there was a heat kill step in it, before it went into the animal feed product.

So -- and those are diversion requests. And so we look at the safety of that. But, you know, you have to look at these rules in two ways, that things -- if there is a problem with the animal feed, it probably needs to go to

-- out of commerce. It is probably not going to correct.

But you might have a problem and you could say, well, the aflatoxin was above 20 parts per million, and it was going to be a pet food. Well, you could easily feed that to swine. You might be able to feed that to swine, because there are higher levels allowed for swine. So there are some corrective actions that you need to consider.

(Slide)

Verification. You know, if you are out there verifying something and you don't validate that it is working or you don't calibrate the instruments and you don't keep records, you are not doing verification. So just enough said, really. You just need to make sure whatever you are doing is working.

(Slide)

Recordkeeping. Written food safety plan. Everything else is obvious up there. If you think it might need a record, it needs a record. And if you think, well, I am not sure this needs a record, it needs a record. And if you say, I don't think this needs a record, it probably needs a record.

(Laughter)

This is a record-heavy rule for documentation.

(Slide)

Recall plan. Over the years we have seen some animal feed firms do incredibly bad jobs of recalling product. They are their own worse enemy. They recall one week's product, and then two weeks later they recall a month's worth of product, and the week after that they recall six months's worth of product. So they have managed to keep their name in the news as not doing a good job for a month. You know, you need a plan that is going to address the contamination, and you recall it immediately.

MR. : (Away from microphone) Dan, I don't know if I can ask a question, but on the recall, in a good many cases, when mixing animal feed, the feed is delivered and consumed by the animals before we would ever have a report back on just if in fact --- ingredients. And I am talking about the --- is what I am talking about ---

DR. McCHESNEY: Right.

MR. RIEBLI: How do you put a recall plan in place for something that no longer exists?

DR. McCHESNEY: Good question. Can we get your name and organization? I was asked to --

MR. RIEBLI: Arnie Riebli, Dairymen's Feed.

DR. McCHESNEY: Yes. That is a good one. Especially when a lot of animal feed in bulk moves very rapidly, you know, if it is out there and we can recall it, we will recall it. You know, I think the answer to that is

you obviously cannot recall something that has been consumed. But this rule moves towards prevention. And I would ay recall product that has been consumed because it had an issue with it is sort of where we are today. And we are being sort of reactive to problems. And that is our mode today. And that is what this is trying to change.

We would hope that we would see less of those incidents where it would be caught before it left the facility. And that is the whole basis, really, for preventive controls, trying to catch things before they leave the facility. You know, obviously you cannot recall something that has been consumed. So that is the best I can do on that one. But the answer is we hope to see fewer preventive controls out there. Or we hope to see preventive controls out there. That will keep that from happening.

(Slide)

Other preventive controls. What we have talked here up until this point are things in the FSMA legislation that Congress said you have to do. We have already heard -- you know, if you look at the legislation, it said you have to do a variety of things. And it just pretty much lists them out in the legislation. And that is what we have just talked about, the preventive controls, the hazard analysis, preventive control plans, verification,

recordkeeping, all of that that was in that little circle that said you have to do these things.

So, you know, comments from comments, while we are willing to listen to everybody's comments saying, well, we shouldn't have to do this, you can make that comment, but we don't have a lot of wiggle room. We are going to have to do it, because we were told to do it under the legislation.

What we are going to talk about now are things that in the legislation said these would be good things to do to make sure the other system is working. What we told you to do is working. They are currently not in the preventive control rules, either for human food or animal feed. And so we are definitely looking for your input on these. And Roberta touched a little bit on these.

(Slide)

Supplier approval and verification program. We surely believe that is helpful. And it can assure that suppliers are complying and practicing adequate control hazards. So supplier verification FDA thinks is an important thing. But it is not in the preventive control rules. So the obvious question is, should FDA require supplier approval and verification, and when and how is a supplier approval and verification program the appropriate control measure?

Now, having said that and asked that question, we have another rule out there for foreign supplier verification program, where we are saying if you are a foreign supplier, you have to have a verification program in it and it has to do this. This rule says you don't have to have a verification program. So those two have to be married up. There is just no way around that. And here I guess a couple days ago I spoke to an international group, who view this as really a trade issue.

So I think while we are looking for your -- the response you want to give us on this, and if your response is I don't think we should have a verification program, we appreciate that response, but it is probably not going to be what is going to happen.

So I will point you to the foreign supplier verification program where there are two options. There is option one and option two. I would point you towards those two options and suggest that one might read those and give us your comments on which one of those should be utilized in this rule or in the human preventive control rule. Because there is going to be some type of supplier verification, because foreign supplier verification is not going away. And this cannot go forward, really, without some type of supplier verification.

And it is, I think, an important thing,

especially in our global economy of knowing your supply chain. And over the years we have had more issues I would say related to the supply chain than we have an actual finished product. The problem with the finished product has occurred somewhere down on the supply chain that has not been caught.

(Slide)

We are also seeking comments on complaints of finished product testing. Review of complaints, pretty simple. Should a review of complaints be part of the preventive controls? I think the prevailing comments so far have been no. Sort of in between. My example I have said is that, you know, over the years we have gotten lots of comments from consumers where they say I don't like the color of your product, I don't like the way it is packaged, I don't like the name of your product, your product is too expensive. Obviously, if you have a complaint filed that those are in, those have nothing to do with preventive controls. So that is not very useful.

If, on the other hand, the comment in your complaint file is that when I opened the bag, it smelled funny, or it looked moldy, or it had insects in it, those are useful comments, you know, something that would inform inspectors going in there to say, well, what are you doing, this is a problem, how do you control this, are you having

other problems, can I see other records. So it is surely a way to start a conversation. Whether it should be required as a preventive control, we are looking for comments on that.

(Slide)

Finished product testing. Another one not in there, but, you know, how do you know your system is working, if you are not testing some product? So the question is, should finished product testing be required? And if so, when and what is appropriate and an appropriate frequency. Now, again, you may say here, well, finished product testing might be appropriate in the pet food industry. And it might be less appropriate in the food animal industry, where you are ultimately going to go dump this on the ground to feed the animal or dump it in a trough.

So, you know, we are looking for questions, when is this appropriate. And this is, I think, one of the areas where we could end up ultimately being different on than a human food rule. And we might actually have differences within the animal feed industry here on this one. So we are looking for, you know, should it be required; if so, when should it be required and how often should it be required.

The other thing I wills ay here is lots of folks

in the feed industry are currently testing for Salmonella. But if in fact you are testing for Salmonella on the animal side or on the human side, you need to have some idea of what the prevalence of Salmonella is in the product. Because we see lots of people say, well, I am testing for Salmonella. And you say, how many samples are you taking? They say, oh, I take two samples a week. How many? Two. Well, unless you have like 100 percent contamination with Salmonella, you are not going to detect that, or you are just going to be -- you know, you might as well go buy a lottery ticket. You are going to have as good a luck at detecting it.

So if you are going to be looking for something and testing end product, you need to have an appropriate, statistically appropriate, plan and that will find what you are looking for. And, you know, I think in that area I would suggest you can get fairly statistically complex. And I will put a plug in for if you are in this area, you might want to talk to the folks at U.C. Davis on how one might establish statistically appropriate sampling plans and actually what they mean, because there are a variety of ways you can do that. But you have to understand what you are looking for, what the results mean, and how to go about it. So there is a lot of merit in sampling, but you need to be doing it correctly.

(Slide)

Environmental testing, same thing. Should environmental testing be required for animal feed products? Again, you know, we have the pet food industry. We have the other animal food industry. Is it appropriate for both of those? Is it appropriate only for one of those or is it appropriate for neither of those? And if so, if it is appropriate, how and when? Should we be using indicator organisms or the actual organisms concerned? Lots of questions in there. It is all laid out in preamble what we are looking for. But again, an area I would point you to to comment on, because they are currently not in the rule. FDA's view is they are important; they probably should be in the rule. But because they weren't required, they are out.

So we are really looking for comments on these areas, whether they should be in or out, how often they should be applied.

(Slide)

Exemptions. The next four slides -- and then we will be done here, four or five, and then we will be done -- talk about exemptions. Qualified facilities are very small businesses. We have three proposed definitions, less than 500,000, less than a million, less than 2.5 million. These are sales into the animal feed industry to animal

feed. So if, in fact, you are a human food manufacturer and you have a co-product of waste stream product going to animal feed, it is only the dollar value -- it is the dollar value of what goes to animal feed that determines whether you are a very small business. Okay?

So on the -- when we were coming in here there was a person mentioned. One of the companies they are with is largely a fertilizer producer, but they also produce phosphate for the animal feed industry. And so the other part of that business that would be counted to determine whether you were a very small business would be the part of the phosphates being sold to animal feed. So that is an important point to remember, because you could be a very large company and still be a very small business on the animal feed side.

The second, what follows the or under there, it says, "Food sales averaging less than $500,000 per year during the last three years in sales to qualified end users must exceed sales to others." That is kind of the fancy way of saying the Tester Amendment. And I think, at least in this rule, the fact that we are starting at the very small business being $500,000 pretty much means that that exemption is not useful to you. You could use it. You could say I want to do that. And it also has a mileage limitation on it. But the fact is I think the $500,000

qualified facility for very small business is a better, well, it is a better exemption. You could say I want to use the Tester one, but the other one, because the way this would end up structured, is I think a better one.

And the goal of the Tester Amendment was really to protect small business or help small business not be overcome by some of the burden of this rule. And so, you know, I think by being a very small facility, you sort of get out of that without some of the other requirements that Tester has.

The Tester Amendment, I think, is probably more important on the human side of the house, more applicable. On the animal food side, I had personally never actually saw it being a very useful exemption, just because of the structure of the industry.

(Slide)

If you make canned pet food, the microbiological hazards are not subject to this. Warehouses, there are some exemptions for warehouses. And there are tons of nuances. So if you are a warehouse person, come talk to us, because there are lots of -- we have got lots of questions on warehousing.

(Slide)

Grain elevators. I know that could be an issue out here, looking at an exemption for grain elevators. In

both rules we thought we excluded grain elevators. And then when the grain elevator people looked at this and come back and say, here is what you have, we realized, because of the way we described holding, that grain elevators were not exempt. We are working on fixing that exemption, because neither on the human side or the animal side can we actually document a problem related to grain elevators.

(Slide)

Again, an exemption here that really applies to more the human side of the house, I think it is not one that you would see used on the animal side. It talks about fruits and vegetables.

(Slide)

Farm related, again, it mirrors the human rule. This might impact some of the animal feed business, but probably not. Again, this is more human food -- it is in the human food rule, and so we mirrored it here.

(Slide)

Effective dates. So when are you going to have to comply with this? Well, the rule becomes effective 60 days after the final rule is published. Right now, the final rule is scheduled for -- the latest it can be published, I think it is June 30, 2015. So, you know, sometime 60 days after that it would become effective. We realize that when something becomes effective, you cannot

put it in place immediately. So we are looking at staged implementation.

If you are a small business, meaning fewer than 500 people, we are proposing two years to implement it after the final rule.

MR. ATKINS: (Away from microphone) Excuse me. That 500 people, would that be 500 employees specifically working the food industry or is that total?

DR. McCHESNEY: Total for your company, all your -- it is total for all your facilities. So if you are somebody like Land O'Lakes -- can we have your name?

MR. ATKINS: (Away from microphone) Kirk Atkins ---

DR. McCHESNEY: That was Kirk Atkins?

MR. ATKINS: (Away from microphone) Yes.

DR. McCHESNEY: It is the total number of people in your company. So the Land O'Lakes facility was -- there are multiple Land O'Lakes facilities. If you put all the people in all those facilities and you total up the number, that is what you get.

So for the feed industry, most of the businesses would likely be small businesses. Now, the question that you may have been asking but maybe didn't ask is, does that count, if you are big -- if you are a human food company, is it just -- is it fewer than 500 people that just work on

the feed side of the house? And we are working on the answer to that question.

You know, I think the answer to that is going to be probably so, because that is consistent with how we look at the dollar value. But that is a question we have been asked, and we will -- if that is what you were really asking, we will just put that in our notebook and work on the answer.

So if you are a very small business, you have three years to implement this. If you are somebody else, like you are the Land O'Lakes, the Cargills, the Nestle's of the world, you have one year.

To go back on this, we have already gotten comments or we will get comments potentially from the feed industry that they would like to see an extension to these compliance dates. In the proposal that we are at least hearing, and then we will submit comments at, is that they would like to propose that GMPs come in on the schedule of one year, two years, or three years, and then have the preventive control part come in at two years, three years, and four years.

And that is probably a reasonable comment. Because as, you know, Roberta said, we chose to do GMP rule making under the preventive control rule. And on the human side, we are asking the human food companies to implement

really the preventive control part of this, where we do the hazard analysis on, because they have been doing GMPs for years. The feed industry implementing really two -- one rule, but they are two separate parts of something. And so, you know, we are surely looking for comments, is that appropriate and how does that impact the safety of the product.

How to comply, you can look to www.regulations.gov or you can to the FSMA website, comment there. It will take you to the same one. The comment period for this rule of preventive control for animal feed is 120 days. It ends February 26. We have already gotten an extension for comments, or we have already gotten a comment requesting an extension for a long time. To be quite truthful, we are under a court order to close the comment period by March 30, 2014. So the likelihood of an extension is we appreciate you asking, but, you know, any more than a couple weeks the answer is probably going to be, is going to be no, because we would hate to see our commissioner in leg band requiring her to stay home or something. You know, we would hate to have her held in contempt or have Mike Taylor held in contempt. So while we understand your pain that there is a lot to comment on, we just don't have a lot of wiggle room here.

And that said, and I will sort of end on that,

the area to understand is that -- we talked about preventive controls where the legislation says you have to do a certain number of things. And we talked about under preventive controls here are the areas where they were optional, so these supplier verification, end product testing, complaints, environmental.

