FOOD AND DRUG ADMINISTRATION (FDA) PUBLIC MEETING

STANDARDS FOR THE GROWING, HARVESTING, PACKING AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION: DRAFT GUIDANCE FOR INDUSTRY

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P R O C E E D I N G S

MS. BARRETT: Okay, folks. If we can go ahead and take seats. And again, thanks for your patience, starting a few minutes later.

Alright. Well, it's good to be in California. I want to welcome everybody to today's FDA Food Safety Modernization Act Public Meeting. We're focused on the Draft Guidance for Standards of Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.

My name is Kari Barrett. I work at FDA in the Office of Foods and Veterinary Medicine, and I work in our Communications and Public Engagement Team and really have focused a lot on FSMA public engagement with our stakeholders over the last now several years. So good to see you all here and appreciate you giving us your day to go through this draft guidance.

I do want to say a few housekeeping notes. I'll be pretty quick. All of you, when you came in at the registration desk, hopefully got a folder. In the folder is the agenda for the day. There is also a list of all the biographies for all the speakers. So I am not going to go through the biography when people come up to the podium. I'm just going to say a name and title, and that way we'll keep it pretty quick.

The PowerPoints will be posted, if they haven't been already, on our FDA website. I just want to say, too, for media, we are not expecting media. But if we do have someone here from the media, please see Rosario (ph) in the back, if you could just put your hand up. She's our media contact person.

And I do want to note, too, at the end of the day, you all are familiar that we do offer time to give public comments. It's an opportunity to give sort of an official statement or to share your comments that's outside of the Q&A that we'll have during the day. It is something that we ask people to register for. But if you are interested in that option and you didn't register, there is room for additional speakers. So

just feel free to take advantage of that, if you would like. If that is something of interest to you and you didn't register, just see the registration desk.

Or actually, Juanita, if you could stand up -- Juanita Yates in the back and she will help you with that. And again, it's just an opportunity to sort of make an official statement for the record.

And just a couple of other quick notes. Exit signs -- just take a minute to see which one is closest to you. Just as a routine, everybody should always be aware of that. Restrooms are on this floor. Cell phones -- please do turn them off. And there -- my understanding is there's not Wi-Fi available unless you are a hotel guest, so I'm sorry about that. But there is discount parking if you drove in today. So if you did not already talk to somebody at the registration desk about that, they can also help you with that feature.

Today's meeting is being webcast and transcribed. We will have the transcription available on the FDA website. It usually does take a couple of weeks to get it up there.

And I do just want to note -- again, this is a public meeting, so there is no expectation of privacy in the meeting. And other questions that you might have or if you need assistance, again, Juanita Yates is a go-to person as well as anybody at the registration desk. So that takes care of the housekeeping.

Now, I'm glad we'll actually start the program. And it really is my pleasure to introduce our kick-off speakers this morning. We are very pleased to have Natalie Krout-Greenberg here with us today. She is the Director, Inspection Services Divisions of the California Department of Food and Agriculture.

And also with her up here, we have Jim Gorny, who will give some opening remarks. Jim is a Senior Science Advisor for Produce Safety in our FDA Center for Food Safety and Applied Nutrition.

So with that, Natalie, I'll turn it over to you.

MS. KROUT-GREENBERG: Good morning. Thank you, Kari.

And welcome to Anaheim, California, home of Micky Mouse, to all of us who are more familiar with Southern California.

As you all are aware, California has had quite a bit going on lately. And I'm not alone when I share how grateful I am to see the rains coming and finally falling from the skies. And I couldn't start this morning without acknowledging all of the first responders who were quick to act when the state experienced some of its worst wildfires earlier this month up in Northern and Southern Californias.

So with that, I would just like to take pause for a minute and reflect on all of those who have been affected by this devastation as well as take -- pay respect to those who have lost their lives to these tremendous fires in the state.

Thank you.

And now, California has also had lots happening on the food safety front and given that we're in the middle of an E. coli outbreak linked to romaine lettuce. While many of you in the room grow products besides leafy greens, I can't express the importance of readiness.

Because we're in the middle of an outbreak, I can't really share much with you other than I can refer you to the Center for Disease Control's website for additional information and timely information. But what I can share with you is the importance of having a rapid response team.

And here in California, we have the California Food Emergency Response Team, or known as CalFERT to most of us. CalFERT was formed in 2005 and is a unique partnership between FDA, the California Department of Public Health, and the California Department of Food and Agriculture. And it's because of this team that we were able to mobilize staff quickly -- in fact, as early as Thanksgiving Day -- to address the outbreak.

We all know that when we're facing critical

times due to public health significance, every day counts. And as each state moves forward with their plans for FSMA, I encourage all of you and I cannot emphasize the importance and the value of these state-federal partnerships in response to programs like this.

So I want to start by addressing the topic of today's discussion, the Food Safety Modernization Act, or FSMA. California is in year three of a cooperative agreement with the FDA to implement FSMA in our state. We have -- we knew it was a large endeavor, and we have one of the few Mediterranean growing climate in the world. And this allows us to produce food not only for the nation, but the world. In fact, we produce over 400 different commodities, a third of these supplying the nation's vegetable supply and two-thirds of the nation's fruit and nuts.

Food safety isn't just something that I do for work. I'm a consumer of California's bounty as well, and I think about what it means to bring a safe food product to our markets every day, especially because I'm surrounded by the most vulnerable ends of the population spectrum, being a mom of two boys who are 5 and 8 and the granddaughter of grandparents 93 through 95 years of age. Food safety matters to me just as much as it matters to all of you in this room.

When the opportunity came along to partner with FDA to implement FSMA in California, we knew it would be a monumental task. Building a program of this magnitude is a lot like watching my kids grow. In their infancy, first, they start by sitting up and gaining their balance. Then crawling leads to walking and, soon, running. And before you know it, because I have boys, they're sprinting. And giving that we have 23,000 farms in California covered under this program, I'm not sure we'll be sprinting, but we will certainly maintain a healthy stride with the team we have in place in order to address the number of farms we have to cover.

Let me start by introducing you to our staff in the Produce Safety Program. Steve Patton, who is

our Branch Chief with Inspection and Compliance Branch, houses the Produce Safety Program under his oversight and has been instrumental in building this program for California.

Shelley Phillips is our program supervisor. We have a team of Bryce Praditkul, DeLarian Dyson, Avery Cromwell, Rodrigo Chipres, Shane Rainey, who are all of our field inspectors. And there's plans to hire three additional staff in 2019.

I would also like to acknowledge our staff up in Sacramento who are our support team as well as Rick Jensen, who is our retired annuitant and brings to us over 41 years of experience in Inspection Services.

This team has taken numerous training courses, not on the regulator training, but safety -- food safety training courses in order to ready themselves for what is ahead. We've completed over 40 On Farm Readiness Reviews with a half a dozen more planned before the end of this year. And in 2019, we plan to continue On Farm Readiness Reviews on a voluntary basis as well as prioritize the farms that we have to inspect and begin inspections in spring of 2019.

The past two years have been focused on FSMA education and readiness, and a large part of this is helping the industry understand the details associated with the rule. One way that we can help achieve this is through subsidized training opportunities. So in the first year, we awarded $450,000 and $423,000 in the second year to expand the reach of the Produce Safety Alliance Grower Training. This year's award includes 38 courses in English, 18 in Spanish, and, to date, we have reached over 180 trainings throughout the state, including 4,900 attendees.

We continue to work closely with NASDA, the National Association of State Departments of Agriculture, serving on several committees in order to help bring consistency across the states as FSMA is implemented and inspections begin.

So I encourage you guys to visit our website as well as our social media pages to learn a little bit

more about us. Sign up for our newsletter. You can reach us by simply Googling California, or CDFA, Produce Safety Program.

We're happy to see the newly released guidance. One of the most common things we hear on farm is the need for resources to help farmers evaluate their farm activities and understand the requirements to ensure compliance. It goes without saying if you've seen one farm, you've seen one farm. And so therefore, examples embedded within the guidance documents really help our field staff and our farmers alike.

In closing, I want to leave you with a few final comments and thoughts. In 2006, we faced the spinach outbreak. And as a result of that, the Leafy Greens Marketing Agreement was formed. A few years later, the California Cantaloupe Advisory Board was formed. Both of these programs reside under the Marketing Act and have oversight by the California Department of Food and Agriculture. They utilize USDA licensed inspectors under the Inspection Services Division to perform over 600 food safety audits annually.

We have learned a tremendous amount about food safety from where we were 12 years ago. With the advancements in research and science, food safety systems are continually improving. Part of the road ahead for us, collectively, is to take the data we know today, leverage the advancements in science, and to be very specific about the areas we see priorities and changes to advance our abilities to bring a safe product to the marketplace each and every time.

2019 is just around the corner. And while guidance documents and embarking on FSMA inspection marks yet another milestone in the implementation of the FSMA law, we all have an obligation and a commitment to continually improving our food safety systems. The Department is focused on doing all we can to reduce risk in every meaningful way and ultimately, truly preventing illness.

I look forward to a productive day ahead, and

I thank you for your attention. And while we don't have time for questions right now, I will be around all day. So please, come find me, and I'm happy to continue this discussion.

Thank you.

(Applause.)

MR. GORNY: So good morning, everybody, and thank you for joining us today for this discussion about the draft Produce Safety Rule, compliance, and implementation guidance. Your feedback is really important to us, and you're going to hear a number of times today that we really encourage people to provide written comments to us or oral comments this afternoon because what we've experienced in the past is it really helps us refine these guidance documents, just like when it helped us refine the Produce Safety Rule. We did a number of sessions like this around the country during the development of the Produce Safety Rule, and these in-person interactions are really critical to their development. So I really want to say it's incredibly valuable.

I'm Jim Gorny. I'm the Senior Science Advisor for FDA CFSAN. We do speak in acronyms. CFSAN stands for the Center for Food Safety and Applied Nutrition. We're based out of -- right out of -- outside of Washington, D.C., in College Park, Maryland. And many of my colleagues have joined me here today from the Center for Food Safety and Applied Nutrition.

So why are we here today? I'd like to compliment you again because I think the reason we're all here today is to push the ball forward on food safety and produce safety, in particular. And what I mean by "we" is produce farmers, buyers, cooperative extension specialists, retail buyers, et cetera. So it's the entire supply chain. So kudos for being here.

And I've got to say I think we all would agree that we can do better. And it's been a tough year, 2018, for sure. We've had an E. coli 15787 in the spring of 2018 associated with romaine lettuce consumption. It caused 5 deaths, over 200 people ill,

and it was the largest Shiga toxin-producing E. coli outbreak in over a decade.

We also this year -- associated with produce this summer, there was a number Cyclosporiasis outbreaks. And yes, you heard me right, plural -- outbreaks. It was associated not only with mixed salad sold at restaurants, but cut vegetables sold at convenience store and prepackaged vegetable trays.