We have a fair amount of latitude to make changes in those areas that were optional. And we have a fair amount of latitude to make changes in the GMPs. We don't have a lot of latitude to make changes in what was required by the legislation, which was the preventive control piece. So when you are doing your comments, you know, think about that. While we appreciate your comments, and, as Roberta said, you know, one person's comment can make a change, can make a difference, realize where we have our ability to make the largest changes in other areas. While we, you know, may say, well, that is a good comment, we may have really some very limited amount of wiggle room. Information is on the FSMA website.

Thank you.

MS. BARRETT: All right. Dan, thank you so much for that statement.

(Applause)

MS. BARRETT: A couple things before we break. One is we will pick up the economic analysis when we come

back. And we will cover that presentation at 10:35. The other is there is an opportunity to give public comment. What that is is usually a short statement, a couple of minutes. Some folks have registered in advance to do that. If you have not registered to advance but you would like to, there is the opportunity, we do have a little time to do that. You would see Aleta during the break and let her know. And then we will call you up.

The other thing I wanted to mention, and I don't know if -- let me go ahead and say it. Dan had talked about some errors of the proposed rule where the language is actually not in the current proposal, but there are significant issues like supplier verification. And I know that we have heard from many stakeholders that if we were to introduce provisions in those areas into a final rule, they would like an opportunity to comment on that language prior to going final. And that is something that we are looking into within the agency of how to provide that opportunity. So I think there will be more on that. I just want to let you know we are certainly looking into how to facilitate something like that.

So let's go ahead and break. And again, if we could come back at 10:35.

(Whereupon, a brief recess was taken.)

MS. BARRETT: All right. Thanks again for

everyone taking a seat. Please do not worry about the time. I will assure you that we will be on track.

And with that, we will have Dan McChesney come up to give a second presentation this morning and this time again on the economic analysis of the proposed rule.

Analysis of Economic Impacts

by Dan McChesney, Ph.D., Director, Office of Surveillance and Compliance, FDA Center for Veterinary Medicine

DR. McCHESNEY: It is good to be back.

(Laughter)

We are going to talk about the economics of this with a few disclaimers. The economic folks that did this were not able to be here. And then the person who did this at the last two meetings is not here. But he at least had some economic training in like a previous life. I have had no economic training here.

But having said that, over the years I have worked on a lot of rules. And we have looked at the economics of this. And it is very challenging on the animal feed side of the house to come up with a correct number and what that number should be, because a lot -- and especially in this area. We are kind of breaking all new ground. We don't really know who is doing what. You know, on the human side you know everyone is doing GMPs. So you can take that equation out. And you know there is some

level of HACCP across the industry. So you have a better idea.

Here, we have no idea. And to make it even a little more challenging because of some administrative procedures, our economists have a limited number of folks they can contact to ask about what are you doing and how much does it cost you and things like that. So it is a reasonably informed number that we will get to, but, you know, I think we are obviously looking for comments on how close did we get here and do we think it is right.

To do any rule, you have to have proposed benefits to the rule, otherwise you have this huge cost and no benefit. It is a little hard to get it through our OMB folks.

(Slide)

What do we say the benefits of this proposed rule are? Well, we reduced the risk of serious illness and death to animals, reduced adverse health and risk to humans, and also reduce the risk of humans consuming food provided from animals that might be contaminated. So those are the benefits. And we tried to figure out how to put a dollar value on that, which in truth is a very difficult thing.

(Slide)

Fewer illness is one. If we have preventive

controls, we would like to see fewer illnesses. We do not expect these preventive control rules to prevent all illnesses. We expect some reduction in illnesses. How do you measure reduction? How do you measure preventive controls, if they are working? You know, if you don't see illnesses, is that just dumb luck or is it the program you put in place? You know, you never know if something doesn't occur, if you have done something positive to prevent it or you just got luck. So it is a difficult thing to measure. And because it is difficult to measure, it is difficult to put a dollar value on it. Having said that, the economists did that.

(Slide)

We already talked about the very small business exemptions, and this what is up here, based on size of qualified facilities. So the economic analysis was done excluding firms that had less than $500,000 in sales, less than $1 million in sales, and less than $2.5 million in sales. What you see when you do this is that you reduce the number of firms fairly dramatically as you go from $500,000 to $2.5 million who would be covered under this rule. However, you don't reduce the amount of food covered by very much at all.

So I think at $2.5 million the amount of food that still remains covered by the GMPs and preventive

control rules, written preventive control rules, is something around 96 percent, just slightly over 96 percent. The number of firms, though, has reduce by about 40 percent. So that is a big cost reduction with very little impact on the safety of the feed supply. And the numbers, you get, at different dollar values, you get similar results on the human side, although the dollar values are different.

(Slide)

What do we say the total annualized domestic cost is, if in fact we applied it to all the firms who had less than -- all the firms that had more than $500,000 is sales? Well, we said it was $95 million. And you can see from $1 million it is $89,000. And then you can see quite a drop when you get to $2.5 million, which just tells you that the animal feed industry is kind of skewed towards the higher end of this. So firms in the animal feed side of the house, firms make a lot of feed, a lot of dollar value of feed.

And, you know, the truth of the matter here is it says the average annualized cost is $17,700 per facility. So you can tell how many facilities are in each of these just by doing the math. You just divide whatever the number is there in the millions of dollars by $17,700. And that is the number of firms that are included.

And the $17,700 is not a this is what is going to cost my firm to do this. This is just a mathematically derived thing that said here is what the total cost is and here is how many firms that covered. And we divided those two numbers and got a dollar value. So there are firms out there who it would likely cost significantly more than $17,000 and firms out there hopefully that will cost less than $17,000.

Where does this compare with the human preventive control rule? The human preventive control rule, if my memory serves me right, is somewhere between $14,000 and $18,000 per facility. So it is in the same ballpark.

There is a question. So we need your name and your firm.

MR. DELANEY: (Away from microphone) Sean Delaney, DVM Consulting. How did you address the variability of things like finished product testing? Because I could imagine with your comment about, you know, statistics and --- random sampling and nutrient analysis, that number could be deceiving --- for a very small firm.

DR. McCHESNEY: Right. These --

MS. SINDELAR: Can you recite what he said or it won't be in the record.

DR. McCHESNEY: Okay. Let's see if I can get this correctly. I think the essence of the question was,

how did you take into account things like finished product testing and a variety of other things that could be a much greater cost for a very small firm and for a very large firm. Is that -- okay.

The things we talked about today, they sort of have a -- I can't really speak for the economists, but I can tell you that what we spoke about today, supply verification, end product testing, environmental testing, are not included in the second analysis, because they were not in the proposed rule. There is a discussion in the rule about what the value of these might be, but it is not in these dollar figures. And that is one of the reasons that, you know -- well, obviously, one of the other reasons, we will be looking for comments. As Kari said, if we repropose something, we put those back in. Obviously the cost, there is going to be an additional cost.

I will tell you that when you look those supply verification, end product testing, environmental testing, they made a much bigger impact on reducing the cost of the human preventive control rule than they did on the animal preventive control rule, because I think the thought was less firms would, if it was required, less firms would be required to do it. So it is non-equal impact.

(Slide)

Total annualized cost for foreign firms. Again,

it is stated on the slide. Again, it is just the cost times how many firms there are. The total cost, if we just pick the $2.5 million, the total annualized cost for foreign firms is $22 million. If we go back to domestic, it is $65 million. So the proposed total cost at at least $2.5 million is $87 million for this rule. That is how one would look at that.

(Slide)

What are the major costs for facilities? The major cost, as it is listed on the slide, hazard analysis, process controls, various sanitation controls, monitoring verification, corrective action, basically everything associated with the prevent control part.

(Slide)

Cost per facilities. An interesting slide that I will admit, as not an economist, I don't quite understand. But I can tell you how they got the numbers. It would seem that the cost under each option should go down as the exemption goes up. But in fact, it goes the other way. And it is just -- the numbers there to the right, the $2.7 million, $3.6 million, and $6.8 million, are just a reflection of the $1,800 per facility to do what is listed under there in those four bullets: Learn about the rule, attest to qualified status, label changes, additional labor for GMPs, times the number of firms that are in the less

than $500,000 category, less than $1 million category, and less than $2.5 million category. And this is all -- these numbers are still all rolled up in the total cost of the rule.

(Slide)

Domestic facility count, just how many facilities do we think are out there? This proved to be a whole lot more challenging than one might have thought. We have been looking -- we have been doing BSE inspections for years. We had one number there. We looked at the firms registered under the Bioterrorism Act previous to, I guess, January of this year. And we had another number. We looked at Dun & Bradstreet, and we had another number. And in many cases, the numbers were not even close.

So we ended up using -- but luckily, people had to re-register. And we cleaned up the registration list. And it turns out the re-registered list and the Dun & Bradstreet numbers are pretty close. And so what we think, at least these cost estimates are based on $6,300 domestic facilities that are just involved in the feed business. So that is pet food, animal feed, the rendering industry, things like that.

We think there is another 6,800 domestic facilities that handle foods for both human and animals. And they are taken account of in the cost of the human

preventive control rule. So we don't count -- we tried not to count them twice. And so these are folks who would be vitamin manufacturers or mineral manufacturers that are doing things like that. So we tried not to do those. So their cost is captured somewhere else.

(Slide)

We have already talked about this, qualified facilities. What do we think are under -- if you are under $500,000, under $1 million, under $2.5 million, what does that look like in firm-wise? So it looks like what it says up there, $1,500, $2,000, and $3,800 below it annually. And if we go back here, I will say -- so that is based on 6,300 domestic firms. And in a minute we will go to foreign firms, which are 1,800. So it is 6,300 plus 1,800, whatever that is. 8,100? So if you take 8,100 and then you take away 3,800 facilities, that is how many would be covered under this total rule, if you use $2.5 million.

(Slide)

Again, this talks about how we got the foreign firms, FDA's food registration. And as the bottom points out, we think there is another 3,900 foreign food facilities registered as handling food for both human and animals. If my recollection serves me correctly, there is something around 90,000 human food firms, in that range. And if you look at foreign food facilities, there are many

more foreign facilities than domestic facilities producing food coming into the U.S. So the numbers are, I think, even more skewed on the human side.

(Slide)

An example of an estimated cost to a facility. Just how do we get these numbers? If you are an economist, it is pretty straightforward stuff. It is basically how many hours is it going to take to do something and what is the cost per hour for the person to do that. Annual cost to update hazard analysis, 50 percent of initial analysis. Remember who said you have to go back and do a reanalysis at least every three years, so there are some proportional costs there.

(Slide)

Primary data sources. Again, a lot of estimates going on here. ERG was the main contractor. They did the cost analysis. We used the FDA registration database for how many firms are out there. We talked to CVM experts and saying, what are firms doing? How are they doing it? Are they doing GMPs now? What are they doing out there? Food GMP survey, there was a -- the legislation required that we do a survey of food firms to see what the cost might be and determine what might be qualified as very small firms. So that data has gone into this.

(Slide)

Industry experts. We did talk to some industry experts, although we were limited to a number of those who we could talk to. We looked at the Bureau of Labor statistics for occupational employment statistics, how many people are involved. In an economic sense, it is facility size. Honestly, the size of the facility impacts the cost.

(Slide)

Areas of comments. Public data on current industry practices. You know, if you look at the economic piece of this, it is predicated on our best guess of what you were doing. If you are doing more, we would like to know that. If you are doing less, I am sure you will tell us because would make the rule more expensive and, you know, just say, well, we didn't quite get it right.

What does the cost to comply with the rule based on an individual basis? Remember, we said the average was $17,700 per firm. That is just an average. You know, if you are a member in the firm that is going to be subject, say, to this room, is it going to cost $17,000 to do this or is it going to cost $34,000? We truly don't know. We are just estimating it. So we would really like to hear from you of what is the real outcome of this. What are you -- And really based on what are you doing.

Then I think -- let me go back to that one. To go back to what are you doing, I didn't say this in the

other presentation, but I will say it here, in that if you look at -- if you are firm that this is going to apply to or a facility that it is applying to, and you look at the rule and you read it and say, my gosh, there are a lot of things I have to do here, I have to do GMPs, I have to do these preventive controls. How am I ever going to do that? That's a lot of work.

And I agree. If you looked at it that way, this looks pretty overpowering. Now, my advice to others has been -- and I will say it again -- that I wouldn't look at it that way. I would look at it as what am I doing now. You know, I may not be doing GMPs. I may have SOPs in place. I am surely controlling my hazards. At least I am hoping are controlling your hazards, because otherwise you would not be in business very long.

So ask yourself: What am I doing now? Try to get some documentation for that or surely just sit down and write it out and say, how do what I am doing now, how does that go with what they are asking me to do in this rule? And I think if you take that approach, you will find out you are a whole lot closer to already being in compliance with most of the things we are asking here, with the exception of records. You are probably not keeping the records we want you to keep, but I think what you are probably doing is probably a lot more in line with what we

are asking be done than just a kind of like a cold hearing of this is. SO I would ask you to look at it in that sense of what am I doing now, and how does that fit with what they are asking me, as opposed to, oh, I have to start all over.

(Slide)

Whether you believe the rule accomplished the intended risk reduction, will we move the safety of animal feed forward, you know, by if we do what is in this rule. If the firms do what is in this rule, will that move it forward? And obviously we want to hear which option to use for qualified facilities. Qualified facilities are really very small businesses. Do you want $500,000, $1 million, or $2.5 million? You know, I think it depends where you might sit. I assume if you are industry, you are sort of sitting at the $2.5 million. You know, if a person who thinks, well, more firms ought to be covered because they contribute to things, then you probably want the lower dollar value. We would like that input.

(Slide)

And you can comment on this piece, also, at the same site.

And I will stop there.

MS. BARRETT: All right. Well, Dan, thank you.