Importantly, Cyclospora was also detected for the first time in cilantro and romaine lettuce that were domestically grown. Up until this point, we've really thought of this parasite, Cyclospora cayetanensis, as, really, an imported produce problem because, typically, it was thought of occurring only in the tropics and subtropics. We've learned differently now in these domestically grown produce-positive samples.

As I said earlier, I think we're all here because I think we can do better. And I'm certain we can.

Now, the FSMA and the Produce Safety Rule, they aren't something new. As you're -- many of you had been following this since 2011 when the Food Safety Modernization Act was signed into law and the Produce Safety Rule was a part of the Food Safety Modernization Act. And again, I'll refer to that as FSMA. Sorry. We speak in acronyms.

FSMA is really the statute. It's written at the 50,000-foot level. The Produce Safety Rule, the Preventative Controls Rule, and the key implementing rules are typically written at the 10,000-foot level. And what we're here to talk about today is really written at the boots-on-the-ground level, meant to inform farmers, inspectors, cooperative extension agents to really understand what implementation may look like when you start to implement the rule. And it's intended to help farmers to understand what compliance and implementation looks like.

You know, sometimes when you're engaged in a really big task, whether it's digging a ditch or, you

know, pruning an orchard or a vineyard, they're huge tasks, right? And sometimes you get tired. It's good to stop for a second, pop your head up, see where you've been, what you've accomplished. And as has been alluded to already, a lot has been accomplished over the last decade or so, but there's certainly more that needs to be done.

And I'd also like to say and talk about a little bit why we're doing this just to remind people of what the end goal is here. And whenever I talk about the Food Safety Modernization Act and Produce Safety Rules and regulations, I think of it in four distinct phases, but they're often not discreet. And that's awareness, understanding, implementation, and verification.

So let me explain what I mean by that. With regard to awareness, you all are already in that category. You're aware that there is a Produce Safety Rule. You take food safety seriously. You're here to participate in these meetings. So that's just awareness about the importance of food safety, and I'll talk a little bit more about that.

What I mean by understanding is really understanding what the Produce Safety Rule says, what farmers need to be doing to produce safe food.

And what I mean by implementation is that's when you get on the do-it side. You understand what you need to do with regard to the Produce Safety Rule. Then you have to get on the do-it side and actually start implementing it in your operation. And that's where it gets tricky, and that's where this implementation and compliance guide really will be very important to folks.

And last but not least, which is often what people want to talk about first and foremost, is verification. And that's the inspection part to make sure that people are actually doing what they are supposed to be doing.

So let me talk about each of these four steps, and let me talk about awareness first. So why are we

doing this? Well, it's all about consumers, right? And who are consumers? Well, that's us and our families.

So when you go to the store, you really can't tell the safe food from the unsafe food, right? Well, that's really the raison d'etre, or reason, why the FDA was actually enfranchised in the 1906 Pure Food and Drug Act and gave FDA authority to regulate foods.

And our motto, or reason for existence, is to promote and protect public health. And one way we do this is by setting enforceable, clear food safety standards and making sure that everybody's following those standards.

The FSMA Produce Safety Rule is all about reducing foodborne illnesses, reducing recalls, and preventing contamination in the first place. It's a preventive approach, as opposed to what we're seeing today, which is a very reactive approach when there are foodborne illness outbreaks.

They all add up to protecting public health. And really, there should be no fear or concern when people go to the produce aisle. And it's a very unfortunate fact when that does occur. So we need to prevent that. That's what the -- that's what we're here today about.

The second reason: Why are we doing this? Because it's all about promoting public health. As I said, FDA's motto is to promote and protect public health, and I can think of no better way to promote and protect public health than having a diet rich in fresh fruits and vegetables, or just fruits and vegetables in general. Your mom was right, and it's been confirmed by scientists now that increase per capita consumption is one of the best tools we have available to reduce obesity, Type 2 diabetes, and the incidence of some cancers.

And consumer confidence is really the key here. So it doesn't matter what type of produce you consume, whether it's conventional, organic, locally grown, conventionally grown, imported, domestic, fresh,

frozen, or canned, we want to see people eating more fresh fruits and vegetables at the FDA because we know it has a health-protective effect.

Probably for this audience, the most important reason as to why we're here with regard to awareness is produce farmers themselves. And I can think of no better time to discuss this issue than right now. It's all about reducing the financial impacts to produce businesses because of foodborne illness outbreaks, recalls, which are often overlooked, but a critical reason why produce safety is so important. That's what this rule is all about. The rule, coupled with compliance and enforcement efforts, is designed so that all suppliers, whether they be domestic suppliers or anywhere else that they're located in the world, play by the same set of rules.

So when even a single lot of contaminated product gets out into the marketplace, it affects everybody who sells into that category, and it jeopardizes everyone's business. An outbreak of foodborne illness tied to a specific produce can devastate an entire commodity for many years. Once word gets out that there's a problem, consumers stop purchasing, distribution centers fill up. Retailers and food service operators say stop sending product because there's no demand for it; there's no pull. And studies have -- and when there's no pull for product, that means there's no work for farm workers. There's no -- everybody suffers. It's not only the farmer, but it's the farm workers because no work -- no product shipments mean no work. So we all understand that.

So studies have shown that it can also take a very long time for recovery. So again, an ounce of prevention is worth a pound of cure. And the take-home message is that sound regulations and enforcement protect the good operators and the damage caused by produce businesses that may be cutting corners. And it helps ensure stability in the marketplace.

Let me talk a little bit about the second step, which is understanding. Understanding is what is

required specifically by produce farmers in the Produce Safety Rule to enhance the produce safety, and it's a critical step in the process. Since the rule was finalized in 2015, a coalition of industry, government, and academia have been working overtime. Through the Produce Safety Alliance -- and Natalie mentioned all the trainings that have happened here in California -- there have been over 27,000 farmers trained throughout the United States and throughout the world on the Produce Safety Alliance curriculum.

I'd also say that the Produce Safety Alliance Curriculum is agnostic in that it tells you about the Produce Safety Rule. We've actually funded certain centers and certain -- we've given grants to reach specific demographics in the produce industry for small growers and other growers that have specific demographics. So it's not a one-size-fits-all with regard to the education outreach efforts, but it is standardized under the Produce Safety Alliance curriculum.

Natalie also mentioned a voluntary, nonregulatory, on farm program called On Farm Readiness Reviews that were developed by the National Association of State Departments of Agriculture and have been implemented by states and cooperative extension. And I would characterize those as the laboratory portion of the Produce Safety Alliance training. You actually go to a farm, see what implementation looks like. You have an open discussion. It's nonregulatory. It's the laboratory portion of the Produce Safety Alliance training. And I would encourage anyone who's interested in those to sign up. See Steve or see Natalie. Those are occurring in California, and they have occurred in California. And I've heard nothing but rave reviews about them, and people have really felt that they were very helpful.

But simply understanding isn't enough. So we're up to the second point. Now we're up to the third point, and that's really what we're here to talk about today. And that's with regard to implementation.

You can be coached on how to swim, but it only becomes very real when you're thrown into the deep end of the pool, right? So that's when you have to try your hardest to turn that knowledge that you learned from the swim instructor into reality with regard to putting those strokes into action and being able to tread water and keep your head above water. It's not always easy, right?

So implementation is all about getting on the do-it side. And once you start, you may need further coaching and to master those skills that you -- to make sure that you understand what's required to be proficient.

And that's what this draft guidance is all about. It's all about how you may comply appropriately and implement the Produce Safety Rule when you encounter specific situations in your farming operation. And you notice I emphasized "may," and I'll talk a little bit more about that.

So does the draft guidance have an answer to every possible scenario that you might encounter on your farm? No. It's simply not possible, right? I mean, farming's very complicated, it's done in many different ways, and we simply can't provide concrete examples. But we do try and provide some commonly encountered concrete examples in what the compliance may look like.

In essence, again, we're trying to coach both farmers, produce farmers, and inspectors on what compliance looks like. What did -- why is this important? It's important because it gets everybody on the same page as to what they may expect to see on a produce farm that's successfully implemented the Produce Safety Rule.

Does it mean that if you're not doing what is in the guidance that you're not in compliance with the Produce Safety Rule? The answer is, no, it doesn't because you may have a specific situation that doesn't fit into the examples provided in the guidance, or you may have chosen to address your specific food safety

challenges in an alternative but equally effective manner.

Let me talk about how this plays into verification, which is really the fourth step along our FSMA journey. Again, verification is just one way of saying that you or someone else -- like a government inspector, for example -- can confirm that -- what we all know should be done to assure food safety -- safe growing, harvesting, packing, and holding of fresh produce -- is actually happening.

The proposed draft Produce Safety Rule guidance plays an important role here by assuring that produce farmers and inspectors are, again, on the same page with regard to what is being expected. And I want to emphasize that the guidance is different from the Produce Safety Rule in this aspect.

Inspectors inspect based on the standard articulated in the Produce Safety Rule, not whether or not a produce farmer is following the guidance. Moreover, if an inspector comes across a commonly encountered situation that you're addressing in a different manner than an example given in the guidance, it doesn't mean that you're out of compliance with the Produce Safety Rule.

The inspectors are being trained to understand each individual's farm's approach. So you should be ready to explain how you arrive at implementing your approach and why you believe it's equally effective. Just because it's not in the guidance doesn't mean that you're doing something wrong. But what you are doing does have to make sense, and it does have to meet the intent of the Produce Safety Rule, which is, again, about that awareness with regard to reducing illnesses, reducing outbreaks, and reducing contamination.

So let me -- a few more closing remarks. So what's the draft guidance all about? Removing most of the guesswork for farmers. The draft Compliance and Implementation Guidance is intended to help farmers with the Produce Safety Rule. And the guidance helps everyone -- produce farmers, buyers, regulators alike -

- understand and envision what -- with concrete examples how to implement the Produce Safety Rule.

It answers questions so produce farmers aren't left to guess what procedures, policies, and practices they need to do to meet the requirements. And I'd like to make that point again. While the provisions of the Produce Safety Rule are regulatory requirements, the recommendations included in the guidance are just that -- recommendations. You may choose to follow examples in the guidance, or you may choose another means of ensuring compliance with specific provisions of the Produce Safety Rule. These examples may not be relevant in every situation and should not be interpreted as being universally applicable.

Also, because the version is a draft, we encourage you to review it. I know it's lengthy. It's a lot of pages. But please read it, take a look at it, submit comments to the docket. That's the only way that we're going to be able to improve it.

So I encourage you to listen carefully to my colleagues from FDA CFSAN today and their upcoming presentations. They're going to go through step-by-step what's in the draft guidance documents chapter-by-chapter and the implementation guidance. Give us your feedback on how it can be improved. And last but not least, put it -- please let us know if there any specific situations that need to be addressed in the guidance that are not currently included.

We also encourage you to consider sharing your perspective on what the compliance looks like in specific situations that you may encounter on your farms, which may be unique. And if you have questions, I'm sure any of us would be happy to have a sidebar conversation with you offline, as all of us will be here today.

Thanks again for your time, and I really appreciate it. I'll be around all day today. And I'm going to hand it back over to Kari.

Thanks, Kari.

(Applause.)

MS. BARRETT: We're now going to do a set change. So I'm going to ask our subject matter experts to come on up for the morning session.

Alright. Okay. So as Jim mentioned, we are now going to really work through the guidance document. We have two speakers to begin with who are going to provide an overview of the document, the Produce Compliance and Implementation Guide. And they are Samir Assar, who is our Director of Division of Produce Safety, our Center for Food Safety and Applied Nutrition, and Karen Killinger, who is a Consumer Safety Officer in our Division of Produce Safety in our Center for Food Safety and Applied Nutrition.

And then Mary Tijerina, who is also a Consumer Safety Officer in the same division and center, is going to begin walking through the chapters with you. And she'll start with Chapter 1, which is on the general provisions, and then Chapter 8, which is recordkeeping.

So with that, I'm going to turn it over to Samir.

MR. ASSAR: Thank you, Kari. Good morning, everyone. Good morning.

Yeah, so I'm Samir Assar. I'm the Director for the Division of Produce Safety, and I'm really happy to be here to talk to you about the guidance and really to discuss the Standards for Growing, Harvesting, Packing, Holding of Produce for Human Consumption: Draft Guidance for Industry. You're going to hear that over and over again.

We certainly encountered confusion as we developed the proposed rule and put that out there around whether those proposed requirements are final requirements and are going to be enforced. This is a draft guidance, and we are looking for your comments. And we certainly appreciate your engagement on this process, being here and being on the webcast as well. We really appreciate the time that you're taking out -- taking to be here, particularly given everything that's going on right now and the holiday season. So -- and

yes, it's a pleasure to be here, and I'm happy you're here as well.

So I want to just take a quick poll. How many of you have actually read the guidance?

Wow. Okay, very good. I would say that's about 60 percent of the audience, so that's good. Appreciate that.

And we -- we're very excited to get it out there to you. We've been looking forward to issuing our current thinking on draft recommendations, and we're really looking forward to the discussion and comments that we'll get from you today as well as throughout this entire process. And I'd like to thank the FDA staff who contributed to the draft guidance, for all the hard work, and, really, the commitment, considering the numerous topics. There are so many topics that needed to be touched on as we move forward with recommendations on the guidance. And so there was a lot of work put into it.

My team, the Division of Produce Safety, worked quite a bit, worked very hard on it, and really considered the diversity of operations, the farming community, not only domestically, but also internationally as well. It's -- it was very important for us to consider the big picture of produce production across the world. We have that responsibility for produce that is being offered and consumed into the -- in the U.S., so which was a challenging task. And we look forward to hearing your feedback on our thinking so far on this.

This is really an important step. The guidance is really an important step to educate before and while we regulate. And we appreciate all of the input that we've received from our stakeholders as well, including our state partners, our educational partners, and other agencies as we continue to implement the Produce Safety Rule. It's really important that there is engagement throughout this entire process, and we are all in this together. It is important that we move forward together as we put forth

produce safety guidance recommendations.

Now what I'll do is I'll kind of describe the FSMA journey that we embarked on, which really started out with -- and when I say FSMA, again, it's the Food Safety Modernization Act. Hopefully, you all know what that means. And that was pass into law in 2011, and it directed us to promulgate a science-based set of minimum standards for the safe production of fruit and vegetables.

And so we published the original proposal for -- that was titled Standards for Growing, Harvesting, Packing and Holding of Produce for Human Consumptions back in January 16th, 2013, and we put that out for comment. And based on the stakeholder input, the comment that we received after the issuance of that proposed rule, we essentially reopened, in a limited way, the docket to focus on specific areas where we received comments. And then we, of course, through that process, received additional comments. And on November 27, 2015, we issued and released the final rule -- the final Produce Safety Rule, Standards for Growing, Harvesting, Packing and Holding of Produce for Human Consumption, which we shorthand refer to as the Produce Safety Rule.

Now, the Produce Safety Rule represents minimum standards for the safe production of fruits and vegetables. And these are science-based, risk-based standards. In many cases, the rule requirements provide flexibility to comply in a way that accounts for the specific conditions and risks on your farm, on farms across the U.S. and, again, internationally as well.

The first compliance date for the large farms, unless they produce sprouts, was in January of this year. And the next compliance date for small farms is happening on January 28th, 2019. And it's important for you to know that we've delayed routine inspections until the spring of 2019 to give farms and state regulators, really, the opportunity for -- to hear more guidance and training and to get further technical

assistance to ensure that they have the tools that they need.

Also, this -- the release of this guidance is a step towards really helping farms implement the rule, as Jim described earlier, and really describes our current thinking. And similar to the rule-making process, it's open for comment. And comments, we will -- you can submit those comments any time in the process. However, we encourage you to submit your comments by April 22nd, 2019, so that we can take them into consideration as we work on the final version of the guidance.

And I just -- really, what's important, also, for you to know is, although this is a draft guidance for implementing and complying with the rule, we're working on finalizing the guidance. We -- the work on guidance for us as a program will continue. And we will -- we understand that there is new information out there and new technologies, science that we need to account for as we, again, work towards implementing the Produce Safety Rule.

So we're going to be -- you know, we have other guidances in mind and in store in the future around the Produce Safety Rule and also just general broad guidance that Karen might touch on as well. And every stage of this process, of the guidance development process, we will be engaged with you, as we have. We've made special trips out to California and the West Coast to really learn about what you do and how you do things and account for that as we develop our approach.

So with that, I would like to go ahead and introduce Karen Killinger, and she'll provide the rest of the overview. She's the project lead for developing this Compliance and Implementation Guidance.

So Karen.

(Applause.)

MS. KILLINGER: Thank you, Samir.

Good morning, everyone. Can everybody hear me in the back? Can you raise your hand if you can hear

me in the back? Awesome. Okay.

Well, it's truly a pleasure to join you and especially on a rainy day here in Southern California. And we're excited to be here to talk with you more about the draft produce safety guidance for industry. And I'd like to start with an overview of the content in the draft guidance, and the chapters are listed here on the next slide. And as you can see, the chapters in the draft guidance closely follow the subparts of the Produce Safety Rule.

We'll have presentations today that cover all of these chapters except Chapter 9 on variances. I'd also like to talk about some topics that are not covered in the draft guidance. At this time, we are choosing not to issue guidance on Subpart Q, Compliance and Enforcement; Subpart R, Withdrawal of a Qualified Exemption; and Subparts E and B with respect to agricultural water and alternatives.

Regarding the status of our efforts on agricultural water, FDA has proposed to extend for covered produce other than sprouts the dates for compliance for the agricultural water provisions so that we can address questions about the practical implementation of compliance with certain provisions and consider how we might further reduce the regulatory burden or increase flexibility while continuing to protect public health.

As we continue to work with stakeholders on issues raised regarding agricultural water, we do not intend to enforce the agricultural water provisions in Subpart E of the produce safety regulation for covered produce other than sprouts. Farms should continue to use good agricultural practices to protect and maintain the quality of their water sources and to ensure that the food they produce is not adulterated under the Food, Drug, and Cosmetic Act.

Moving on, with respect to Subpart M, we released a draft guidance last year to primarily assist sprout operations to comply with the sprout-specific requirements in Subpart M. The recommendations of this

draft guidance are applicable and may be helpful to sprout operations to take into consideration regarding compliance with several other subparts of the Produce Safety Rule.

Finally, I'd like to note that the draft guidance does not address the farm definition. In the guidance document titled Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practices and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs, that draft -- or the -- excuse me -- that guidance was issued to state our intent not to enforce certain regulatory requirements, including aspects of the farm definition and written assurances.

Before we move into talking on more detail about the draft guidance for industry, I'd like to take a minute to talk in more general terms about an FDA rule, content, and purpose versus a guidance document. So this table summarizes some information. And as you can see, an FDA rule is comprised of the codified and the preamble. And let's start with the first column and talk about the codified of the rule.

The codified states the specific legally binding requirements. And in many cases, these legal requirements use the word "must." The codified is a numbered section and is located in -- near the end of the document. It's also important to note that the codified often provides definitions for certain terms.

Moving on to the second column and the content covered in the preamble, the preamble often represents the bulk of the rule and describes our thinking as we developed the rule as well as our rationale for certain provisions and, for a final rule, covers responses to comments that we received on the proposed rule.

Moving on to the third column, which is about guidance documents, guidance contains nonbinding recommendations, as mentioned several times already today. And the intent is to assist in understanding how to comply with the rule requirements. Guidance documents, when finalized, reflect our current

thinking, and, in some cases, we update them from time to time.

Oftentimes, our recommendations use the word "should" or "recommend." In a guidance document, when the word "must" or a specific numbered citation is listed, that specifies a rule requirement.

We typically issue a draft guidance and have a time for comment periods so that we can receive stakeholder comments. And as mentioned earlier, although comments can be submitted at any time, we'd encourage your comments on the draft produce safety guidance for industry by April 22nd of 2019 so that we can take your comments into consideration as we work on the final guidance.

Now I'd like to provide an overview of our approach as we worked on the draft guidance and also cover some key concepts that are in the introduction and background of the draft guidance.

Regarding our overall approach, as Samir mentioned already, we've made an effort to consider the diversity of farming operations as we worked on the draft guidance. We understand that there are operational differences that need to be taken into consideration, and there's also differences in awareness with respect to some food safety topics.

As a starting point, we reviewed the comments that we received for the final rule, and we also reviewed scientific literature as appropriate. We considered what materials are already available from industry groups and educational group, and we made an effort to communicate within FDA as well as with other agencies on topics where the rule impacts or can be impacted by the rule to try to develop consistent approaches across the board. We also had the opportunity to work with commissioned state representatives appointed by NASDA, AFTO (ph), and ASTO (ph) to receive feedback on the draft guidance document.

We continue to value our engagement with stakeholders. And our engagement since the rule has

published at various meetings, listening sessions, and -- excuse me -- educational farm tours has been incredibly helpful to us.

I'd like to note that another important way to communicate with us since the rule published is through the Technical Assistance Network, or TAN. I understand that some of you may be frustrated with our response time on TAN inquiries. But we've worked to streamline our process, and our response time continues to improve. Please keep in mind that the TAN allows us to review your questions and understand farm-specific scenarios. So the TAN inquiries were an important source of information for us as we worked on the draft guidance.

Moving on, there are some key concepts in the background and introduction of the draft guidance that I'd like to highlight. First, I want to emphasize that the draft guidance, when finalized, is intended to provide our recommendations to comply with the requirements of the Produce Safety Rule. These are nonbinding recommendations.

In many cases, the rule requirements are flexible, and there may be many ways to comply with the given requirement. You may use an alternate approach as long as it satisfies the requirements of the applicable statutes and regulations.

We also made an effort to include several examples in the draft guidance to illustrate one or, in some cases, more than one way to comply with a given requirement. Some examples illustrate situations where a change is needed in practices, processes, or procedures based on the requirements. Please keep in mind we did not intend to cover every possible scenario in our examples.