(Applause)

MS. BARRETT: I really do want to thank Dan for stepping up to provide that presentation. And I want to also offer, since we don't have an economist here today, that if someone came, and that was important to you and you really wanted to discussing it or if you had a specific question on the economic analysis, if you want to see me, you know, as we end today, I can give you my card. And I can get you in touch with our economist. I am happy to do that. And we can facilitate your questions that way.

We are now going to spend a little time talking about technical assistance and the implementation of this rule and how we are preparing for that. Cathie Marshall will talk. Cathie is a regulatory policy analyst in the Office of the Center Director for the center for Veterinary Medicine. And she has been very engaged on this proposed rule.

So Cathie, if you could come up?

Technical Assistance

By Cathie Marshall, DVM, MBA, Regulatory Policy Analyst,

Office of the Center Director,

FDA Center for Veterinary Medicine

DR. MARSHALL: Good morning. And I also wanted to thank you all for attending this public meeting. I am glad you are here. And this meeting, this particular public meeting, is special for me, because prior to joining

FDA I was a veterinarian in private practice here in Sacramento for 12 years. And prior to Sacramento, I was in Southern California for a few years. So it is good to be back in California.

When I joined VA, I actually joined Detroit District Office as an investigator. So you are thinking: You left California and went to Detroit? Really? You went from where you could watch the 49ers on Sunday to the Detroit Lions, who at the time were like maybe winning one or two games a year? But the folks in Detroit District are wonderful, and I learned a lot in the field.

And then I went to CVM. I joined compliance about 2006. And six or seven months later, melamine happened. And I was very involved in melamine. And it was very difficult. And I was very empathetic with all the veterinarians out there who were trying to treat these animals having no idea what was going on or what they could do to save these animals.

So right now, I am a regulatory policy analyst. And I help develop regulations, guidance, policies. And all my background in the field and as a veterinarian and in compliance has help0ed me with this position. I have spent a lot of hours on this regulation along with a lot of other folks. So it is very important.

So now that you have heard a little background on

the proposed rule, and it published October 29, so I am sure some of you have spent a little time reading the rule -- let me rephrase that. I think some of you might have spent a lot of time reading the rule. It is very long. It is shorter than the human food rule, as the preamble is. It is a very long and complex piece of regulation. And so we know there are going to be a lot of questions on it. The industry is going to need a lot of help understanding and implementing this regulation.

(Slide)

So what are we going to do as an agency to help industry? And there are several areas we are working on to assist industry, guidance documents, of course. There are going to be a lot of different guidance documents we are developing, as Roberta mentioned. If you know FDA, you know we like our guidance documents. Is there anybody here who has n ever seen a guidance document from FDA?

(No response)

(Slide)

DR. MARSHALL: So we are all well aware of those. And obviously we cannot issue those guidance documents until we have the final rule, but we are working hand in hand with the final rule to get those. So they will come out fairly soon after the final rule issues.

Then second, the agency is developing the

information center. There is an e-mail address, that I will have in a minute for you, where people can e-mail us with questions that they have on either the final rule or on how they can implement certain provisions of the rule. And that is up and running now. We have received some questions on the rule. Obviously we can't give you information on the final rule because we don't have it yet.

And then lastly, FDA has partnered with academia, researchers, a lot of state regulatory officials, and formed a partnership known as the Food Safety Preventive Controls Alliance. Catchy name. I wonder where they got that. And so we call it just the Alliance for short. And the alliance has been instrumental in developing training materials and helping disseminate information to industry.

(Slide)

And so, as I said, it is a public/private alliance. And really, it is geared to assist small, very small, medium-sized businesses, because they are most likely the ones needing the assistance and implementing this regulation. We assume that the larger businesses are going to have the training staff, the technical folks, to go through this rule and train their staff on how to comply. Certainly that does not mean that large business cannot participate in the training.

(Slide)

So some of the goals of this alliance are to develop a standardized, uniform training and education program. We want to make sure everybody is on the same page, that we are all getting the same training, so everybody is getting the same information. And then the alliance will also, as I said, help conduct outreach to industry either through association meetings or some other type of venues, and again, especially the small, very small businesses, who need to be more informed on what is going on with prevent controls.

(Slide)

Right now the alliance are developing a variety of training materials and delivery mechanisms. They are developing information to train the trainers, the people that will be taking this information back to the facility to train their staff. And we are looking at probably a combination of web-based or on-hands training and person-type training. And this training will also be used for state and federal regulators or foreign regulators. So again, everybody is receiving the same type of training, the same information.

And once a person has completed this training, they will have the qualifications to be considered a qualified individual. If you have looked at the regulation proposed rule, you know that qualified individuals are

instrumental in the preventive controls rule. They ar5e required to perform or oversee the performance of much of the food safety plan. So once they receive this training, they will be considered a qualified individual. And the information we have from these trainings will also be incorporated in some of the guidance documents.

(Slide)

And again, this alliance is hoping to be a source of information for industry, any science, technical elements relevant to the preventive controls rule.

(Slide)

Our target audience is personnel at these animal food facilities that manufacture, process, pack, or hold animal food. And of course this is human food, also. This alliance is doing both. We are not focusing on animal food here. And again, the emphasis on the small businesses.

Our target audience is also regulatory personnel, state, foreign, federal regulators, and then anyone else who is interested, consultants, large businesses, if they want to undertake this education. So anybody who wants to learn about preventive controls will be welcome.

(Slide)

So prior to the final rule, the first step is developing these training materials. And the alliance is working on developing the training for a variety of food

products, animal, human, and a variety of food types and processes. They are also developing protocols, one, to ensure that it is uniform and cost effective training. Obviously, if we are targeting small and very small businesses, we do not want this to be extremely expensive or small businesses are not going to be able to partake in this training.

Developing protocols to maintain records of certificates of people who have taken the training and then protocols to list the courses being provided by the trainers, so people are aware of what is available.

And then once the final rule publishes, many folks in FDA are going to get a good night's sleep. But we are also going to provide that training. So you all didn't see that coming. Right?

So the first thing is train the trainer. Obviously the people that are going to be doing the training need to understand what is going on. So that is the first step, get these people trained, and then provide the basic training and preventive controls, again, either internet or instructor-led training. And then continuing to provide outreach even after the final rule to industry, answering questions.

So for the guidance documents, information is being collected already for these guidance documents. Work

has begun. And again, we cannot publish or issues these guidances until we have a final rule. But we are working on certain aspects that we know are going to be in the final regulations. So certainly we can start these guidance documents.

And we have a large team of subject matter experts. They have technical experience in food safety, food supply systems. They have experience in other regulations, like HACCP regulations, on the human food side. They have experience in developing regulations and guidances and policies. And many of these folks are the same folks that helped write these regulations. So there is a lot of people participating and working on these guidance documents.

And in May of 2011, we did publish a notice. I don't know if any of you remember that notice or commented on that notice, where we asked the public, and specifically industry, to submit information about preventive controls and other practices they are doing now in their food facilities to address these hazards. And we did receive quite a few comments. And those will be useful when we work on these guidances.

Now that docket has closed, so you cannot comment on that anymore. But certainly if you have information on, hey, I would like to see this in a guidance or this would

be helpful, then submit it as a comment to this proposed rule, because we certainly want to see it.

(Slide)

And as far as guidances, we will have general guidances basically on how to conduct a hazard analysis and preventive controls, validation in the preventive controls. That seems to be a particularly confusing area. I know when I did HACCP inspections, validation was always a little tough for some folks.

And then the current good manufacturing practices, as has been said, CGMPs are now going to be required for the animal food facilities, whereas before they were just covered under the act. We didn't have specific regulations for CGMPs. So we see the need for guidance out there. We don't know what these final CGMPs are going to look like. I will tell you, when we were writing these regulations, we actually did start a little bit different GMPs than the human food GMPs, but it is very difficult working on them to justify, you know, why you need a certain GMP for human food, but not animal food. And so if you do have comments on these GMPs, we would like to see comments not just, oh, we don't think this applies to animal food, but why you don't think it applies to animal food and the justification, and any scientific information for that. If you want to submit technical

articles or research papers, you can do that in your comment.

And then, of course, small entity compliance guide, we are required to do that by law. And there is a website. I think there is a handout out there that has the website where you can submit comments

(Slide)

And then as far as more specific guidance documents, we are looking at several types of feed to use as examples of creating a food safety plan from kind of start to finish or hazard analysis, preventive controls, et cetera. So with dry feed, such as dairy feed or chicken feed, liquid supplements, minerals, vitamins, animal co-products, such as meat byproducts or poultry byproducts. We have plant co-products, such as soy and bean meal, corn distillers grain, another one, wheat bran. And then pet food, of course pet food, and there are a lot of varieties of pet food. You have your dry or extruded pet food, canned, semi-moist, raw pet food. And as Dan mentioned, the canned pet foods will be exempt from the microbiological hazards from preventive controls, but they will have to address other hazards and certainly the CGMPs.

So these are still in the works. We don't know quite how they are going to appear at this time, but these are the areas we are looking at.

(Slide)

This is the e-mail address for the information center, if you want to jot that down. I will give you a minute. It is up and running. We had a few questions. And once the rule becomes final, we expect that this will be used much more. And this is obviously for the animal food rule, since it is animalpc@fda.hss.gov. I will give everybody a minute.

(Pause)

So this is all well and good. It sounds wonderful. But where are we? So our progress to date, the alliance has made a lot of progress on the human food training materials. And since these regulations are very similar, the training materials for the human food can be used for the animal food. We will take those templates. We will modify them to fit the animal food, where there are some differences, and use them to develop the training there.

At this point, I don't know if there is going to be combined training, separate training. I don't know if that is all worked out yet. Especially for facilities that handled both human and animal food, that would make sense. And the training is going to be basically how to develop and implement a food safety plan.

And for the animal food rule what they are

looking at right now is, using as an example, pig starter pellets. So you are a facility that manufactures pig starter pellets. How are you going to set up your food safety plan? What are your hazards? What are your prevent controls? How are you going to monitor it, et cetera, et cetera. So that is what the training would be.

(Slide)

These are the websites again. I can give handouts on those. And then for those of you who like Twitter, you can follow us at FDAfood or FDAanimalhealth#FSMAmatters.

Any questions? Yes, sir.

MR. YABROFF: Will the --

DR. MARSHALL: I need your name and --

MR. YABROFF: Rick Yabroff, J.D. Heiskell. Will the preventive controls identified in the guidance end up being required and subject to enforcement?

DR. MARSHALL: The question was, will the FDA preventive controls guidance be subject to enforcement? Guidance documents are our current thinking on a topic and the recommendations we make. They are not enforceable. If you have other ways you can comply with a regulation, that's fine, as long as it does meet the requirements of the regulation.

MS. BARRETT: All right. Well, Cathie, thank

you.

(Applause)

MS. BARRETT: All right. And as mentioned, we will have time for Q&A as we get a little further in the agenda.

At this point, I would typically show a second video, but I am going to not do that, because we did not have great success with the first one, and also, frankly, because of the audience. The video that we have is about the rule-making process. And it is helpful. And we use it mainly for audiences that are foreign audiences that are not familiar with the U.S. system. And I think all of you have that background and that experience.

And also, as we have gone through the presentations, you have basically seen the steps that we cover, that legislation is passed, that there are then regulations developed to implement that legislation, that they are put out in proposed form, that there is an opportunity and a transparent process for anyone to comment, a final rule, that there are staggered compliance dates depending on size and maybe other criteria, training, the continued outreach, technical assistance, et cetera.

So we have really basically gone through the steps that the video covers. But if it is something of interest to you, it is also available on our FSMA website.

And again, if you are working with others who may not be as familiar, you might recommend the video to them.

And with that, we are really going to know switch gears and get into the public comment session. As mentioned, we do have a few individuals who have signed up in advance to offer their public comment. And we are going to talk about that process. Roberta and Dan and Cathie are our panel, who will listen to the public comment. It usually is listening, but if they do have a clarifying question for the person offering comment, they are welcome to ask that. And at the end of the comment session, if they have any reflection on what they heard, they are also certainly welcome to offer that, too.

For the individuals who are giving public comment, typically in our room we would have a microphone, and they would come p to the microphone in the aisle and speak. We don't have that setup. So I am going to ask if they would actually come up here to the podium to give their remarks. I know not everyone is comfortable with that, but, really, this is a very friendly audience. So please do feel comfortable. It also will assist our transcriber in ensuring that what you say is in fact captured for the public record, which is very important.

So I will call you up by name. And if, again, you could give your comments. We had asked that they be

limited to three minutes. Truthfully, if they are three to five, that is perfectly fine. When we get to five minutes, if you have not wrapped up, I will ask you to wrap up. I will also remind you, too, to submit your written comments to the docket.

Public Comments

MS. BARRETT: Okay. So with that, we will go ahead and get started. And our first speaker is Jenna Areias. Am I getting that right, Jenna? California Department of Food and Agriculture. And again, as you begin your presentation, if you will say your name -- you may correct me -- and your organization and then offer your comments.

So thank you. Please come on up.

MS. AREIAS: (Away from microphone)

MS. SINDELAR: You need to speak into a microphone. None of this will get recorded.

MS. BARRETT: Okay. That's okay. I don't think she needed it. She is just saying that instead she has an alternate who will speak on her behalf. And Rick is coming up.

And Rick, if you will introduce yourself. Thank you.

MR. JENSEN: Hi. My name is Rick Jensen. I am the Director for the Division of Inspection Services at the

California Department of Food and Agriculture. And I am always happy to be put on the spot for Jenna.

So I will try to keep my comments very brief. I think in general, number one, we want to thank you for coming out and doing this. Our early reviews of the rule, the program has done a very good job of tearing it apart as best they can. And they are all kind of assigned a certain section, and they are working on that. But I think at a very high level the areas that were brought up as some of the most critical areas, we are finding those, as well that I think we believe need additional comments.

Just as an example is just the whole looking at pet foods and dry grained animal food for livestock, for human food. Those create some areas which really push us into an area. But we really encourage you to be looking at risk and practices associated with those risks. But that can work both ways, as well, as you are looking at small firms or other moderate-sized firms that perhaps are manufacturing products that have high risk. So that can work both ways.

Secondly, I want to talk a little bit about the program and about our relationship and partnership with the feed industry in California. It was about 2005, we worked together with the industry to develop what we call SAFE, which is our acronym. We are not as good as the

federal government at acronyms, but it means Safe Animal Feed Education Program.

And that program is voluntary. We work with feed manufacturers to install or implement HACCP even all the way to good manufacturing practices. It is an educational piece. We conduct audits and reviews of the work that they do and just have been benchmarking and trying to move this industry, move these folks forward to what we ended up getting with FSMA. So I think California has been, you know, looking ahead. And I mean California in entirety, particularly the industry.

And to that end, a couple of years ago, year and a half ago, we undertook a very strategic process with the industry and with our advisory board to start positioning our program and to put us into a place to help carry out the implementation and education and perhaps the enforcement or verification of compliance with the rule here in the State of California. We currently have a relationship and contracts with FDA to do certain work. And we are prepared. We are getting more prepared. And we really are very interested in carrying that piece out.

MS. WAGNER: (Away from microphone) Rick, what percentage of the industry participates in the SAFE Program?

MR. JENSEN: Ask me a technical thing?

Jenna?

MS AREIAS: What was the question?

MR. JENSEN: What percentage of the industry participates in these SAFE program?

MS. SINDELAR: I am sorry. If it doesn't come through the mic, we don't capture it. And the real value in transcribing this meeting is to get these very important comments and questions on the record. So it is not just this audience, but the rest of the United States and the world, actually, to hear these concerns. So I would really appreciate it. I know you are speaking on behalf of Jenna, but these types of comments need to go into the record and clearly articulated for everyone's benefit.

MR. JENSEN: So the question is, what percentage of California feed manufacturers take part in our SAFE program? Sixty percent.

MS. WAGNER: (Away from microphone)

MS. SINDELAR: He needs to repeat that because it needs to go into the -- you have to do the same thing.

MR. JENSEN: So the question is, is the program documented? Well, yes. All of our audits and inspections are very well documented. They are conducted just as if an audit occurs.

MS. WAGNER: (Away from microphone)

MR. JENSEN: And the framework for the program, I

believe on our website there is an overview of what the SAFE program is. And that -- would you like the website for that?

MS. WAGNER: (Away from microphone) That would be great. I have your card.

MR. JENSEN: Okay. Any other questions?

(No response)

MR. JENSEN: Thank you.

MS. BARRETT: Thank you. All right. Thank you very much.

And again, I apologize. It is a little more challenging since we don't have a microphone in the room. And we will work on that, too, as we do Q&A. We will make sure that we capture the questions for the transcript.

So our second speaker is Mollie Morrissette, the Association for Truth and Food Labeling. Mollie, if you will come up?

MS. MORRISSETTE: Well, I am so thrilled to be here. This is new to me, but I have gotten inundated. I have immersed myself into the regulatory process, because I care about animals, in particular pets. And that is my focus. So I will try to do this as quickly as possible.

Thank you for the opportunity to comment on the current proposed rule for animal food related to the implementation of the Food Safety Modernization Act. My

name is Mollie Morrissette. I am the co-founder of the Association for Truth in Pet Food, the largest pet food consumer stakeholder group in the United States, representing over $82 million U.S. households that share their homes with pets. We provide a national forum to discuss current and emerging issues and information pertaining to all aspects of pet food safety.

While the efforts of government regulatory agencies are often credited with making the U.S. food supply among the safest in the world, I think we can all agree the system needs improvement, in particular concerning the animal food sector. It is critical that decision-makers understand the relationship between animal health and food safety, which is a complex association requiring careful evaluation of many variables.

The Centers for Disease Control estimates that each year in the United States 48 million people get sick, 128,000 are hospitalized, and 3,000 die each year from food-borne diseases, a health burden that is largely preventable. Yet, unlike statistics kept for human food-borne illness, the burden of pet food-borne illness remains unknown. But what we do know is that nearly three quarters of all U.S. households share their homes with pets. And Americans are expected to spend $21.6 billion on pet food this year alone.

Because so many Americans share their homes with pets, it is important to be cognizant of the frequent confluence of human and animal food ingredients and the risks they pose to not only pets, but to the people living with them. As an example, the *Journal of Pediatrics* published that human Salmonella infections were linked to contaminated dry dog food, dry dog and dry cat food, confirming that exposure to tainted pet food also made humans sick, including many children.

I haven't done this before. Whew. Take a deep breath, drink of water.

Okay. So six years following the largest pet food recall in U.S. history when more than 8,500 cats and dogs died from eating contaminated pet food, Congress enacted the Food Safety Modernization Act, the most comp0rehensive reform of our nation's food safety laws and regulations in more than 70 years.

Am I standing behind the camera? Oh, no. You didn't get me? Just kidding.

MS. SINDELAR: Start again.

MS. MORRISSETTE: Yes. I will start over. Hello everybody.

(Laughter)

That single event, the intentional adulteration of a pet food ingredient exposed deep flaws in our food

safety system. When the same contaminant was found in infant formula, it heightened public and media scrutiny of the entire food safety system and left Americans with a chilling thought, that the very same toxin that killed thousands of pets could kill them, as well as their children, triggering Americans to question the safety of all food, not just pet food.

Although the proposed rule is similar to FDA's current good manufacturing practice and hazard analysis in risk-based preventive controls for human food, there are significant differences in the way the two rules address relevant hazards. Although there are many reasons why it would of benefit to have separate rules to address the unique needs of animals, the intention of FSMA was to assure the safety of all food, whether for man or other animals.

However, it appears as if the agency has -- maybe I shouldn't read that part.

However, it appears as if the agency has selectively modified the applicability of those laws to adopt the needs and requirements of the industry that makes the food rather than to the animals who consume it, who will consume it.

MS. : (Away from microphone)

MS. MORRISSETTE: Okay. I just -- I feel so bad.

MS. : (Away from microphone) No, no. You are fine.

MS. MORRISSETTE: It seems that way. Maybe -- oh, okay. Only a little bit left.

Domestic animals are perhaps the most vulnerable population of --- beings. Under the law, they are the property of humans and enjoy extremely limited protection from abuse and neglect. Animals receive legal protections only when human and animal interests align. And when they conflict, laws are sculpted to further man's interest at the sacrifice of the well-being of animals. In this context, it is important to remember that FSMA out of the death of thousands of American pets, a result of the intentional adulteration of their food.

The tragic irony is that while those pets brought about the most significant advance in food safety in 70 years has largely been forgotten as the proposed for animal food applies completely separate and disparate standards for food for animals. Like the millions of Americans who share their homes from pets, our hope for a better future, where we can be assured of the safety of pet food, rests entirely with FSMA.

However, that dream will never be realized if significant changes are not made to the proposed rule. We ask you consider modifying the proposals in favor of

implementing this landmark law to bring about the change necessary to modernize the food safety system not just for man but for the pets we share our homes with and our lives with.

Thanks for considering my comments. And that's it. Any questions, anybody?

(Laughter)

I need a drink of water.

MS. BARRETT: Thank you very, very much.

MS. MORRISSETTE: You're welcome.

MS. BARRETT: I really do appreciate it. And for any of you who have stood at a podium, it is not always easy. So you did a great job. It is a perspective that is valued, and we are glad that you could offer remarks today.

So we have one additional individual giving comment. It is Leah Wilkinson, American Feed Industry Association.

Leah?

MS. WILKINSON: Good morning. I am Leah Wilkinson, Director of Ingredients, Pet Food, and State Affairs for the American Feed Industry Association, based out of Arlington, Virginia. Thank you to FDA for holding these public meetings to be able to provide the information to the industry, but also to gather the public feedback.

A little bit about AFIA. We were founded in 1909

to promote feed safety and uniformity of feed law and regulations across the United States. For 104 years AFI has promoted feed safety and in 2004 developed our hallmark Safe Feed/Safe Food Certification Program, which is now administered by the Safe Quality Food Institute or better known as SQF.

We have had 104 year unbroken chain of meetings with the Association of American Feed Control officials representing the state and federal feed regulators. AFIA's safe feed programs, which we now have several, are based off of the same concept in this rule of the hazard identification and prevent controls approach, which were designed for the liquid and dry feed industries pet food, ingredient industries. And we also have a separate program that is developed to help ingredient companies export to the European Union. There are more than 500 facilities certified in these various programs.

AFIA has more than 550 members, who manufacture or distribute feed ingredients, pet food, equipment, and provide services to the industry. These feed products include both commercial and non-commercial products and operations. AFIA members make 78 percent of the 165 million tons of ready-to-eat animal feed manufactured in the United States. They make over 75 percent of the non-grain ingredients used in feed in the United States. This

industry also imports a number of products, including vitamins, as only one vitamin is manufactured in the United States.

Obviously, the rules drafted by the Food and Drug Administration will have a major impact on the feed industry and AFIA's membership. We have provided accolades -- we have a few accolades and concerns, some of which you have heard from Richard Sellers at previous public meetings, but just wanted to be repeated today.

One of our principal concerns is the lack of time to review the rules. And we clearly understand the constraints FDA is under with respect to the court ordered timeline for the Food Safety Modernization Act rule-makings. This industry has never seen the magnitude of such rule-making with such a major impact on all the feed industry. We are expected to review, answer questions -- and somebody said 60-some different questions -- plus provide comments in just over four months. In fact, except for medicated feed, this industry has never seen good manufacturing practices regulations. And FDA is proposing to implement those, as well as the hazard analysis and risk-based preventive controls, in a very short time frame.

We think FDA and the industry will have their hands quite full for the next decade in implementing these rules. We hope that FDA prevails on their appeal of this

unrealistic court-ordered timeline. However, we do note that FDA almost took a year to draft the rules, plus the back and forth of a couple years with the Office of Management and Budget, and now expects the feed industry to review those and provide our comments in some 14 weeks.

As has been noted, AFIA, as well as our partners, the National Grain and Feed Association, the National Renderers Association, and the Pet Food Institute, has asked for an extension to March 31 and beyond, if FDA prevails in its appeal. While it is only four additional weeks, they would be much appreciated additional weeks, if granted, especially if we can have a decision from FDA sooner rather than later to figure into our review timeline.

We will continue to provide you comments, even past that deadline, because we know we won't get through it all, in order to give you the best feedback from the industry, while you take your 15 months that you have to finalize the rules.

One other major concern is the link between human food and animal food in the proposed rules that is common throughout the preamble in the rules. We believe the spirit and in some places the language of FSMA clearly divides the two, but there are many references in human food rules, to the human food rules, and the actual

requirements lead us to believe FDA clearly did not understand the congressional intent to more separate human food and animal food requirements.

We hope that you will maybe hear from members of Congress during the rule-making to make that a little bit more clear. And that in the 15 months that you do have, we will obviously be providing comments on those areas. And during those 15 months, you can realign the final rule to more publish whether a different risk between human food and animal feed and what the differences are.

A few accolades. On first blush, this is a really very well constructed set of rules. Realizing the devil is in the details and being an organization that strongly supported the congressional intent embody in FSMA, we believe these rules provide a clear guidepost for compliance that can coalesce the feed industry around a basic feed safety standard. It is embodied in one of AFIA's Safe Feed/Safe Food Program and one most of our members recognize.

What does concern us is the likelihood that the majority of the feed mills, not the majority of feed tonnage, will have much difficulty in understanding and crafting programs and fully implementing these rules. AFIA has been across the country over the last couple of years presenting on this. And it is the small and the medium

operations that we think will have the most difficulty understanding these concepts.

One, two, and three years may not be sufficient time to fully implement the final rules, but we will provide written comments to FDA with data and rationale, if we think additional time is needed.

We did make a request at an earlier public meeting for FDA to consider a phase-in of the GMP rules for one year and then add the preventive control rules on a two or three-year, four-year phase-in after that. We are pleased to hear that FDA is considering that request. And we will continue to comment on that. The phase-in would allow for much better compliance as the industry adjusts to a new set of rules.

Finally, we are pleased to be involved in the Animal Feed Steering Committee of the Food Safety Preventive Controls Alliance. We look forward to assisting FDA in developing the guidance documents that were outlined earlier, including the dry feed, liquid feed, pet food, animal product ingredients, plant product ingredients, and where we cover the vitamin, mineral, and micro-ingredient products. We also offer up our industry members, staff, facilities for training for either the states or FDA, as we work to implement this.

I also just want to make everyone aware we do

have a webinar on this topic that is being sponsored by feed stuffs next Wednesday, December 11. It is free. You can sign up on the feed stuffs website or you can ask me for more information.

Again, thank you for the opportunity to provide the comments.

(Applause)

MS. BARRETT: Thank you. I was remiss earlier. We do actually have one additional individual who had wanted to give a public comment. If you would like to come up?

And is there anyone else who had wanted to give public comment? Okay. We will come to you second.

And please come on up. If you will say your name and again your organization.

MS. COVELLO: My name is Kelly Covello. I am President of Almond Hullers and Processors Association, the almond industry's trade association. Our members represent 90 percent of the almond industry based on tonnage. I do want to thank FDA for the opportunity to comment on the proposed preventive controls for animal food today.

By way of background, 100 percent of the U.S. commercial almond production is in California. The production also represents over 80 percent of the global supply of almonds. There are no other states in the U.S.

that produce almonds and almond byproducts, such as almond hulls which are used for livestock feed. Almond hulls can be used for a variety of livestock but are predominantly used in dairy cattle rations.

Almond hulls have provided the California dairy industry, who has struggled immensely over the last several years, with local, high-quality feed alternatives to other high-priced feed commodities. Almond hulls are typically sold in California and some neighboring states, but are not shipped on a regular basis to all parts of the U.S.