The introduction also notes that the draft guidance is intended to help the owner, operator, or agent in charge of a covered farm to comply. That is you, as defined in the Produce Safety Rule. So in the draft guidance, many of the recommendations are framed as "you should" to note that something is recommended

but not required.

I'd also like to note that not all of the definitions are provided in the guidance, so it may be helpful to review the definitions in the Produce Safety Rule as you go over the guidance language. These definitions are in the codified portion of the rule, which is the numbered section, and we provided those in your packet today. You have the definitions as provided in the Federal Register Notice. For the most current version, please refer to the Code of Federal Regulations.

I'd like to move on to cover some concepts that are touched on in several of the chapters. As mentioned previously, the rule requirements are intended to be flexible, so there may be more than one way to comply. So in most cases, there is a general recommendation that a first step towards compliance is to evaluate your procedures, processes, and practices, keeping in mind the framework of the rule requirements to assist you in identifying a way to comply with the rule that best fits your operation.

The draft guidance also mentions that it's important to consider the extent of your practices, including any infrequent practices or changes that may occur over time in your operation so that you can ensure that these practices or changes are accounted for, given the requirements of the rule.

In several chapters, we provide summaries, often using bulleted lists at the beginning of the chapter or, in some cases, at the beginning of a section to highlight recommended steps towards implementation. And we hope you find these summaries helpful.

Again, we made an effort to include numerous examples in the draft guidance to illustrate specific concepts. There are over 51 examples in the guidance using a numbering system within each chapter, and there's even more examples embedded within the narrative. So we hope you find those helpful.

With respect to the examples, we generally

identify a specific type of covered produce for illustrative purposes. And in several places, we note that, even if you use the same type of covered produce and similar practices, you should perform your own evaluation of your farm's specific practices and conditions.

In a few places, we've also provided visual aids to summarize certain concepts or information, and those will be introduced in the presentations throughout the day. We'd appreciate your comments on these overall approaches in the draft guidance and whether you find them helpful to emphasize key points and provide specific examples.

We understand that resources are important, and there are several resources available in addition to the draft guidance for industry. And so we encourage you to visit our webpage for the draft guidance, which is provided in the upper right-hand corner of the slide. And there, the draft guidance is available for download.

And we also developed at-a-glance overviews, which provides a summary of each chapter and key concepts from each chapter. These at-a-glance overviews are available for download as a group on our draft guidance webpage.

Moving on, we also have two fact sheets available on our webpage for the final Produce Safety Rule, which is also provided on the slide. And these fact sheets cover topics, including rarely consumed raw produce and biological soil amendments of animal origin.

Next, an important way to continue to communicate with us continues to be the Technical Assistance Network. If you have questions about the interpretation or applicability of the Produce Safety Rule to your farm, your practices, and your produce. The TAN is a helpful way for us to receive those questions and provide a response back. More information on how to access the TAN is also available on the slide.

It's also important to note that we've increased our staff to help address produce safety with the addition of the Produce Safety Network, or PSN. And this spans both the Center for Food Safety and Applied Nutrition as well as the Office of Regulatory Affairs. We have 7 CFSAN and 16 ORA Produce Safety Network staff members who are regionally based to help collaborate and communicate with regional partners to support high levels of compliance within the farming community.

And I'd like to acknowledge some of our PSN staff that are with us today. We have Dr. Kurt Nolte with the Division of Produce Safety and Produce Safety Network staff member. We also have Steven Hughes, Division of Produce Safety and Produce Safety Network Team Leader, and Lieutenant Mark Chen from -- or Lieutenant Commander Mark Chen with the Produce Safety Network. And some of our PSN staff will serve on the panel today, so we'll hear more from them later this morning.

With respect to other resources, we also have other guidance available. And three of these guidances are listed on the slide. With respect to guidance related to produce, we first issued the guidance for industry, which is the Small Entity Compliance Guidance, the first -- or the first guidance document listed on the slide. And this guidance document is intended to help small entities comply with the rule and provides a summary of definitions and rule requirements.

Next, as I mentioned earlier, we also released a draft guidance last year to help sprout operations comply with the sprout-specific requirement in Subpart M.

And we recently issued a guide to minimize food safety hazards of fresh-cut produce to help fresh-cut processors review guidance related to requirements for the current good manufacturing practices and requirements for hazard analysis and preventive controls.

We also intend to provide other guidance documents, including an updated version of the guide to minimize microbial food safety hazards for fresh fruits and vegetables and a draft guidance on alternate curricula. We also intend to post updates and new questions for TAN frequently asked questions on the Produce Safety Rule.

So several speakers today have already mentioned that this is a process towards implementation. And so what are our next steps? Well, this is one of four public meetings for us to hear from stakeholders and understand initial reactions to the draft guidance. And we appreciate everyone being here today.

And most importantly, you have the opportunity to share your thoughts with us on this draft guidance through a formal comment. Comments must be submitted to the docket for us to consider them as we work on the final guidance. And as mentioned, you may submit comments at any time. But for your comment to be submitted in time for us to consider it as we work on the final guidance, please submit your comments by April 22nd of 2019.

There are several ways to access the docket to gather more information and submit a comment. So first, on the slide, the first website is for the Federal Register Notice of availability for the draft guidance. And there you can access more information, including comment submission, either electronically or a written paper comment as well as how to submit confidential information in your comments, if you're interested in that.

I'd like to note that in the background section of the Federal Register Notice, we provide questions where we seek specific comments, information, or data. And we'll mention these questions in our presentations today, specifically in the presentations for Chapter 5, Domesticated Animals -- Domesticated and Wild Animals, and Chapter 7, Equipment, Tools, Buildings, and Sanitation. And a copy of the Federal

Register Notice is available in your packet. So I'd ask that you look there if you'd like to see the questions in writing. They're available in your packet.

I'd also like to take a minute to describe information that's particularly helpful to us when you submit comments. It's helpful for us to hear both what you find positive in the draft guidance as well as changes that you'd like to see in the document so that the final guidance is balanced and applicable to a variety of circumstances.

Commenting on positive aspects of the guidance helps us understand that certain language or concepts should be retained. We also encourage substantive comments that thoughtfully describe your position on changes that should be considered. Please submit your comments with sufficient specificity and information and examples so that it can help us understand how it relates to specific farm practices or conditions.

The slide also provides other ways to access the docket to submit your comments. And another way to access the docket is go -- to go directly to www.regulations.gov and enter the docket number. Or there's a link there where you can go to the draft guidance directly to submit a comment.

As a reminder, our efforts with the guidance is likely to continue after we issue the first final version. We intend to update the guidance, similar to our updating of the Seafood HACCP guidance, which is in its fourth edition.

It's important to us that this document continues to reflect our current thinking as we learn from each other through the implementation process and that we take into consideration new scientific information as it becomes available. We also may choose to issue other more targeted guidance documents.

We look forward to discussing the draft guidance with you today and appreciate you being here to have these conversations. If you have questions, please hold on to them until the question session at

the end of the morning session. And please keep in mind as we move into our presentations on the draft guidance chapters that these presentations will be overviews. We cannot cover all of the information in the presentations today. And thank you again for the opportunity to share information with you, and we look forward to hearing from you today.

(Applause.)

MS. TIJERINA: Hello and good morning. I'd like to thank everyone again for your interest and your participation today. My name is Mary Tijerina, and I'm with the Division of Produce Safety, the Fresh Produce Branch. They're in College Park, Maryland.

Is that a little better? Okay.

We'll start by discussing Chapter 1, General Provisions, and Chapter 8, Records. Chapter 1 provides draft guidance to help determine the applicability of the Produce Safety Rule to your farm and your produce. Many of you may have questions about this topic, and we'd like to hear those at the end of the morning session today. Records is another important topic that impacts several farm activities, so we'll cover the general recommendations for records early in our discussion today.

Let's start with an overview of the content in Chapter 1. We recommend you consider the topics discussed in this chapter in the order in which they are being presented. Starting with Section 1, Produce; then Section 2, Raw Agricultural Commodity; and following with the sections on Covered Produce, Covered Farms, and Covered Activities. Please note that the section numbers and titles are listed on this slide and are provided on later slides to provide a sense of where the information is located in the guidance.

As we were writing this chapter, we aimed to provide clarification about these topics to help you determine whether the requirements of the Produce Safety Rule apply to your farm and your produce. We were also mindful of the numerous questions that we've received through the Technical Assistance Network that

were relevant to this chapter.

Generally, the Produce Safety Rule applies when three conditions are present: Covered produced, covered farms, and covered activities. Note that under the Covered Produce section there are subsections that discuss produce that is not covered, which will be discussed in this presentation. Additionally, some produce may be eligible for exemption by commercial processing that adequately reduces the presence of microorganisms of public health significance, which we will refer to as the commercial processing exemption.

In the Covered Farms section, we discuss the $25,000 threshold for covered farms and farms that may be eligible for qualified exemption.

We have heard from stakeholders that having a tool to assist in determining whether your farm and your produce is covered by the Produce Safety Rule is important. This figure is available on page 8 of the draft guidance, and a link to a PDF version is available on our draft guidance webpage.

I won't take the time to walk through each step this morning, but this is an updated figure summarizing the steps in the order recommended in the draft guidance. We hope you will find this to be a useful tool and welcome your comments on it.

The first topic we recommend that you consider is whether your food is produce, which is covered in Section 1. It is important to note that produce is a term defined in the codified of the rule. There are several produce commodities covered by the Produce Safety Rule, and we provide additional examples of produce in the draft guidance.

We received several comments on the rule about the term "produce" and food that is covered by the rule, and we've received numerous Technical Assistance Network inquiries on these topics.

Thanks to those of you who have submitted TAN inquiries so we can understand your farm situation and your questions. While we cannot address every scenario, we included discussion of some types of

produce that are not subject to the rule. We mentioned that produce that is reasonably expected to be used for biofuels, clothing, animal food, or only for the propagation of a crop are not subject to the Produce Safety Rule.

Additionally, the draft guidance mentions that the following do not fit the definition of produce: Grains, saps, and algae, for example. The draft guidance also provides examples related to the harvestable or harvested part of the crop, and we'd welcome your comments on this topic.

Moving on to Section 2, you should next consider whether your food is a raw agricultural commodity, also called a RAC, R-A-C. The term "RAC" is defined in the Food, Drug, and Cosmetic Act. The draft guidance provides examples of activities that do not change a RAC into a processed food, including hydrocooling, refrigeration, and removal of stems and leaves. We also list activities that change a RAC to a processed food, like chopping, cutting, cooking, and irradiation.

Further, we provide some examples of produce RACs and activities that change them into processed foods. For example, oranges are RACS but, once processed to make orange juice, changes into a processed food.

Next, you should consider whether your food is covered produce, which is addressed in Section 3. The topics listed on the slide describe produce that is not covered by the Produce Safety Rule or is eligible for an exemption. Produce that is rarely consumed raw is not covered. The rule includes the complete list of produce designated rarely consumed raw. This list was finalized in the Produce Safety Rule, and the produce identified cannot be adjusted in the draft guidance document.

In the preamble of the final rule, we stated that we intend to consider updating the list of rarely consumed raw commodities in the future as appropriate. Any changes to the RCR list would require rule-making

and cannot be adjusted through comments on this draft guidance. We determined that these produce are almost always eaten cooked. The draft guidance provides some additional clarification on this topic, and we have a fact sheet available online that reviews more information about the rarely consumed raw list. Produce grown for personal or on-farm consumption is also not subject to the Produce Safety Rule. The draft guidance provides some additional -- excuse me -- some additional information on this topic.

We discuss three conditions that you must meet to be eligible for the commercial processing exemption, which are reviewed on the slide. First, the produce must receive commercial processing that adequately reduces microorganisms of public health significance, such as processing that meets the requirements of the low-acid canned foods regulation, the juice HACCP regulation, or a validated process to eliminated spore-forming microorganisms.

We recognized through stakeholder comments that there was a need to clarify the types of commercial processing steps that adequately reduce microorganisms of public health significance, so we mention in the draft guidance that freezing and washing are commercial processes that generally do not significantly reduce the presence of microorganisms.

Keep in mind that only a portion of your produce might be eligible for the commercial processing exemption -- for example, if some of your produce receives adequate commercial processing, but then some of your produce is sold into the fresh market.

Another aspect of the commercial processing exemption is disclosure. The draft guidance discusses that a disclosure statement can be provided in a variety of documents that accompany the produce, such as labels, bill of lading, freight bills, or other documents associated with shipment of the produce in order to communicate that the produce has not been processed to adequately reduce the presence of microorganisms of public health significance.

You must also maintain documentation of your disclosures. You can keep records of your disclosure statements on several forms, such as by keeping a sample disclosure and a list of associated shipments or copies of documentation for each shipment. As indicated on the slide, we announced that we intend to exercise enforcement discretion regarding the written assurance requirements, which means we do not intend to enforce the written assurance requirements while we consider options for these requirements.

Moving on to the last two sections of this chapter, first, covered farms include farms and mixed-type facilities. Some farms may not be covered because they are under the $25,000 threshold, and some farms may be eligible for a qualified exemption.

We were aware that there were some comments on the rule and many TANs inquiries related to what sales to include in the calculations so to assist you in determining whether your farm is above or below the $25,000 threshold. The draft guidance describes the types of produce sales that should be included in your calculations, such as all produce sold, not just covered produce, in the applicable three years. Produce sales such as at farmer's markets, direct to consumers, or online sales would also be included.

Keep in mind the calculation includes the previous three years. So if 2018 is the applicable year, total produce sales for 2015, '16, and 2017 would be included in the calculation.

Farms that exceed the $25,000 threshold may be eligible for a qualified exemption. For the qualified exemption calculations, all food sales are included, not just produce sales. We were also aware of TAN inquiries on what to include in these calculations as well.

The draft guidance mentions that livestock sales are included in food sales as well as sales of hay, grain, wine, and other food. In the draft guidance, we provide several example calculations related to both the $25,000 threshold and qualified

exemptions to demonstrate how these calculations would be performed in specific scenarios. We look forward to your comments on these examples to illustrate how to perform the calculations. Note that farms that are eligible for a qualified exemption remain subject to modified requirements under the Produce Safety Rule.

Finally, covered farms must comply with all applicable requirements when conducting covered activities. The draft guidance provides some examples, such as for a farm that compost a biological soil amendment of animal origin, or BSAAO. The farm needs to implement the relevant rule provisions applicable to this activity.

This concludes our review of Chapter 1. And now let's move to Chapter 8, Records.

The topics on this slide list the sections covered in the draft guidance and the section titles generally aligned with the rule requirements. Please note the section numbers and titles are listed on this slide and are provided on later slides to provide a sense of where the information is located. This chapter provides a brief expansion on certain topics, as many of the requirements are generally self-explanatory.

As we worked on the draft guidance, we targeted providing clarification about rule requirements and providing our current thinking on topics based on comments on the Produce Safety Rule, stakeholder questions, and input through our engagement with educational partners.

Records keep track of measures to minimize the risk of hazards, help identify patterns, and document compliance. Based on our inspection of sprout operations, we observe some challenges with keeping records required by the Produce Safety Rule. It's important to develop a strategy for keeping the required records. The required records for your farm will depend on the requirements of the Produce Safety Rule that are applicable to your farm.

So let's start with the recommendations

associated with general requirements for all records. The topics listed on the slide are all discussed in the draft guidance. We will not have time to discuss each of them today, but selected a few to highlight, which are in bold on the slide. We expanded on these topics based on stakeholder comments from the Produce Safety Rule requesting information on the content of required records.

Your records must list the farm name and location. The location should include a postal address or a physical location. Your records must also include, as applicable, the location of the growing area or other activity area. The draft guidance recommends establishing a system to document locations applicable to your records.

You may already have identifiers that work to meet this requirement, such as on-farm maps that have unique names for fields and buildings. Required records must also include actual values and observations. These records should be accurate without rounding or generalization. For example, records stating "pass," "okay," or "greater than six" do not accurately reflect an actual value or observation. These types of records do not ensure that required measures were taken to minimize hazards and do not allow you to determine trends in the recorded information.

The next topic, records, must be created when the activity is performed or observed to ensure accuracy and limit the potential for human error, such as forgetting the value to be recorded, confusing multiple values, or not creating the record at all.

Our next topic is Review by a Supervisor or Responsible Party. Supervisory review of records is important to ensure completeness of the records, accuracy, and that any necessary corrective measures are performed.

The draft guidance recommends that supervisors should look for any unexpected results and follow up as needed. Generally, we believe record reviews should

occur within one week after the record is created. In some cases, a shorter or longer time frame would be appropriate.

The draft guidance describes some examples of ways to comply with the requirements for records storage and format in Sections 2 and 5. We also discuss the use of existing records in Section 3. Regarding records storage, the draft guidance recommends evaluating how frequently you access your records and developing a strategy that fits your needs. We understand that farms could have multiple growing sites where records may be generated, and you can choose to store records at the individual growing sites or consolidate them at a single site, such as the farm's main office.

Moving on to record format, there are several options, and some are listed on the slide. Keep in mind that the record should be sufficient to determine if the original record was changed. And paper and electronic records, or a combination, can be used.

With respect to use of existing records, if existing records contain some of the required information, you can keep additional information required for compliance separately or in combination with existing records. For example, if a record received from a third party does not include the name and the location, you could record this information separately or add it to the existing record.

Section 7 reviews specific record requirements. There are four chapters of the draft guidance that provides more specific recommendations on required records, and we encourage you to review this information in Chapters 1, 2, 4, and 7.

Finally, the draft guidance discusses that it is important for your personnel to understand your procedures and expectations for activities involving required records. You should direct your supervisors and responsible parties to ensure that records are created and reviewed and any corrections are made as needed.

This was a brief summary of the topics covered in the draft guidance for Chapters 1 and 8. And we look forward to your comments on the content of these chapters. If you have any questions or comments, please hold on to them for right now. We welcome your questions related to Chapters 1 and 8 at the Questions session before lunch. If you have comments on these chapters, we look forward to hearing them in the Comments session this afternoon.

Thank you for your attention.

(Applause.)

MS. BARRETT: Great. Thank you so much to Samir, Karen, and Mary. And we are going to go ahead and take a break, and we'll reconvene at 10:15.

(Break.)

MS. BARRETT: Okay. It's 10:15. So again, if you can please take your seats, and we'll get started back on our program.

Yeah, yeah. You're good.

So I do have a message for our webcast audience.

We're good? Okay.

Folks, if you're listening in via webcast, I just want to remind you to please mute your phones or your microphones. They are not automatically muted. So please be aware of that. We appreciate that. And again, if you can mute your phones and microphones if you are listening in via webcast.

Okay. So after that commercial, let's go ahead and get back to our program this morning. We do have another presentation on a couple of chapters before we get to some questions and the answers period.

So our next speaker is Amber Nair. Amber is a Consumer Safety Officer in our Division of Produce Safety in our FDA Center for Food Safety and Applied Nutrition. And she's going to speak to two chapters, one on the Personnel Qualifications and Training, which is Chapter 2. And the other is Health and Hygiene, which is Chapter 3.

So Amber.

MS. NAIR: Good morning. It's nice to see you all. I'm Amber Nair from the Division of Produce Safety, Fresh Produce Branch, and it's a pleasure to be here with you today to discuss recommendations for the draft guidance. I'm going to cover Chapter 2, Personnel Qualifications and Training, and Chapter 3, Health and Hygiene.

Just sit tight. We're having some technical difficulties.

(Pause.)

MS. NAIR: Bear with me a moment. Okay. Here we go.

Okay. Now we're ready to get started. Let's start with Chapter 2 of the draft guidance.

This slide lists the sections of the draft guidance related to Personnel Qualifications and Training. We don't have time to discuss all of these sections today, so we'll highlight a few in more detail. Please note the section numbers and titles are listed on this slide and are provided on later slides to provide a sense of where the information is located in the draft guidance.

As we work on this chapter, we targeted providing recommendations and examples to describe options for implementation on the farm. We considered stakeholder comments, TAN inquiries, and our engagement with our educational partners as we developed this chapter.

The recommendations in this chapter will help you to evaluate personnel's assigned duties, identify personnel subject to the qualifications and training requirements, evaluate whether personnel have the necessary qualifications to perform their duties, and provide training at frequencies to comply with the rule, among other topics.

On this slide, we cover two sections of Chapter 2 -- Section 1, Evaluating Personnel's Assigned Duties, and Section 8, Supervision to Ensure Compliance with the Requirements of the Produce Safety Rule. For these topics, we took into consideration some of the

TAN inquiries -- that's the Technical Assistance Network -- inquiries that we have received as well as stakeholder comments.

In Section 1, we recommend the owner, operator, or agent in charge of a covered farm review the assigned duties of all of your personnel and observe them to help you identify the personnel subject to the qualifications and training requirements.

As a reminder, all personnel who handle covered produce or food contact surfaces or who are engaged in the supervision thereof must have a combination of education, training, and experience necessary to perform their assigned duties in compliance with the Produce Safety Rule.

You should consider the breadth of covered activities on your farm and how they are performed to determine whether personnel performing these activities contact covered produce or food contact surfaces. In some cases, infrequent contact with covered produce or food contact surfaces could occur. And the draft guidance provides some examples of these situations.

Moving on to Section 8 of Chapter 2, Supervision to Ensure Compliance, for this topic. We also recommend evaluating your operations and ensuring that you identify personnel to supervise each aspect of your operation for compliance. As a reminder, you must assign personnel to supervise your operations to ensure compliance with the requirements of the Produce Safety Rule.

You could find that you need multiple individuals to fill this role. But in some cases, one person could be able to perform all of the necessary duties. Such personnel can include full-time, permanent, temporary, part-time, seasonal, contracted, or other personnel.