FDA has stressed that preventative controls for the animal food rule need to be based on risk, and we agree with this approach. However, as proposed, there are requirements that are not risk based and are overly prescriptive. It is imperative that requirements of the animal feed rule are consistent and not in contradiction with requirements of the food rules. And that is for both the preventative control rules for human food and produce safety for firms that are subject to both sets of the rules.

We appreciate FDA's efforts in performing the draft qualitative risk assessment, which defines the risk of activity animal food combinations for activities conducted at a farm mix-type facility, which is one of the supporting documents to this rule. And many activities

taking place at the almond huller/sheller fall within the activities defined as a low-risk activity animal food combination.

Some of the low-risk designations differ between rules. For example, fumigation treatments are considered a low-risk food activity combination for human food, but appear not to be considered a low-risk food activity combination for animals. If the rules were to remain unchanged, it is possible and a huller/sheller would have more stringent requirements for their byproducts than for the food products that they are processing. There really is no science to support that the risk profile for this activity is different for animals or for humans.

Additionally, the low-risk activity designation relies on the definition of on-farm or farm mix-type facility. A huller/sheller may meet either of those definitions or neither of those definitions, but the fact that performing these low-risk activities on other growers' raw Ag commodities triggers preventative controls, unnecessarily subjects operations to requirements that are not risk based.

Due to the expense of operating a huller/sheller, it is rare that a huller/sheller will hull and shell their own product, as it is economically unfeasible. The most important fact is the risk profile of the activities

performed at the facility, and the risk to the animal consuming almond hulls does not change regardless of which growers' raw Ag commodities the low-risk activity they are being performed on.

Within the draft risk assessment, FDA acknowledges that there is very limited, and in some cases no, data on serious adverse health consequences or death in humans or animals from hazards associated with manufacturing, processing, packing, or holding activities conducted on animal foods, making risk-based requirement virtually impossible for some scenarios. Due to the significantly different risk profiles for pet food and livestock feed, we recommend FDA consider requirements for pet food and livestock feed in separate rules or possibly separate guidance documents. Due to the diversity of feed products, and in particular for plant byproducts, such as almond hulls, industry-specific guidance for GMPs that can be modified as technology and data become available makes better sense than overly prescriptive, hard to change regulations.

In the preamble of the risk assessment, FDA identified that one critical gap is the lack of federal feed regulations, such as good manufacturing practices, to provide baseline requirements for producing safe animal food, including pet food, animal feed, and raw materials

and ingredients.

And while federal regulations may be lacking, it is imperative that FDA recognize state regulations that are currently in place. California Department of Food and Agriculture has commercial feed rules and regulations in place, under which almonds, almond hulls and shells are regulation. And the current regulations have provided adequate safeguards for livestock, which have provided sufficient safety oversight for decades.

As the proposed produce safety rule for human food is currently drafted, a state or a foreign government may request a variance from one or more requirements of the produce safety rule where the state determines that their procedures, processes, and practices under the variance are reasonably likely to provide the same level of public health protection as the requirements of the rule. To my knowledge, this type of variance is not available for the animal feed regulations. And it is our opinion that it should be, since there are state feed regulation inspection programs and feed safety programs in place that may provide the same level of protection.

We also encourage FDA to allow variance requests by other U.S. governments, trade associations, and universities who may be funding research to develop improved guidelines or practices or may already have

programs in place.

As the rule is currently drafted, the requirement to register under Section 415 automatically subjects the facility to requirements of preventative controls rule for feed, and for human food for that matter. The requirement to register under Section 415 is related to security risks, as detailed in the Bioterrorism Act. Security risk is not equivalent or indicative to a food safety risk or a feed safety risk. There isn't a risk-based rationale why the registration requirement should trigger requirements for the animal preventative controls rule, animal feed preventative controls rule.

Lastly, I would like to request that FDA consider a second comment period before going to the final rule. You posed over 60 questions to industry, and we would like the opportunity to be able to see how you interpret our comments to those questions before going to a final rule.

Overall, we are supportive of FDA's efforts to update the food and feed safety systems in the U.S. But we just think it is imperative that any new requirements are risk based and feasible for industry.

So thank you.

(Applause)

MS. BARRETT: Thank you very much.

DR. McCHESNEY: Kari, I have a question for the

last speaker.

MS. BARRETT: Yes. Actually, before you sit down, come on over here. This is where it gets to be -- Dan is going to ask a clarifying question. And I will bring you back the microphone.

DR. McCHESNEY: I think this was an issue that was raised two or three years ago, when I came out and spoke in Modesto at this issue about almond hullers. When you send us your comments, could you sort of send a description of that industry?

MS. COVELLO: Yes.

DR. McCHESNEY: Because I think it is one of these ones we don't necessarily understand. And it is --

MS. COVELLO: We get caught in the cross hairs of all of them.

DR. McCHESNEY: Right. So I think it would be very helpful to understand how this works and who is doing what to, I think, really understand whether they should be included or not included.

DR. MARSHALL: And you were talking about the qualitative risk assessment. And I would like you submit comments to that specifically, too, on those issues. I have not checked it recently, so maybe you have, but --

MS. COVELLO: (Away from microphone) I have not yet, but I will ---

DR. MARSHALL: Okay. Thank you.

MS. WAGNER: I actually just have a comment. You mentioned that registration relative to the BT Act should not trigger preventive controls. Unfortunately, that is what the legislation did.

MS. COVELLO: (Away from microphone) I know that ---

MS. BARRETT: I guess if you have any remark on that --

MS. COVELLO: Yes. Our comments to the food regulations go through the whole process of how almond hulling and shelling works, and even harvesting, because we harvest to the orchard floor, which is different. Coming into the huller/sheller, we get a lot of dirt and dust and orchard debris. So we are kind of a unique situation.

The other thing I would put out there is if FDA is unfamiliar with this industry and would like to learn about it, we did help co-host a tour for the folks writing the preventative controls for human foods. And I would love to facilitate a tour like that, if necessary.

MS. BARRETT: Thank you again.

And we do have one other individual, who will give public comment.

MR. ZANOBINI: Chris Zanobini, California Grain and Feed Association. And I serve as the Chief Executive

Officer.

A little background on the California Grain and Feed Association. It dates back to 1924. We have approximately 250 members. And we, too, represent about 90 percent of the feed processing sold here in the State of California.

I would like to echo the comments, not having to repeat everything that was said previously, but I would like to echo the comments made by Rick Jensen at CDFA, by Leah at AFIA, and then the comments that Kelly just made, and reiterate some of the facts and some of our initial concerns that we have with the feed rule.

As was stated earlier, there are separate proposals for human and animal feed. We do believe that maybe it should be taken a bit further in that there should be a further separation between animal feed and pet food, particularly when you look at from a risk level.

Here in California we have, as was stated earlier, we have our SAFE Program and a close relationship between industry and the Department of Food and Agriculture with our feed inspection program. We do have an industry board. They do advise the Secretary on issues related to feed. And we do have a program that has been stated before that does have regulations and currently inspections and really does verification over the feed that is sold here in

California. And we really hope that FDA will look to this program as a regulatory partner for inspection and verification within the rule.

Another concern that we have is that California is the only state that has two FDA districts within it. We have a northern and a southern California district. And we need to make sure that those districts are very coordinated when looking at this rule here particularly in our state.

When looking a firm size, we question whether it should be risk based, not just based on dollar amount or number of employees.

We also have concerns about nutrient inadequacies, making sure that those are risk based. And then also, we need a clear definition of moisture, again based on risk.

Furthermore, we want to make sure that we do not leave items to guidance documents that really should be spelled out in the rule. And again, we want to make sure that these questions that we have been asked to comment on are put back out for public comment. So we do have the opportunity to review them and respond appropriately.

Lastly is on environmental monitoring. We want to make sure that is based on risk factors for the validation and verification process. Again, we have had very little time at this point to really dig in and review

the rule. We are currently in that process. We do believe we need more time to comment, to further understand. It is, like Leah had indicated, this is a new frontier for the feed industry. And I think it is going to take quite a bit of time to get people together, get people's comments together, and really get a true understanding of what it is going to take to implement this.

Thank you.

(Applause)

MS. BARRETT: Is just really want to thank everyone who did offer their public comment. It is very much appreciated, to hear your remarks and to capture them in the transcript, as Aleta mentioned, for the benefit of really all audiences.

A couple of things. What I would like to do is, as mentioned, we will have the panel in just a moment reflect on some of what they heard. But I want to put a suggestion out and see how you respond to this. What I would like to suggest is we will hear for a few minutes from the panel. Then we will do the Q&A and allow -- you know, we could allow up to an hour, if you like. And then Roberta has an implementation presentation that she will give. And I think that is probably about 15 minutes.

So what I would like to suggest is that we just move through the agenda and not break for lunch, because

the thought of sending you all out and getting you through security, I just -- I don't see how that would be very efficient use of your time. And I think if we all went to the little café, we would overwhelm them.

So that is what I would like to do. So just a general nod, if people are comfortable with that approach. If, during the Q&A, you would like to get a cup of coffee or water or something, feel free to do that. Use the restroom. I know we are holding you a little bit longer. But I do feel like that would probably be the best use of time.

So with that, I am going to go ahead and pass the microphone to the panel for their reflections on the public comment.

Response from Panelists

MS. WAGNER: Okay. First I want to emphasize that I am on the human feed side of the house. But, you know, what we heard over and over again is that you need more time to comments. This rule is, between the GMPs and the preventive controls, is really new, and you need some time to take it -- you know, take some time to look over that. I heard several times that pet food and animal feed may be different enough to support different standards. I am not sure that we would go as far as different rules, but perhaps some different standards relative to both the

preventive control side and the GMP side.

And then I just -- I heard loud and clear, and we have heard this in other venues -- I principally did the public meetings for the human preventive controls and the import rules -- but consistency in implementation of the rule. So you are talking about California and two districts. We have twenty district offices across the country. So we absolutely recognize the need to implement these rules in a consistent manner. And that is going to take a lot of training and education and outreach to your regulatories, not just the regulators in FDA, but the regulators in the states, as well.

MS. BARRETT: And that was Roberta --

MS. WAGNER: Roberta Wagner.

DR. McCHESNEY: I would just add onto what Roberta said, that I guess the other piece that we are surely interested in is hearing more about unique situations. We heard about the almond growers today, which seems to me to be a fairly unique business. And I heard that last time, two years ago when I was out here. It is kind of a unique business, unique in the way that you could actually end up being subject to preventive controls for animal feed and not to human food, which is a little strange.

So, you know, we obviously need to look at that.

And we have heard in other meetings where there are similar situations, especially in warehousing and some other types of things.

And then other thing I think we heard is that the way we classify nutrient imbalances is surely giving people lots of heartburn. We are really talking about doing that as a process control. We don't expect you to test everything, nor do we expect FDA to be the nutritionist. You know, we just expect the feed mills to make the feed as is stated, so it is really a process in mixing control, that type of issue. And I think that hopefully we will move it to clarify it that way.

With that, I will turn it over to Cathie.

DR. MARSHALL: Going back to the topic on having either probably not different rules, but different requirements for animal feed, livestock feed, and pet food, one of the big issues there is define pet. I think we all conceptually in our head know what a pet is, but legally that is going to be tough part. How do we define that? Is a horse, is livestock under USA? But how many people consider their horses pets or companion animals? And that is something that we need feedback on. If you want different requirements, then we need to know how legally we can define and make a clear divide between what is livestock or food-producing animals and what is a pet. So

that is an important area, too, that we need information on.

DR. McCHESNEY: That is a really important issue, because we have struggled with that under pet food labeling issues, how we get things that -- you know, dogs and cats are obviously pets. What about horses? And then we have a variety of fish, iguanas, snakes, this whole other myriad of things. And then --

MS. : Birdseed.

DR. McCHESNEY: And then somebody says: What about my pot-belly pig? And what about the cow I keep in my backyard, who is a family member? So it sounds trivial, but it is actually, from a regulatory standpoint, it is incredibly challenging to divide what a pet is.

So any insights you have on that would be very, very helpful.

MS. : You mean right now?

DR. MARSHALL: No, to comment on. No, no, no, no. To comment.

And as he mentioned, the pet food labeling regulations, we are still working on those. They kind of got put on hold because of preventive controls. I don't know if that proposed rule will be publishing before the end of the comment period, because we did have to deal with that issue of what is pet food in that proposed rule. That

might be something we can use. If I said it, I would be lying, but probably not. So --

DR. McCHESNEY: And the other -- you know, one option is just to say this rule applies to dog and cat food. I mean, you could have that. You could just -- you need some, I think, justification of why one was saying that, because that does sound kind of arbitrary. Because, you know, a person who likes their fish may be out checking that.

DR. MARSHALL: Well, we did have recalls on fish food during the melamine. So --

Questions and Answers

MS. BARRETT: All right. So Q&A with one microphone on a short leash is, I admit, going to be a little bit challenging. But we are going to be okay. We are going to work through this. And what that means is if you have a question, if you could come up. I am actually -- let me move this out of the way. I think we can get about here.

So if you can come up and ask your question, state your name, your organization, and ask your question into the microphone. I will hold it, so you don't need to do that. Then I will pass it to the panel for their response. And we will work like that. And hopefully it will go somewhat smoothly.

So again, I appreciate your patience and welcome the first question. Come on up. Thank you.

MR. RIEBLI: My name is Arnie Riebli with Dairymen's Feed. And I actually have three questions. The first is, in your presentation earlier, you talked about Salmonella. Well, there are 2,700 different types of Salmonella. Some Salmonellas impact animal feed, and some Salmonellas impact humans. I think that your defage* type is probably going to have to be delineated as to what Salmonella we are talking about and how we are going to handle that.

My second question is, are you going to treat organic feed manufacturing differently than you treat conventional feed manufacturing? And where you have conventional and organic in the same mill, how are those practices going to be implemented?

The third question I have is on meat and bonemeal. Meat and bonemeal can and will be a contributor to Salmonella. If you are not using meat and bonemeal, are you going to be under the same guidance guidelines as a mill that does use meat and bonemeal?

Thank you.

MS. BARRETT: Dan McChesney?

DR. McCHESNEY: The question of Salmonella serotypes we have already dealt with in a guidance

document, where we talk about if you are making a pet food product, then we are concerned for all Salmonella serotypes, again, based on the human health implications of bringing the food into the home. For animal feed, for food animals, we delineated six or eight serotypes, some specific for dairy feed. And so those are the only serotypes we would be concerned of on the food animal side, what is listed in the guidance document.

Meat and bonemeal, if you are not using meat and bonemeal, then you just -- you would need to -- you would not have a hazard that is associated with it. And you would just need to keep records that you aren't using. I mean, just, you know, here is what I buy, as simple as that. And that goes back to somewhat of sort of how you document things under the BSE regulation, where if you are not using -- it is kind of strange. If you are not using ruminant byproduct in a -- you have to -- you don't have to have any controls, but you have to have some record saying that just showing you are using poultry, poultry byproduct, or soybeans.

So if you are not using a product that would be a hazard, you don't have to control for that other than to say, you know, we don't use it; here is the documentation I don't use it, which would be just your purchase records.

Organic feed versus conventional, I don't see

there is any difference in the way they are manufactured. For the manufacturing piece, we really don't differentiate between organic and conventional. It is how they are -- this is process control and facility control. So it really wouldn't play into that. I know there are a lot of issues associated with organic and others in the produce rule, but from our side I don't see that.

MS. BARRETT: Okay. Thank you.

Another question, please?

MS. GRIMM: My name is Katherine Grimm. And I work for Nutri-Dyn. And I am trying to find out if there is going to be nutraceutical, such as glucosamine, covered within the regulations, as well as how much in depth they are going to get into controls of documentation and change control.

MS. BARRETT: Dan?

DR. McCHESNEY: If you are an ingredient supplier of glucosamine, you are likely covered under this rule, no matter where it is going. And it is kind of an interesting dilemma, because on the human side of the house, dietary supplements are regulated as foods. And there are GMPs in place under 111. And actually, correct me if I am wrong, I think the GMPs apply to finished dietary supplements, but not to ingredients that might go into those dietary supplements.

MS. WAGNER: No. There are also some provisions around the ingredients.

DR. McCHESNEY: Okay. So they are covered under that. On the animal side of the house, the products are regulated as drugs, because we don't have the ability to regulate as dietary supplements because of the way the dietary supplement law was written. So that does present some unique challenges.

Where dietary supplements would be regulated as drugs -- the animal nutritional supplements are regulated as drugs and would not be covered under this preventive control rule. However, ingredients going to them that are food would be, if you have to register under the Bioterrorism Act.

So do you want to --

DR. MARSHALL: And there is a fine line. I mean, a lot of them are regulated as food.

DR. McCHESNEY: Yes. And then the question -- you know, we also see the other piece that would go into that is most of the nutritional animal supplements are in pill or tablet form or -- really pill or tablet form. But we are now seeing more products like glucosamine and chondroitin put into pet food where they would, I think, clearly come under this rule. So it is going to require very good records of where you are selling.

And I think the bottom line probably is that you will be subject to this rule. But, you know, we are willing to -- send us a question, if you have very -- you know, this is my business, and this is how I do it. It is going to be -- I think in many things like this we are going to have to have almost answers to individual firms. Yes, if you do it this way, you are in, and if you do it this way, you are out. And we can maybe do that in guidance. But we really need to know how that works and why you have a different issue.

In the scheme of things, you are not necessarily that different. You are not unlike the question from the almond folks, where they are kind of different, too. And so we are getting this category, we are getting this little group of people who are kind of different that are not clearly in or clearly out. And we just really need to know the specifics of what you are doing.

DR. MARSHALL: Are you registered as a food facility under the Bioterrorism Act?

MS. BARRETT: They are nodding yes.

DR. MARSHALL: The answer was yes.

MS. BARRETT: All right. The next question?

MS. MORRISSETTE: Me.

MS. BARRETT: Okay. Please come up, and I will hold this for you.

MS. MORRISSETTE: This one is kind of a whopper. So --

MS. BARRETT: Say your name and your association again.

MS. MORRISSETTE: Mollie Morrissette, the Association for Truth in Pet Food. I have to just read it, because I cannot memorize it.

The standard by which all food is judged, whether it be wholesome and safe, rests entirely on the FD&C Act. The FD&C Act implicitly makes no distinction between food for animals and food for humans. The law applies equally to all food. Blah, blah, blah, blah.

And here gets to the hard part, where one of the basic statutory components of the FD&C Act is adulteration giving the FD&C the authority to pull the product, hold the companies responsible regardless for whom the food is intended. Now here is where it gets kind of achy. Despite the statute, the FDA makes a disturbing proposal in the animal food rule, the allowance of waste material in animal food.

And in the proposed food for animals rule there is a quote. This is a quote from the FDA. "In some facilities, waste from human food production, such as products that may not be edible for humans or lack nutrient value for humans, are used and sold for animal food." Da,

da, da, da, da. And then another quote was that "Human food waste that is used for animal food should be treated as food for the purposes of its animal food use and as waste for the purposes of its role in human food."

And this brings a really interesting dilemma, because waste, you know, there are two different kinds of waste. There is the achy, you know, the horrible stuff that's been denatured and the byproducts that you don't want to know about that end up going to the renderer. And then there is edible parts of animals that simply are not going to ever enter the human food stream because they are not marketable products in the U.S.

So I want a definition of what, when you say adding waste material, what does that mean. And could we -- and I know that it is going to be really hard for industry to let go of waste. I know that. I know that probably won't ever happen. But if we could separate them by quality or grades. I don't know. It is just -- I am putting it out there.

MS. BARRETT: Thank you.

DR. McCHESNEY: I can start and then others can jump in.

MS. BARRETT: Okay. I will put this here. Okay.

DR. McCHESNEY: I mean, I think one of the things that -- one example of something that would be a waste

product or probably more appropriately a co-product that does not have nutrition for humans would be the almond hulls we just heard about. Right. So that is a perfectly acceptable source, independent of what you call it, whether you call it waste or co-product.

The other products that come out of the human food industry can have a variety of things. And while they may not be edible because their stems are from some produce product or they did not meet a quality standard, so you have salty snacks, you have potato chips are didn't quite -- they are not quite the perfect potato chip or the pretzel. And so we have waste. That is called waste, although it is -- a lot of that is sold into the animal food industry.

And then there are other products, human food products, where there is some problem with them. So we will just pick on Salmonella in cookie dough or something, where that could go to animal feed, because it surely has nutritional value, if there was a step involved to address the Salmonella in it.

So the overriding principle is that if there is a hazard in the product that is going to animal feed, it needs to be addressed or addressed more controlled. And so that is what -- we do that, actually, we do that now. And, you know, I don't think we have a definition of waste in

the rules. But, you know, for other products, like USDA has something they will call inedible. And that is just trimmings in a variety of products.

MS. MORRISSETTE: Yes.

DR. McCHESNEY: Although, while they call it an inedible, it is a very nutritional, valuable product for animals.

MS. MORRISSETTE: Yes.

DR. McCHESNEY: And so it is edible in our terminology. Their inedible becomes something that can be used in animals. But the hazard still has to be -- the hazard still -- whatever it is, there is a hazard associated with the product coming in, and it has to be controlled.

You know, we have had -- you see byproducts from the distilling industry, like fuel ethanol industry, where you will have distillers' grains going to animal feed, which turns out to be a good supplement. One of the -- what that process does is it tends to concentrate things that are in the byproduct that is going over. So things like aflatoxin get concentrated two or three times. So that becomes an issue. If you are feeding those grains, you need to realize that you might have an aflatoxin problem. But it is still a hazard to be controlled.

And so I will just leave it there. Others?

MS. WAGNER: I mean, my only comment more would be that when we have --

MS. BARRETT: Roberta?

MS. WAGNER: Yes. Roberta. When we have contaminated human food that folks want to divert to the animal food arena, we have a compliance policy guide that explains how to do that. And there are some -- you know, you have to put a proposal forward. And our technical experts in CDM will have to review the proposal. So there is a lot of -- you know, we take it very seriously. And there is some decision making that occurs when folks want to do that.

MS. MORRISSETTE: (Away from microphone) I have worked on the compliance side for this.

DR. McCHESNEY: And, you know, having said that -- you know, Roberta kind of made me think of things, because a lot of things, we do get a lot of requests for diversions. And we, one, look at -- we have looked at safety in the past, and we continue to look at safety. But we also know where in the past we have gotten seafood diversions, like shrimp or things, because they have had high histamine levels, where they were basically inedible for humans, they were considered spoiled. And the diversion was, well, we want to send that to cat food. And we actually turned that diversion down, because cats turn

out to be picky eaters, and they pick up high histamine in cat food. And so if it went there, we were pretty sure they were not going to be eating the product.

So we do -- virtually all of it is risk based. If we know there is a problem associated in something that an animal will choose not to eat, we have also turned -- we turn those down. So there is a little bit of judgment that goes into this that is not strictly safety related.

MS. MORRISSETTE: But will the industry -- sorry. One more comment. Will industry understand what waste is, as well as you do? I mean, waste can mean a lot of things, too. It will mean one thing to a butcher and one thing to a renderer.

MS. BARRETT: So do you want to -- for the comments, then, to comment on defining waste?

MS. MORRISSETTE: Yes.

MS. BARRETT: This is Mollie Morrissette --

MS. MORRISSETTE: Oh, I am sorry.

MS. BARRETT: -- speaking for the record.

MS. MORRISSETTE: Sorry. Yes, I will put that in my comment.

MS. BARRETT: Roberta?

MS. WAGNER: And just to correct the record -- this is Roberta -- it would be the scumbria-producing fish, not shrimp, that produces --

DR. McCHESNEY: Oh, sorry.

(Laughter)

MS. BARRETT: Thank you for the clarification.

Okay. Another question? And your name and organization?

MR. REED: Hi. My name is Jeff Reed with the Grange Co-op. In the future, you guys have talked about having third-party state inspectors and FDA doing inspections. That has been in the record so far. How are you guys going to define and keep these to where they are separated or we are not getting multiple inspections? We had the privilege this year of getting a very thorough FDA inspection in the spring, followed up three weeks later by our state inspector coming in and doing the state inspection and adding on an FDA inspection.

MS. BARRETT: Let's see. State your name.

MS. WAGNER: Roberta Wagner. It is actually a very good question, and we struggle with this, because FDA does contract with our SAFE partners obviously to do both human and animal food and feed inspections. And what I can say is I am on the governance board for the Partnership for Food Protection. And that is a true partnership between our state regulatory partners and FDA. And we have a number of work groups. And one of the things that we are attempting to do is -- and there actually will be a

document. And it might have been already published. It is a best practices document for better coordination between the state and FDA regulators.

And in that document it specifically says we need to do joint work planning. And if at all possible, we should not be in the same firms within six months of each other. So that would give you some relief. I know the districts have state liaisons now. The district offices have state liaisons now. And they do sit down with their state counterparts. Most of them have face-to-face meetings and talk about the firms that FDA plans on inspecting in our fiscal year, which is different than the states perhaps. And then the states share what they are going to be doing. So we try not to step on each other's toes. And it still happens periodically.

I think I had a really good example. There was a firm out on the West Coast that said they had six regulatory inspections in a six-month period. Now, here is the situation. They had USDA in there because they were an organic firm. They did both human and animal food and feed. They were a seasonal operation. There was just a number of things that were going on. They had a BSE inspection. They had -- you know, the list went on. But once you actually probed into it, those six regulators were out there doing different things. This was a seasonal

operation. You only had a six-month period to get in there.

I am not going to say that is going to go away immediately, but we are aware of it. And we will be working on that as we further integrate the food safety systems between the states and FDA.

MS. BARRETT: Thank you.

Another question?

MR. DELANEY: Sean Delaney, DVM Consulting. You alluded, Dr. Marshall, to labeling at the very beginning. Is that comment meaning there won't be a comment section for any recommendations on labeling that may come from the FDA on packaging?

DR. MARSHALL: On labeling for?

MR. DELANEY: Pets is what I am most interested in.

DR. MARSHALL: No. That proposed rule is in process. I just can't tell you when it will publish. Does that answer your question or --

MR. DELANEY: And the comment period?

DR. MARSHALL: I'm sorry?

MS. BARRETT: There will be.

DR. MARSHALL: Oh, there definitely will be a comment period. Oh, yes. Probably 120 days minimum.

MS. BARRETT: So separate rule-making with

comment period, 120 days perhaps.

Okay. Another question?

MR. FERREE: Hi. My name is Bruce Ferree. I am with a food manufacturer known as California Natural Products. We are a USDA canner. We're a FDA canner. We're a water bottler. We're dairy. We're organic. And the question really goes to the waste. Everybody has waste. And I think a lot of it will be handled based on how you define a very small processor. The dollar values given are only for the waste streams. And I believe most waste streams are picked up at no cost by farmers.

The question goes to, those people that do not qualify as a very small processor, will the FSPCA -- did I get that right, Preventive Controls Alliance? -- be able to provide some guidance to help manufacturers understand what is the difference in risk between feeding to swine versus going into a pet food market?

DR. MARSHALL: This is Cathie Marshall. I believe so. I mean, that is the -- I can't tell you exactly what guidances are in development right now, but that's a good question. And whether it will be in one guidance with all these different nuances or if we will have all separate guidances. But yes, that is something we need to address, because there are differences in these different food products.

MS. BARRETT: Thank you.

Okay. Another question?

MR. YABROFF: I am Rick Yabroff with J.D. Heiskell. And I have three questions, so I will -- the first is, as somebody who is going to be involved in implementing GMPs, we have a number of dairy feed mills across the country, none of which have to comply with GMPs. So I am actually more concerned about implementing GMPs than I am preventative controls, because I believe we have very few hazards.