The assigned personnel play an integral role in ensuring food safety. The owner operator or agent in charge of a covered farm should also ensure that assigned personnel are aware of their role in recognizing and ensuring the correction of deviations

from your food safety procedures and the requirements of the Produce Safety Rule.

It's important to note that the Produce Safety Rule specifies requirements for personnel qualifications and training. We will next move on to some of the draft recommendations related to personnel qualifications covered in Section 2 of Chapter 2.

For personnel that handle covered produce or food contact surfaces or those engaged in the supervision thereof, the owner, operator, or agent in charge of a covered farm should evaluate whether these personnel have a combination of education, training, and experience to perform their assigned duties.

Appropriate qualifications prepare them to perform their assigned duties in a way that meets the requirements of the Produce Safety Rule. They should also be able to apply their knowledge when performing their job duties.

The draft guidance provides several examples about evaluating the education, training, and experience of farm workers and supervisors. Your evaluation can help you decide if additional steps need to be taken in order to ensure they have the appropriate qualifications for their assigned duties.

Now that we've discussed some of the recommendations for personnel qualifications, let's move on to some of the general recommendations for training. This slide discusses the content in Sections 3 and 4 related to training frequency and easily understandable training in Chapter 2. In this section, we were aware of stakeholder comments from the rule and expanded our discussion on some of these topics.

First, let's discuss Section 3 on Training Frequency. As a reminder, you are required to provide training upon hiring; periodically thereafter, at least once annually; and as necessary and appropriate and in light of observations or information indicating personnel are not meeting the requirements of the rule.

Training helps provide personnel with a knowledge base to promote safe practices and minimize

the potential for contamination and foodborne illness. There is a great deal of flexibility in how you arrange the timing and frequency of periodic training as long as it occurs once annually. Factors to consider when determining timing of training include the type, number, and timing of your crop and the timing of hiring and initial training of personnel. Several examples are included in the draft guidance to illustrate the flexibility around implementing the required training. Some of the examples illustrate options for periodic refresher training.

Moving on to Section 4 of Chapter 2, Easily Understandable Training, as I review some of the recommendations around making sure the training is easily understood, the draft guidance discusses several considerations on these topics, including structuring shorter or longer training sessions, depending on the type and depth of information being presented.

In some cases, delivering training at or near workstations can be useful to connect with specific job duties, add to (ph) administrations, or use visual aids during the training. Hands-on activities can be useful to show personnel how to conduct specific job duties and allow workers to practice certain skills. Signs, visual aids, pictures, and graphics can also be useful tools.

So on this slide, we cover some of the training recommendations in Sections 5 through 7 of Chapter 2 in the guidance. For these sections, we are aware of stakeholder comments from the rule as well as information from our educational partners. The draft guidance discusses that the training should focus on principles that will help personnel understand how to perform their duties in a way that meets the requirements of the Produce Safety Rule.

Additionally, training topics should help personnel understand how their actions can affect the safety of covered produce and food contact services. Further, the training should help personnel understand the routes of contamination so they can recognize how

on-farm practices can result in contamination. Training should also include your farm's food safety procedures so personnel are aware of them.

Next, the draft guidance discusses recommendations and examples related to the required minimum training topics. Training personnel who handle covered produce or food contact surfaces or those who are engaged in the supervision thereof on food hygiene and food safety provides a knowledge base to help ensure compliance.

The draft guidance recommends that the following training topics should be included: Relevant sources of foodborne pathogens such as humans, animals, and their waste; routes of contamination, such as animals or pests contaminating covered produce or food contact surfaces or handling an untreated biological soil amendment of animal origin in a way that it contacts covered produce during application; and other recommended topics, which include preventive and corrective measures.

Training on health and personnel hygiene should ensure that personnel understand that they have the responsibility to take action to prevent contamination due to their own health. The draft guidance recommends training personnel to recognize and respond to situations that present the potential for contamination and to report any situations they become aware of that could result in contamination.

The draft guidance also contains recommendations and examples related to training that covers the standards in Subparts C through O of the Produce Safety Rule that are applicable to an employee's job responsibilities and recommendations for training those who conduct harvest activities.

Another training requirement specifies that, at a minimum, at least one supervisor or responsible party for your farm must complete food safety training at least equivalent to that received under the standardized curriculum recognized as adequate by FDA. The standardized curriculum was developed by the

Produce Safety Alliance, or PSA, and is offered as one way to meet this requirement. We'll hear more from some of our educational partners as part of our panel discussion on this topic later this morning.

This wraps up our overview of Chapter 2, and we'll move on to discussing Chapter 3. And this discusses recommendations related to health and hygiene in the draft guidance. In this chapter, we were aware of stakeholder comments from the rule expanded on some of those concepts and provided examples to illustrate options for compliance.

This chapter is divided into three main sections, which are listed on this slide. Again, in this section, the numbers and titles are listed on the slide and are provided on later slides to provide a sense of where the information is located.

I'd like to point out that, at the beginning of Sections 1 and 2, there is an overview and a summary of some of the key recommendations for each section. We hope you find these useful to become familiar with the content of these sections.

In this chapter, communication on the farm is emphasized, and it's important for owners, operators, or agents in charge of a covered farm to communicate the responsibility of personnel and supervisors or responsible parties to prevent contamination through hygienic practices.

In Sections 1 and 2, this chapter discusses recommendations directed at the owner, operator, or agent in charge of a covered farm as well as recommendations directed at supervisors or responsible parties and at farm personnel to prevent the contamination through hygienic practices.

So let's move on to talking about content in Section 1 of Chapter 3. The main bullets on the next two slides list the subsection topics. In the first subsection, the draft guidance reviews the signs and symptoms of applicable health conditions. These can include vomiting, diarrhea, abdominal cramps, sore throat with fever, jaundice, and open wounds.

As a reminder, the owner, operator, or agent in charge of a covered farm must take measures to prevent contamination of covered produce and food contact surfaces with microorganisms of public health significance from any person with an applicable health condition. This could include full-time, part-time, contracted personnel, volunteers, and visitors.

In the subsection on self-identification of applicable health conditions, the draft guidance recommends that you should ensure that personnel who have the potential to contaminate covered produce or food contact surfaces can identify applicable health conditions. There is also discussion of training requirements and recommendations related to health and hygiene topics.

As a reminder, the owner, operator, or agent in charge of a covered farm must instruct personnel to notify their supervisors or responsible party if they have, or if there is a reasonable possibility that they have, an applicable health condition.

The draft guidance also provides recommendations to promote self-identification of applicable health conditions by personnel, including training all personnel who may contaminate covered produce or food contact surfaces on applicable health conditions and how to identify them, encouraging personnel to be aware of exposure to individuals with symptoms of an applicable health condition, and informing personnel who notify -- who to notify if there is a reasonable possibility that they have an applicable health condition.

Next, let's review some of -- some more of the content related to preventing ill or infected persons from contaminating covered produce. The role of supervisors and responsible parties is important for implementation of health and hygiene practices.

The draft guidance recommends that the owner, operator, or agent in charge of a covered farm should ensure that supervisors and responsible parties are aware of their responsibilities regarding the health

and personal hygiene requirements of the Produce Safety Rule.

Now let's discuss some of the content on addressing reports of applicable health conditions. In this section, the draft guidance provides clarification and examples related to individuals who could contaminate covered produce or food contact surfaces, recommendations, and examples for appropriate measures to prevent contamination when a worker reports an applicable health condition and recommendations to assist in making decisions about excluding or reassigning workers with applicable health conditions.

In the next subsection, the draft guidance discusses requirements, recommendations, and examples on responding to potential contamination of covered produce or food contact surfaces.

So moving on to Section 2, hygienic practices, in this section, we were aware of stakeholder comments from the rule as well as feedback from our educational partners. As a reminder, personnel who work in an operation in which covered produce or food contact surfaces are at risk of contamination or certain hazards must use hygienic practices to the extent necessary to protect against such contamination. This requirement is not limited to personnel who handle covered produce and food contact surfaces, but also applies to others who work in the operation.

The draft guidance provides a list of recommendations at the beginning of each section to help identify steps for implementation, and they are listed on this slide.

There is a recommendation that you should ensure that all applicable personnel are aware of hygienic practices, requirements, and can identify and correct or report on hygienic practices.

The draft guidance also recommends identifying personnel whose job duties are likely to involve interaction with potential sources of contamination, such as handling trash, raw manure, or animals, and whether they should be aware of and follow hygienic

practices to protect against contamination.

There is also a recommendation that you should ensure that personnel are aware of farm procedures associated with the minimum hygienic requirements of the Produce Safety Rule, including avoiding contact with animals other than working animals and wearing jewelry.

Continuing on, the main bullets on this slide represent the subsections in Section 2 of Chapter 3. The draft guidance recommends that you should evaluate those covered activities where covered produce or food contact surfaces are at risk of contamination and ensure that your personnel are following hygienic practices.

As mentioned previously, you should ensure that all personnel use hygienic practices as necessary to protect against contamination. The draft guidance provides some examples of personnel, such as loading dock staff or those who handle livestock, who may need to use hygienic practices if they enter in any areas where they could contaminate covered produce or food contact surfaces.

Moving on to the role of supervisors, the draft guidance recommends that supervisors or other responsible parties should ensure that other personnel consistently follow hygienic practices on your farm. As mention on the previous slide, these supervisors or responsible party should observe and communicate with relevant personnel about hygienic practices to ensure awareness and implementation. They should also be aware of your farm's procedures.

In the subsection -- oops -- in the subsection on Required Hygienic Practices, the draft guidance provides recommendations and examples related to each of the requirements described in 112.32(b), including maintaining adequate personal cleanliness through handwashing and using gloves.

Now let's discuss Section 3 of Chapter 3, Measures to Prevent Visitors from Contaminating Covered Produce and Food Contact Surfaces. As we worked on

this section, we were mindful of stakeholder comments to the rule. Keep in mind that the term "visitor" is defined in the Produce Safety Rule.

The draft guidance recommends that the owner, operator, or agent in charge of a covered farm evaluate the different types of visitors and their interactions with covered produce and food contact surfaces to determine appropriate approaches. There is flexibility in how to meet the requirements, and the draft guidance describes options and examples on possible implementation strategies.

As a reminder, you must make toilet and handwashing facilities accessible to visitors, and you should inform visitors of a location of accessible toilet and handwashing facilities.

This concludes the overview of the draft guidance for Chapters 2 and 3. We'd appreciate hearing your questions in the session later this morning, and we look forward to your comments on these recommendations.

Thank you.

(Applause.)

MS. BARRETT: Alright. So at this time, I'm pleased to bring Jim Gorny back to the podium. As noted earlier, Jim is a Senior Science Advisor for Produce Safety in our FDA Center for Food Safety and Applied Nutrition. Jim will be moderating today's panel discussion with external stakeholders, so if those stakeholders can come up as well.

Thank you.

MR. GORNY: So everybody can take a minute or two, stretch, get up, wake up a little bit.