So I would like to know what is the rationale for applying GMPs to all animal food types? And why isn't their application risk based like preventative controls?

The second question is related. Is FDA developing criteria for de minimis hazard activities? Because this could be the basis for exempting some activities from GMPs.

The third question is, does the definition of reasonably likely to occur include published guidance documents? In which case the FDA guidance on preventative controls would become enforceable because they now fall under the definition of reasonably likely to occur.

Thank you.

MS. BARRETT: Very good.

Okay. Dan, I am going to start with you.

DR. McCHESNEY: The first one is related to GMPs and hazards. The legislation required us to have preventive controls and control hazards through preventive controls, that GMPs are a way of controlling a whole variety of hazards in probably a more uniform way. So if we just pick on pest control, you can control pests through GMPs by saying routinely my building is sealed up, you know, the roof doesn't leak, I have a pest control operation, or you could have said controlling pests is a hazard under preventive controls, and you would have to put in all the verification requirements.

So GMPs in many ways are what used to be called or are still called in HACCP like a prerequisite program that gets you out of doing a lot of specific controls for a variety of areas, because they are viewed as universal going across.

And that question -- so that is sort of the answer to why GMPs for everybody. The other piece that is in there goes to the question that GMA is asking of the way they read it, they currently read this, and I think I am right on this, is that the way we have defined things that are reasonably likely to occur, hazards that you control, such as pests or things that are GMP-type ones, would, at least in their view, require the same documentation that we are saying is required under preventive controls, because

they are hazards that are controlling.

We don't happen to see it that way. But that is sort of the -- so that is the first one. GMPs are a way of reducing the amount of hazards you have to control under preventive controls. De minimis activities, I mean, I think if you can show hazards are not reasonably likely to occur, or whatever terminology we find out, then, you know, you would not have to control it. You would have to say here is the basis for that and why it is not a problem for me.

This is sort of like mixing metaphors, but we have had similar things -- especially since you are in the dairy industry, you probably understand this -- is that ruminant protein, under the BSE regulation, your feed, you know, you don't really have to have a hazard program saying you don't use ruminant dried protein in dairy feed. You just have to have some documentation showing that you are using soybean meal or poultry meal or some other thing. So you just -- you don't have that hazard. You just say: I don't have that hazard because I don't use that product.

And that -- someone else asked a question, I think, over here about meat and bonemeal, I think the gentleman from the dairy industry. So I don't know that we are going to be de minimis, but if you have a hazard that is not likely to occur in your product, we are not going to

do that.

And then the reasonably likely to occur, what was your question? I forgot. I wrote down "reasonably likely" --

DR. MARSHALL: Basically if it is in guidance, if it is going to be reasonably likely to -- I think what we will have -- and this Cathie Marshall. What we will have in guidance are going to be the obvious hazards that -- well, in certain food that is already -- Salmonella in pet food, where we already have incidents of illness.

MR. YABROFF: In pet food.

DR. MARSHALL: In pet food, nutrient imbalance. There was just a recent recall of poultry feed for calcium levels. So I don't think that the guidance -- you know, again, the guidances aren't in, so I can't say exactly. The regulations do allow FDA to recognize a hazard, if a new -- like with melamine, if we find out there is a new intentional adulteration, something that no one has ever heard of, now we are aware of it. Melamine would not have been a hazard we would have considered long ago. Now we do consider that. And you have to think about it. Is it reasonably likely to occur? It may not be.

So you may have hazards that you identify, but are they reasonably likely to occur in your industry? Maybe not. Or in what you are doing, maybe not.

MR. YABROFF: Can I just follow up?

MS. BARRETT: Again, state your name.

MR. YABROFF: Rick Yabroff, J.D. Heiskell. In your presentation on guidance, you said that you are going to be developing guidance for a number of activities and industries.

DR. MARSHALL: Right.

MR. YABROFF: Well, if you make up an example of, well, you know, in dry blending you could, you know, this and this could happen, doesn't that become defacto regulation, because now we have to assume that it could happen at all of our facilities that do those activities? So instead of it being site specific, we have to go to whatever guidance FDA prepares relative to our industry and assume that that is now reasonably likely to occur. That is my concern that I would like you to address.

MS. BARRETT: Thank you.

Roberta?

MS. WAGNER: Yes. I guess the one thing I was going to say, we can identified hazards, but you have to look at the practices and what is really going on. You even have to look at where are you getting certain components for your pet food or -- certain parts of the country might be a little bit, or certain parts of the world might be a little bit more risky than others.

So, I mean, I think it is one thing to identify hazards that could potentially be reasonably likely to occur relative to a given production, you know, of food or feed. You have to look at the practices. And there are a lot of other things that could factor into that. So I don't think the guidance would ever be that prescriptive. I just -- I cannot imagine it being that prescriptive in this case.

DR. MARSHALL: This is Cathie again. Well, another example like aflatoxin, I assume aflatoxin would be a hazard you would identify. And so for dairy feed that is probably one we would use as an example in the guidance document.

DR. McCHESNEY: The other thing is that I think if we go back, and FDA has evolved over the years, and if we look at the seafood HACCP program, there is a seafood hazard guide that sort of like every hazard known --

MS. : I was hoping you wouldn't go there.

DR. McCHESNEY: I mean, that was a huge amount of work. And it sort of takes a little bit of burden off industry, maybe rightly or wrongly. That has not been FDA's tact going forward either in juice or in other rules that were not -- so we are not seeing right hazards because we realize it can be viewed as, well, that is the only one

I have to deal with. And maybe there are other ones.

The issue you raised -- I was on the U.S. delegation to the CODEX task force on good animal feeding practices. And we spent a long time debating whether there should be lists of hazards associated for that very reason, of that, well, if there is a list of hazards someplace, somebody is going to say, you are going -- and this was on an international level. So somebody, even for a trader, you are going to say you are controlling this, this, and this, when in fact it is not even something that is relative to maybe a dairy feed.

And so there are lots of things around lists of what do they mean and how are they used, and we are cognizant of that. And I think, you know, as Cathie said, I think if we used a dairy example, we would use one that was surely a hazard in dairy feed in the U.S. Aflatoxin would be one. And then if there were other lists out, I mean, they would be out there with a huge amount of caveats. So these are hazards that might occur in your feed, but obviously not in everyone's product, you know, based on where you are sourcing things.

And so we are very cognizant that lists are bad things, or are generally bad things to put out because they get defaulted to you have to control for this, when in fact you may or may not have to control for it. And, you know,

I think there is comment not made directly to this, but -- and I forget who made it. But it sort of goes along the line, well, if we are in the California SAFE program, can that be -- you know, what does that get me? Can that be used or can we get an exemption because we are under that?

It is sort of the same thing that, you know, what might be a hazard in California may not be a hazard in New York, because maybe they don't even have that ingredient. So it is just not -- for a dairy in New York, it could have completely different hazards than a dairy in California.

MS. WAGNER: And I guess one thing we have to be careful about, when we are talking about seafood HACCP and juice HACCP, it is written under a different framework. It basically written around -- there are critical control points. There are places in your process where you absolutely have to put in some sort of control to mitigate a particular hazard.

And under the preventive controls rules, you may have preventive controls that are not critical control points and that require critical limits. So that is where they are a little bit different.

MS. BARRETT: I just want to get a sense at this time of how many more questions do we have. If you are going to have a question, if you could just raise your hand. Okay. A couple more.

All right. If you would come on up. And again, state your name and your organization.

MS. FERRIGNI: Hi. My name is Kristin Ferrigni. I am with Roll Global. We manufacture a variety of agricultural products, including pistachios and almonds and fruit products and such. So my question relates to the product that is human food waste that may get diverted for use in animal feed. And I would like to understand more about the nutritional requirements and is there an expectation that this byproduct meets certain nutritional standards or that we maintain certain, you know, testing or anything like that.

DR. McCHESNEY: No. The only expectation -- Dan McChesney -- the only expectation is the product is truthfully labeled. So if it is pistachio whatever, it is just pistachios. And I think there are some -- there are AAFCO definitions for a variety of things, which -- so as long as it meets that definition, that is all that is required. We are not asking you to require the nutrient balance or any of that. We are just requiring it to be what it says it is.

And the whole issue on nutrient balance is really a processing issue. If someone is going to use one of your products, they need to figure out, you know, what -- if it has a certain protein they need to figure out what that

protein content is, whoever is formulating the feed, and use that accordingly. But it is not, other than -- your responsibility is to label it correctly. And that would be it.

MS. FERRIGNI: Can I ask a follow-up question?

MS. BARRETT: Sure.

MS. FERRIGNI: Okay.

DR. McCHESNEY: And I would then say address any hazards that might be associated with, although I am not sure what that would be.

MS. FERRIGNI: Well, one thing just to add to that is customarily this product will be taken off to farms. And there is maybe no labeling at all. So, you know, loaded into trucks and taken to farms for feed. So I was just curious about, I guess, the paperwork, I mean, the requirements, when we are not actually saying that it meets a specific nutritional requirement.

DR. McCHESNEY: No, it wouldn't.

MS. FERRIGNI: Okay.

DR. McCHESNEY: I mean, I think it just has to, wherever on the bill of -- if you are -- do you give this away or do you sell this? Maybe that is one question.

MS. FERRIGNI: We well.

DR. McCHESNEY: Okay. So you are selling them something. The question was, do you give this away or do

you sell it? And the answer was her company sells it.

So you sell them something, whatever it is called. And I just think it has to be truthfully -- whatever you are selling, you need a record that this was sold to the firm. But beyond that, you don't need anything.

MS. FERRIGNI: Okay.

MS. BARRETT: Okay. Great. Thank you.

Another question? Did you have a second question?

MS. FERRIGNI: No. I would rather go last.

MS. BARRETT: Okay. Another question?

MR. YABROFF: Rick Yabroff, J.D. Heiskell. Could you talk a little bit about what would be enforceable under this regulation? I understand, for example, a written food safety plan, but would -- I am just interested in what would be the subject of an inspection or what would be enforceable.

And also -- oh, I just lost my thought here. There was -- in the proposed rule, there is a discussion about entering hazards on some kind of a database or website, registering. And I know that a lot of companies are going to be very against that, particularly larger companies. But as a smaller company, I am wondering if there is any other mechanism or is that the primary

mechanism to level the playing field to make sure everybody is actually complying. I mean, I think there is a large value in that. Obviously implementation is not going to be easy of this rule. And how will FDA ensure that companies are implementing this rule so that there is a level playing field in the industry?

MS. BARRETT: Thank you.

We will start with Dan.

DR. McCHESNEY: Yes. What was your last -- your second to your last question, your statement?

MR. YABROFF: Enforceability. What is going to be enforceable, what --

DR. McCHESNEY: No. There was something else.

MS. BARRETT: Something about food safety.

DR. McCHESNEY: I just -

MS. WAGNER: It basically it was --

DR. McCHESNEY: Implement. Right.

MS. WAGNER: I think you are getting to the implementation and what kind of industry oversight are we going to have to ascertain if they are in compliance with the new standards. That is actually my last, you know, the gist of my last presentation. So we can talk to you a little bit about that.

We don't have final rules yet. I mean, so -- but we are already talking about how might we implement an

oversight program to assure industry compliance. And it is probably going to be a phased-in approach. We might handle produce, the produce safety rule, a little bit different than the preventive control rules, but they will all have like an education outreach, perhaps some technical assistance.

We are talking about how we might train our investigators to actually, you know, for the first round of inspections, perhaps they won't be regulatory type inspections. Perhaps you will have done a self-assessment, for example. And we will come out and talk to you about that. If you have questions, is there a way we can engage the subject matter experts in the centers and/or through academia to help answer your questions?

So we are doing a lot of brainstorming around that right now, but we certainly don't know what it is going to look like at this point.

DR. McCHESNEY: Dan McChesney. I remembered. The question I think you asked was about facility profiling.

MR. YABROFF: Yes.

DR. McCHESNEY: Okay. And we are asking about that in the proposed rule. We are asking for comments. Should that be required? And Roberta can comment on this, but I think the thought behind that would be -- and this

isn't a detailed plan, but just saying basically what hazards are associated with your product. And I think sort of the overall thought behind that is that before an inspector would show up, you would say, well, I am going to a feed mill that makes dairy feed. And you might look at company profiles that are dairy manufacturers and say these are hazards that these firms say are associated with them. And you might have a list of, let's say, three hazards. And these are some control things they have.

So if you were going to show that at your facility, if in fact you looked and you had one hazard and sort of the norm was three hazards, the question would be, well, do you have other hazards? Why aren't you considering these other ones also hazards?

And it could be that, you know, I make dairy feed in California, and it is not a problem in California. It could be as simple as that. But I think that was sort of the intent of the profiling.

MS. WAGNER: I can tell you on the human feed side --

MS. BARRETT: Your name?

MS. WAGNER: Oh, it's Roberta.

On the human feed side, GMA and some of their members came in to pilot industry profiling. And they are very opposed to it, quite frankly, because they said just

basically saying you manufacture this type of food or you warehouse this type of, and just listing hazards without knowing a lot of other information, you could really misinterpret what they have provided to us. And their major concern was if we were going to use the profile in a way to designate firms as high risk, non-high risk, which affects the inspection frequency in the domestic arena, at least. Again, very concerned.

They would -- you know, GMA basically told us on the human feed side that they prefer we do that type of assessment on profiling onsite during inspections. So we will take that under advisement.

MS. BARRETT: Thank you.

Molly, I know you will speak last on your question.

Is there another question before we go to Molly's question? Anyone else?

Okay. All right. And also, too, when we do end today, our panel will be here at the close. So if you want to come up and talk to someone, you certainly have that opportunity, as well.

So Molly, do you want to come up and ask a question?

MS. MORRISSETTE: Yes.

MS. BARRETT: And again, if you will say your

full name and organization.