So the idea here is we wanted to have a little bit of a panel discussion to talk about what implementation looks like and how these guidance documents -- this draft guidance document can be used from the perspective of industry, government, and -- Walter, why don't you -- you want to come over here? I won't bite, honest. I'm not going to -- I'm going to stay at the podium.

So as I said, we have a fantastic panel lined up for you -- Dr. Linda Harris from the University of California at Davis, who's currently the head at the Department of Food Science there, and she's been working in Produce Safety for a number of years. All the bios are in your packet, but I just wanted to introduce these folks briefly. Steve Patton with the California Department of Food and Ag -- I believe he's the Division Director of Inspections; is that right?

MR. PATTON: Branch chief.

MR. GORNY: Branch chief.

Walter Ram, Vice President of Food Safety with Giumarra Foods, a major produce company with -- that does -- that grows both domestically and internationally. And I'll let Walter talk about that. Mark Chen with our Produce Safety Network on the ORA side and Kurt Nolte from our Produce Safety network at FDA on the CFSAN side.

So we've kind of prepared our panel here. And I'll start on this end, and we'll just go down the line. We'll do kind of one question at a time.

And Linda, why don't you explain what your role is in all this Produce Safety Rule rollout and implementation and guidance and potentially, you know -- how you could potentially be using the guidance documents as they are because I know you do a lot of education outreach.

DR. HARRIS: Yeah, sure. I'm just going to preface my comments by saying that I'm at UC Davis, University of California, Davis. So I'm really going to be speaking more broadly about the University of California.

And at UC Davis, we have the Western Center for Food Safety, the Western Institute for Food Safety and Security. We've also been participating as a collaborator on the Western Regional Center to enhance food safety, which is out of Oregon State. And of course, I'm a cooperative extension specialist, which is throughout the whole University of California system. So there's a lot of pieces within the

University of California that have been working on aspects of the Produce Safety Rule, both from research and providing some of the data used for the scientific basis for some of the recommendations.

But also, we've been very active in training. And the training activities, just some examples, early on, we were heavily involved in California in providing train the trainer for produce -- the Produce Safety Alliance standardized curriculum. We have grants through CDFA through a variety of sources, actually, to provide some of the subsidized training that was mentioned earlier.

We've done a lot of partnerships with commodity boards in California to provide specific targeted PSA training to growers around a specific commodity, which I think has been very effective. And then we've also partnered with organizations that their clientele is the smaller, more limited resource farm, so smaller organic growers or just smaller growers in general. And for example, we've done a fair amount of work with the Community Alliance for Family Farms.

So I'll stop there as a --

MR. GORNY: Thank you.

DR. HARRIS: -- initial summary.

MR. GORNY: So do you also handle questions from farmers with regard to when they're trying to implement the Produce Safety Rule?

DR. HARRIS: So we do. We have -- we try and maintain a website that has as much information as possible for growers. I would say less so individual grower questions. We work through the commodity boards more where they will have specific questions that we might try to answer. So yes, we are available, but there's a lot of growers in California.

MR. GORNY: So it sounds like you're really dealing with many of the specialty demographics of the produce industry.

DR. HARRIS: Right.

MR. GORNY: And Steve, it sounds like, from what Natalie said, maybe you can tell us how CDFA is

approaching education outreach with regard to understanding and then the implementation part.

MR. PATTON: So for the education outreach piece, we'll certainly be using the guidance document. And you alluded to it earlier, Jim, in two different ways. It serves dual purposes. It's going to serve to inform our inspectors. It provides a tremendous amount of wealth in there. They're going to be able to do a much more in-depth inspection based off the guidance document.

And we're going to use it, obviously, to train the growers as well. We have a number of opportunities. Some of the funds that we took Natalie talked about. We are using it to contract out to provide the produce safety training that's necessary for the growers to take as part of the regulatory requirements, and we're going to make sure that our contractors have that and have that available. We're also going to use it during our On Farm Readiness Reviews as we continue to do those and educate the growers. We're going to have it out there and available for them as well.

MR. GORNY: Okay, great. And how -- could you recap those numbers again that Natalie went over? They were pretty impressive, like 180 trainings, I think.

MR. PATTON: So far, yes, we've had 180 trainings, I believe. Again, we're reaching 25,000-plus growers. So we're --

MR. GORNY: Wow, that's a huge --

MR. PATTON: That's a huge --

(Crosstalk.)

MR. GORNY: -- State of California.

MR. PATTON: Yeah. Now, that -- we're not the only ones obviously providing that training. There are a number of great resources out there, and people have been excellent in providing those trainings up and down the state and will continue to do so.

MR. GORNY: Great. Thank you.

MR. PATTON: Yeah.

MR. GORNY: Walter, could you talk a little

bit about what you do at Giumarra and what Giumarra produces and how you might potentially be using these guidance documents and what your approach to food safety is at the Giumarra Companies?

MR. RAM: That's all?

MR. GORNY: That's all. In two minutes or less, please.

MR. RAM: Yeah. We're a family-owned, vertically integrated produce company. We began as Giumarra Vineyards in Central San Joaquin Valley. And we spread out to a wholesale operation in Los Angeles and, eventually, a dozen different shipping operations that we have grow -- shipping divisions, I should say. And we have growing operations in 16 countries. And actually, it's more than that now.

And we're growers, packers, shippers, importers, exporters. We have a juice plant. We wear quite a few hats. And I'm a VP of food safety, so on the top of the food chain when it comes to that. But quite frankly, I've got a fabulous staff that makes me look good all the time, but that's not enough.

What makes our food safety program successful is that we have participation at every single level all the way down to the growing end. Example: At Giumarra Vineyards every year, we will have a training session. And it's way before the grape season starts. So we have about 50 supervisors, a half dozen superintendents, the family members of bosses.

And we go over -- what's -- what we did well last year, last -- the season before, what's coming up, this one, we go over new learnings that we've had from Center for Produce Safety, from ARS, anything new that's come along -- regulatory changes. And from there, it works as a train the trainer. It trickles down.

And one thing that we found is important is that we respect the chain of command. So if I'm on a farm and I see something, I don't -- unless it's something that's egregious, I'm not out there with a while clipboard or out bothering anybody. I usually

talk to the appropriate supervisor. And that really works as a learning experience and keeps the buy-in for everybody.

You know, we don't want to embarrass anybody. We're not interested in assigning blame. We want to correct any problems that we see or, you know, find a better way of doing things. And sometimes that comes from, you know, people that are right on the ground.

MR. GORNY: So it sounds like you take information from various sources. You mentioned ARS, the Center for Produce Safety. How do you think the guidance will play into your directives and implementation of the Produce Safety Rule in …

MR. RAM: Well, it's actually the reference manual for us because, you know, if we -- even our food safety coordinators at every division, you know, if we refer them to the Federal Register, I mean, it's like reading Greek. And with the guidance, it's a -- it really is the -- it's the index. It's the go-to document if you have any questions, where you go get the answer before you try calling up FDA, as an example.

And most of the industry has already been -- I shouldn't say most, but a good part of the industry has been doing a lot of this already, not in the guise of the Produce Safety Rule, but mostly for good agricultural practices. And there are some market differences, agricultural water being one of them. These are items that we discuss regularly with our divisions, and I have already mentioned Giumarra Vineyards is one.

And you know, and we don't always only go by the Produce Safety Rule. As a regulation, the rule is a set of minimums, the very least that we should be doing. A good example is commodities that are rarely consumed raw. While we recognize that as the -- in the Produce Safety Rule, we don't really care as far as what we do with -- you know, with our products. If we're growing asparagus or other commodities that are on the list, which we do, they still have to go through

the same GAP practices that we demand of all of our other contracted growers.

MR. GORNY: So thank you, Walter. That was -- thank you very much for sharing that.

So we're very fortunate today to have two of our Produce Safety Network folks from FDA, and folks obviously think that sometimes FDA is a monolith. But we're broken up into various branches: Center for Food Safety and Applied Nutrition, our office of the -- you know, various offices.

So Mark Chen is with the Produce Safety Network on the ORA side, the Office of Regulatory Affairs. Those are the folks who typically conduct inspections of food facilities. And we have now a dedicated cadre of people who will be doing inspections in states that are not going to be doing the inspections, and they also do the foreign inspections.

And then we have Kurt Nolte with the Produce Safety Network on the Center for Food Safety and Applied Nutrition.

So I'm hoping that they -- we can introduce them to you. If you're in this neck of the woods, Kurt is in Yuma, Arizona, or thereabouts. And Mark is in Long Beach.

So maybe you guys can compare and contrast the difference between what you do and how you're going to use the guidance and -- you know, with regard to inspections for Mark and for education outreach for Kurt.

So Mark, why don't you go ahead. Or who wants to go first? It's up to you guys.

MR. CHEN: As Jim mentioned, I'm with the Office of Regulatory Affairs with the Produce Safety Network, and we are a specialized cadre of investigators out in the field that focus on the inspectional, investigational, and unfortunately a little bit of the enforcement component at FDA.

We are the boots on the ground. So when you see someone from FDA at a farm conducting an inspection or an investigation if it's related to a positive

sample or an outbreak, it's going to be likely myself or one of my colleagues.

In states such as California, Arizona, and New Mexico, Washington, states that have cooperative agreements to conduct inspections, routine produce safety inspections, we provide support and technical assistance in terms of the inspectional approaches and the -- and implementation. We're -- so in this case, I work with California, Arizona, Hawaii, and the U.S. Pacific territories. So I do work with Steve and Natalie routinely on developing their inspectional program and how we can move forward in California.

In terms of utilizing the guidance, as investigators, we use the guidance to give us a basis of comparison for what we are seeing out in the field. Ultimately, in the end, we conduct inspections and investigations to the rule, to the codified rule, and not to the guidance.

So I think it's been mentioned a couple of times in the speakers this morning that the guidance provides examples of how you can meet the rule, but you are always welcome to provide -- to meet the rule in alternative methods. And so when we are out there as investigators, if we're looking at something and we have a little bit of a question as to whether what you are doing meets the requirements of the rule, we may turn to the guidance and look at it and say, Alright, is this example covered; does it meet all of those pieces that are discussed in the guidance?

If not, and we continue to have questions, that's when we turn to our technical experts -- in this case, Kurt here from the CFSAN side -- and we give them a call and say, well, here's what we're seeing out in the field. Does this meet the rule or not? It's not necessarily covered in the guidance. It's not -- there's not an example in the guidance that's very similar to this. What do you think? And so then they will help us interpret what you are doing as to whether it meets the rule itself.

So once again, the main thing is we use it as

a base of comparison, but we do not inspect to that guidance.

MR. GORNY: Great job. Thanks, Mark.

DR. NOLTE: And on my side, I'm not involved in inspections, and I'm not involved in investigations either. So my -- I guess a good way to look at my role is as an extension agent. And I think everybody in the room here knows the history of cooperative extension. I come from a backbone of cooperative extension just like Linda.