MS. MORRISSETTE: Molly Morrissette, the Association for Truth in Pet Food. I hate to keep harping on this same subject, but I really need to understand it. Waste product, it needs to be defined as what does it mean, and will there be a standard applied to what is a waste product. Are these moldy hot pockets from Walmart? Is it, you know, denatured cancerous parts from a slaughter facility?

Because if you -- if there is no framework with which to define that word waste, then it leaves it open to a very vast interpretation. And that makes me really uncomfortable.

And the second part is, even if there was a definition of waste, oh, like, you know, the peelings of apples or something that is safe, that is not contaminated with anything, that is diverted to animal food, when we have compliance policies that go around the FD&C laws saying that if a food is adulterated, you know, you may not necessarily be -- what is the word -- you won't -- the compliance policies allow you a lot more freedom, even though the FD&C says one thing, the compliance policy says something else. So it gives them a lot of room. And that is scary to me as a pet parent. I don't want that burden.

MS. BARRETT: I don't think the comment was

heard. Was there further reflection on it?

DR. McCHESNEY: Yes. I think maybe the further reflection was -- I mean, that comment and the gentleman back there who commented is that, talking about guidance, we may need something more, something about the waste stream or the co-product stream. I mean, I think that is sort of something more focused on what are we -- what is our thinking in that area and sort of what is eligible and what is not eligible. And I think the way to do that would be some type of guidance.

MS. WAGNER: Initially. And then maybe it would end up as a compliance policy. I mean, that is kind of how --

DR. McCHESNEY: You know, there is a -- I mean, I think if you talk to folks, there is a fairly broad -- I mean, people talk about the waste stream or the co-product stream or the byproduct stream. And I think the terminology may somewhat depend on what part of that business it is. If it is a big part of your business, it is the co-product stream. If it is something you give away, it may be the waste stream.

MS. BARRETT: Thank you. All questions are really valuable in this discussion. And I just want to thank everyone who did ask a question. And again, it will be in the transcript for the record. And also, if you can

send in your comments, too.

Okay. We are going to transition to the end session, which is around implementation. Roberta has already referenced a few things. But this is an opportunity for her to sort of give you the framework that we have put in place as we look at implementation issues.

And with, Roberta? Thank you.

Looking Ahead Toward FSMA Implementation

By Roberta Wagner, Deputy Director for Regulatory Affairs,

FDA Center for Food Safety and Applied Nutrition

MS. WAGNER: Okay. And I will try to make this a little bit brief, because, I don't know about you, but I am starving. So --

Anyway, we will just round out the meeting. We had talked to you a little bit about what we are doing with FSMA implementation. And, you know, I would say phase one of the implementation has been the rule making and the guidance and preparing guidance to issues that are associated with the various rules. And I am not sure if you have been on our FSMA website, but there is the whole structure with the six teams. There was imports, preventive controls, and really what was -- and they call it the FSMA Implementation Team. The FIT is what we call it.

And again, what was done under that particular --

MS. BARRETT: I'm sorry.

MS. WAGNER: That is not necessary, really.

So what has been, you know, going on under that structure really is the rule making and guidance. And then we had to update the Feed, Drug and Cosmetic Act because of FSMA in several sections. And we have issued some guidance relative to the prior notice center and things like that.

So that structure is -- some of it is slowly closing down, but a lot of it will remain intact until the rule making and the guidance writing is done. So we have that structure.

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And I am actually going to move through some of this very quickly and get to the new structure that we have set up, which we call the FOT, the FSMA Operations Team structure. So we have the FIT. FIT is the rule making and the guidance and the pictures on the FSMA website. And now we have created the FOT, which is really starting to think about how we are going to operationalize or, I would just put it this way, gain industry compliance with final rules. And so that can be done obviously through education and outreach, through industry guidance, eventually through inspection. I hope we don't have to move into the enforcement arena. But again, FSMA is giving us new enforcement tools that, if we have to go that way, we will

go that way.

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Again, as important as it is to get the final FSMA rules right and get them out there, if they are not implemented well, in other words, if we cannot get industry compliance, we have not achieved what we want to achieve. And that is a reduction in food-borne illness. You know, that is the bottom line.

We know that it is critical to implement these rules right. And I have heard, you know, several comments, and we get this often, is how are you going to implement these rules in a high-quality consistent manner. And, you know, we have to look at our pool of regulators that will help us oversee compliance with these rules, not just as FDA but as the FDA and state, because as you heard earlier today, the states do a lot of inspections under FDA contract. They do a lot of inspections on their own, quite frankly, as well. So we have to consider that.

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Again, we have to work with our partners. One thing we are really thinking about that we have to do is change resource planning and deployment strategies to achieve better public health outcomes. Everything has to be risk based. FSMA, so the many, many different sections that -- and 201, in particular, says: FDA, you have to

allocate your resources based on risk. And it talks about our operational resources. We need to do our inspections and allocate resources to do those inspections based on risk. We need to target sampling and sampling at the border, for example, based on risk.

So if FSMA drives it home to FDA, you had better have some rationale for why you are doing what you are doing, why you are out at certain firms more often than others, why you are sampling things, why you are doing environmental sampling in what facility. So that is one thing is we are moving through FSMA implementation that we are working with. And we are doing a lot of risk modeling right now.

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So the operational approach. This is the FSMA Operations Team. It is literally a pretty separate group from the folks that are on the FIT team. So we are trying to divide and conquer here, but there has to be communication between the two groups. So we have set up a manner to do that.

The FOT team has a steering committee. It is high-level senior managers across FDA's food program. And FDA's food program is split up. There are three different components. We have the Center for Food Safety and Applied Nutrition, the Center for Vet Medicine, and then -- and

that is really your technical experts. You have Dan and others from CBM here. You have me from CFSAN. We don't have Office of Regulatory Affairs here, except there are a few folks out in the audience that I know are from ORA. The ORA is your boots on the ground. So it is critical that all of us are together, the technical experts and the boots on the ground.

So what we have done, we have a steering committee that is co-chaired by a senior leader from ORA and then basically somebody right under Mike Taylor right now, Linda Tollefson. So she is up in the Commissioner's office. And that is who we have running the steering committee, as well as the directors of the Office of Compliance from CVM and CFSAN.

We have advisors to the steering committee and to work groups that have been composed under the FOT. We also have a project management team, a full-time project management team. So we are investing resources now. And just so you know, the FOT was set up in January of last year. So we are definitely thinking about how we are going to implement these rules. We are dedicating resources to that.

Under the FOT structure, we have form three work groups. We have preventive controls, and that is for human and animal food, produce safety, and import controls. And

really, what these work groups have been tasked with is, here are some regulations, you have to start framing out how are we going to gain industry compliance with these regulations, what will the compliance and enforcement strategies look like, or what could they look like.

These three work groups are co-chaired by either somebody from CFSAN or CVM, our technical centers, and somebody from the Office of Regulatory Affairs, so an investigator for the most part, an inspector or supervisory inspector.

They are co-chaired. There is 15 people or so. And I need to say that each worker right now has at least one representative from a state regulatory agency. The produce group has five representatives from state organizations. And they are the big players in Ag relative to the states.

So we recognize immediately that, as we are developing compliance and enforcement strategies, it can't just be the feds sitting there developing these strategies. We have to have our state regulatory partners. I would also say for produce, we have USDA also sitting on the work groups.

And the FSMA Operations Team, they are getting their direction from what we call the Foods Program Executive Committee. We call it the FPEC. That is run by

Mike Taylor. So it is Mike Taylor. It is the center directors from the Center for Food Safety and Applied Nutrition and CVM and the head of the Office of Regulatory Affairs or the ACRA. They comprise the FPEC. It is the FPEC that is giving the direction to this FOT structure. So it is up at that high, very high level.

Again, what they are doing right now is they are starting to frame things out, having a lot of conversations with people. And I do know that the FPEC and some other senior leaders were going to be meeting in January. And we want them to kind of do a download of the brainstorming and what they have done so far. And then we are going to start giving them some more strategic direction. So that is kind of the next steps.

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You know, there are certain ingredients to success for FSMA implementation and what I am calling the phase two kind of operationalizing final rules. And the bottom line is we have to continue to strengthen our state partnerships or strengthen our relationships with our state partners. And one way we can do that is through the Partnership for Food Protection, which I mentioned already.

We have been building an integrated food safety system in the United States for the past ten years. FSMA legislates it. It says FDA or the feds and the states, you

need to integrate. And the question that came earlier about why do I have a state regulator out and then an FDA regulator out, that is the core of the issue here. And there might be reasons for that to happen. You know, the state might get a consumer complaint, and they need to go follow up. You know, we might have a recall. We need to go follow up. But where we coordinate and leverage resources, we need to be doing that.

The Partnership for Food Protection has been around for many years now. It is a series of committees and work groups. And they tackle all sorts of issues from training, how do we, you know, get consistent training out to our fed and state partners; to IT, how do we share data seamlessly; to inspections or if there are certain data elements that we should all be collecting so we can track and trend what everybody is doing across the board. The states do thousands of inspections, far more than FDA. It would be nice if we could pool our data and keep an eye on what is going on and trend the data.

So a lot of this work is going on under the Partnership for Food Protection. And what we are going to be doing is they are downloading what they have been doing over the last many years to the FOT group. And then the FOT will be able to use some of the work they have done. We have built several best practices documents through the

Partnership for Food Protection. And like I said, you know, I have been kind of a liaison there. We are setting up briefings for the FOT work groups, so the PFP can download what they have been doing. So that is the connect there.

Let me just move to the fourth bullet there. We have to develop risk-based metrics in line wit the public health prevention framework. We count a lot of widgets in FDA. We count the number of inspections we do. We count the number of warning letters we issue. That is not getting to whether or not we are having an impact on public health.

And so under FSMA it is prevention. And the ultimate goal is to reduce the number of illnesses. And, you know, it can be pet or animal. I don't care. But from food and animal feed. So we are going to have new metrics. And we are going to, you know, be able to measure the impact of what we are doing and industry compliance on reducing the number of food-borne illnesses. So different metrics. We are going to be looking at things very differently. And that is the only way we are going to be successful in implementation. We need to show that all of the things that we are asking industry to do will have an impact.

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So, you know, next step is we just -- you know, we are going to work toward figuring out how we gain voluntary industry compliance. And we will have to work with the whole span of partners to do that. From our state regulatory partners and international regulatory partners to academics to the industry to consumer groups, you know, we are going to need everybody to help us, you know, once these final rules are out, to get folks into -- and what we want is voluntary compliance. We don't want compliance that is driven by enforcement, if we don't need to go in that direction.

We will be linking risk-based priority sets with actual budget planning and execution. And, you know, one thing we are already talking about is this whole consistency and making sure we are doing high quality consistent inspections in the field. One of the models that has been proposed is we have a lot of technical experts in our centers. You know, we have our dairy experts. We have our egg experts. We have our GMP experts. And how do we link those folks up real time with the investigators when they are doing inspections, so they can answer industry's questions? And even if they see things they don't know, does this mean anything? Should this be identified as a hazard? Should it not?

So we are trying to set up a system now where the

investigators can real time connect with the subject matter experts while they are out doing inspections, so they do a better quality inspection. And perhaps they can help answer some of the questions industry has, as we move through with implementing these particular rules.

You know, we tested out -- about a week ago, I had one of the subject matter experts in the center mention to me that an investigator actually out in San Francisco was out at a firm, had some questions on registration, had some other very technical questions on the manufacturing process they were inspecting, and via instant mail got their answers, you know, got questions answered, and they were able to provide some consultation, which we don't like to say we do, but they did to the firm.

And bottom line, it is just through instant messaging and contact between an inspector and a technical expert in the center that we were able to, you know, perform a much better inspection, and an inspection that I think industry got some value out of, as well. So that is one of the approaches we are thinking for the future as we move forward with implementation of some of these rules.

(Slide)

Bottom line, I think you have heard today that we have invested, we continue to invest, a lot of resources in implementation of FSMA. That is the only way we are going

to be successful. We need all of you. Everybody sitting in this room, we need all of our stakeholders to help us be successful. There is a lot left to do. We recognize that. You know, we have people in FDA that are writing, continue to write, new proposed rules. We are going to have folks now that have to -- you know, they are going to go through all your comments that we are receiving and analyze those and reshape rules that have been proposed. So we have folks working on that.

We have folks working on guidance documents. And now we have this whole new group of folks that are really working on how do we operationalize this? How do we help industry gain compliance with some of these rules, which we know are new and novel and vast? Particularly if you fall into a couple categories, you are an importer and you are a manufacturer and that type of thing.

Again, we need to continue active and positive engagement with our stakeholders. And, you know, what I want to say is that we have been engaging you relative to the rule-making process. Our goal is to engage you relative to how do we implement the rules once they are final. That is the next step. So you will be hearing more and more from us relative to that piece.

Are there any questions?

(No response)

MS. WAGNER: You have been a great audience. Thank you.

MS. BARRETT: Thank you, Roberta.

(Applause)

MS. BARRETT: You have been a great audience. And I can tell that you are ready to go now. I can see it on your face. I do appreciate you sitting through with the program so that we could conclude now.

Just a couple of things before you walk right out the door. Again, send your written comments. They are so critical. Tell us about your experience and data where you can. That really helps support your recommendations. We have to justify changes that are made or new ideas that are introduced.

Also, too, comment on what you like, knowing that others may be commenting from the other perspective. So that is something to keep in mind, as well.

But we had a lot of very thoughtful comment today from those who were offering public comment, as well as your questions. We do appreciate that.

I want to remind everyone to sign up for the FSMA list serve. Please do that. I think you will find that helpful. As was also mentioned, we are tweeting at FDAfood and at FDAanimalhealth. So check that out and get engaged.

We do have the videos that we talked about.

There are also fact sheets on the website. Submit your comments by February 26, or if that is extended, you would learn that through the FSMA list serve.

And please keep working with us. We find this very, very valuable. I hope that you found that this was time well spent. And thank you again.

(Applause)

(Whereupon, the meeting was adjourned at 1:05 p.m.)