And so the extension service has been around for a long time. And essentially, it's a circulatory system of land-grant universities, and that's the role I play in my current position right now.

So being in this role, I serve as the intermediary between the Center, the CFSAN Center, and growers and state agencies, grower associations to assist with any or all questions that folks might have about the interpretation of the rule. I provide maybe a little clearer or more grower-friendly approach to -- in -- you know, explaining the rule to those that need that sort of hands-on personal touch that a lot of folks need.

Some folks are afraid to ask questions. I know that from a former educator. I know that the folks in the back of the room are probably more important than those in the front because those in the back are kind of shy and may not have a really good way to approach a question. So I'm that guy in the room that has a level of comfort by interacting with a large variety of different personalities and groups, and that's a part of what I do.

How can I explain how the guidance is going to be used? So you've heard this morning about providing resources. And being a former educator, having that resource is a pretty important thing to read, and I hope everyone can get a chance to read it.

But there is also that hands-on, one-on-one approach which gravitates to a lot of folks in the room here, I know, because many of you don't like to read.

And so you need that personal phone call or someone to talk to or someone to help explain what does this word mean, what's the real meaning behind this particular sentence.

And so I feel like my role is -- in the guidance is to provide that means of starting a conversation -- picking up the phone, giving some folks a call. If you don't understand something, this guidance document is a way to get some additional answers that you've always been wondering about. I always tell my students, you know, answer the question: Do you know what you don't know? And so the guidance provides you with an answer to that question.

So I don't want to talk too much here. But the guidance is a great way to get information that you always wanted to know about the rule.

MR. GORNY: So the take-home message: Don't be afraid to contact the FDA Produce Safety Network on the CFSAN side of the house, in particular, because they're a wealth of resources.

So let me just ask you a question, Kurt. So if somebody asks you a question -- Mark calls you up and sees something and -- or a farmer calls you up and sees something and it's not in the rule, it's not in the preamble, it's not in the guidance, what do you do then?

DR. NOLTE: Well, one of the great things about having an extension model that I referred to earlier is that, if I don't know the answer, then I have a really good subset of folks that I can lean on. Some of them you have heard this morning. Subject matter experts are always available -- maybe not to the general public, but they're certainly available to me. And so if there is something in the rule that growers don't understand that I can't help with, I can always lean on my colleagues to get on the hotline to help me out, for sure.

MR. GORNY: What Kurt just pointed out is the importance of consistency. So we're making sure that, if something that hasn't been addressed in the guidance

or the preamble or the rule itself that's specific, we make sure that it goes back to our center experts who are basically -- you know, there is a cadre of them for each of these specific subject areas. And we make sure that basically CFSAN PSN members across the country and across the world are answering the question in a similar manner because it's really important for consistency and a harmonized approach. We don't want to see differences.

So thank you for that answer. It was really helpful.

So I'm sure you've all read this, the guidance, from cover to cover, highlighted it, taken notes.

Linda, was there anything in the guidance that you said, wow, that really helped clarify things for me, like, yeah, that was great? And you can be thinking about that down the line if there was anything in there for Steve or Walter that you thought was, wow, that really helped things.

DR. HARRIS: Yeah. So a lot of the growers that I work with contract out for a lot of the services that, you know, I naively thought were done by themselves, so things like pruning or application of agricultural chemicals or harvest activities. And so you know, that means there's one layer more to the system.

And I think there was some confusion for me and others on where contract harvesters fell. At one time, I thought that they were classified as a farm, but the guidance document clearly says that they are performing harvesting activities. And the covered farm and the covered grower is the responsible entity for managing the workers during harvests.

MR. GORNY: You got it right.

DR. HARRIS: I copied it and pasted it right here. So yeah, that was an, okay, I've got to change the way I communicate on that. Yeah.

MR. GORNY: So what you're getting here is a CliffNotes version? If you didn't read the whole

document, at least it's pointing you to places where --

DR. HARRIS: That's right.

MR. GORNY: -- you can really look and see if there's some specific answers to questions that may be in your mind.

DR. HARRIS: Well, I think that that's the key, right? If there are things that you're not quite sure how it works, this provides a resource to at least get you one step closer. It might not explain exactly how you're going to manage that, but it at least it explains that the grower is -- you know, in this particular case, that the grower is responsible for the contractors.

MR. GORNY: Yeah. Steve, any thoughts on -- any wow moments?

MR. PATTON: Certainly. So for us, the large farms, while not being routinely inspected this year, we understand they're in compliance. But as we moved out and down to some of those smaller farms, the question that we get most often deals with compost. And I thought the section on composting was really straight-forward how-to step-by-step, particularly with the animal origin, you know, the biological soil amends, BSA, IAO (ph) --

MR. GORNY: The SOW (ph).

MR. PATTON: -- the SOW, whatever it is, yeah, our acronyms that we love.

But it really did. It provided great documentation on how to just take the steps, how to look at it. First, is it of animal origin? And then is it treated or untreated? And then what do you do if it's not treated, how to make it treated, validation steps, you know. It had a tremendous amount of assistance in there that we're going to be able to provide some of those smaller growers that really didn't have access probably to that information before.

MR. GORNY: Yeah, I think there's also some checklists in there that are --

MR. PATTON: Absolutely.

MR. GORNY: And so which I think are really

helpful. You can tear them out, print them off, use them as checklists. And there's also -- I just want to point out that there are a guidance-at-a-glance documents also available so that you can look at those. And again, those truly are CliffNotes. It takes each chapter down to about three to five pages.

So Walter, your thoughts on any, you know, wow moments in the guidance, the --

MR. RAM: I also like the biological soil amendments because it was finally written down somewhere where we had a reference document. But without being facetious, the Table of Contents wowed me because we had put out an internal FSMA document for -- you know, for our divisions and our growers that pretty much explain in plain English where we've come, how this was already relevant. And then we included at the end of each chapter for -- one chapter was for each rule -- the fact sheets that you could get off of fda.gov. But the fact sheets were the CliffNotes version and really a 50,000-foot overview. And this was the detailed version of those fact sheets.

So when we were looking at -- when the growers had questions on the fact sheets, this gave the detail where they could go and get the individual information that you're looking for.

MR. GORNY: Great. So I'm going to skip Mark, and I'm going to skip Kurt because you guys helped put this together. So you can't overtly praise it too much. And thank you for those.

But now let's turn to what can be improved. So Linda, anything missing in the document with regard to, gee, I -- of course, I've got to take ag water off the table because we're revisiting that in farm definition. That was already discussed. But that's an obvious one. But anything that, like, wow?

And I'll put a second part to that question specifically to you. Anything that's missing and may require further research to inform it? Because again, we want to be science-based and risk-based in these approaches.

DR. HARRIS: Well, I think it's already been mentioned that, you know, a little bit -- this helps. The guidance document helps. I think there's still going to be those specific questions that come up with individual crops, with individual growing circumstances, with things that come up in the middle of the growing season.

So I think, actually, as far as more guidance, I think I would encourage FDA to, you know, use the TAN process and look for recurring questions and things that could be then translated into question and answer or, perhaps, further guidance as you get clearer information on what some of the remaining questions still are.

As far as research goes, we're actively involved in research pertaining to the Produce Safety Rule, and we have been for a number of years. So we have teams of people working on biological soil amendments of animal origins, a variety of different aspects, but survival after application. And that's in collaboration with researchers across the country.

Of course, I'm not going to mention it, but we are working on aspects of agricultural water testing, cooperative testing. And also, we have some research on survival of pathogens on various types of produce after application. We're working on post-harvest handling and prevention of cross-contamination in packing houses.

And one of the things that I think I have still some questions about is sanitation of harvest equipment, especially when it pertains to mechanically harvested crops. So you've got big equipment with conveyor belts and moving parts, and it's used for long periods of time. And you know just how to manage sanitation and what's effective sanitation procedures and frequencies for those equipment. I think those are still some areas that could benefit from further research.

MR. GORNY: So Steve, I know you guys do a lot of education outreach through the -- with the PSA

curriculum. You've been engaged in what I call the laboratory portion of it, the On Farm Readiness Reviews. Any questions that you fielded out there and maybe aren't addressed in the guidance and people have a burning need to know and --

MR. PATTON: I can't speak to anything, Jim, specifically.

MR. GORNY: Okay.

MR. PATTON: I think we don't know what we don't know.

(Crosstalk.)

MR. PATTON: You know, I think as we move forward and the research becomes available, I certainly encourage FDA -- and I know you will because you have in the past -- to update the guidance.

I agree with Linda in the situation where the equipment. There's some examples in there, and there's some language in there that talks about, well, you look at the type of equipment, you look at the temperature, the humidity, where -- is it indoors or outdoors, how is it being used, you know. So it allows us to do a little bit more in-depth inspection, but it doesn't really get down to when and where, maybe the frequencies of how we should.

We can suggest it, you know. We want to educate while we're regulating. But we're -- you know, we're -- we'll look for some more examples there, I think.

MR. GORNY: Okay.

MR. PATTON: Okay.

MR. GORNY: Walter, same to you.

MR. RAM: Actually, in the introduction, or somewhere early on in it, it mentions that this is FDA's -- based on FDA's current thinking. And what I -- the question that came to mind was: Is this a living document, or will this one be -- just show up in the same link on fda.gov? And you know, a mechanism for updating regularly, you know, might be really useful.

MR. GORNY: Yeah. I think the answer is, is this is Version 1 when we finalize it. And I'm looking

for Samir to give me a big, yes, it'll be updated on a regular basis as the science progresses and as we know more and can provide risk-based and science-based approaches to these preventive measures.

So I know you're also on the Technical Committee of the Center for Produce Safety. Any specific burning questions that maybe we don't have enough science to provide guidance on today that maybe is in the pipeline or should be in the pipeline?

MR. RAM: Well, one thing about the produce rule that -- most everything on there is their conclusions that we're -- that were supported by data that we already have. And a lot of the items are missing is because the data doesn't exist. So in my mind, it's the items that are left off are because we don't have that information, and those are where the RFPs are coming from.

MR. GORNY: So I'll address this question to both Steve and Walter. Is there any need -- so the agricultural industry in California is extremely diverse. You go to a grocery store or a distribution center. There's 300 different produce items. Is there any need, potentially, for more commodity-specific guidance? And what's the role of industry and trade associations and others to help provide that? Because you know, we don't know everything. We don't know everything inside the beltway in Washington, and you guys know your business better than any of us ever will. Is there some way to lump or categorize and potentially provide us?

I'm going to go to Walter and Steve, I guess, on that, and I'll let Kurt chime in on that one, too, if he wants to. But I'd really like to hear from Walter and Steve on that.

MR. PATTON: So I will certainly start, and the answer is yes. I think the more specificity to -- specific to the commodity is absolutely going to be crucial. We've taken the approach based on the rule as it stands. And the large farm, small farm, very small farms, we've gone out with the broad you need to get

the grower training because that's what's required by the law.

I think as we finish those rounds in the next year, we're going to start focusing on the smaller farms. And then along with that, we will start looking at ways to incorporate the commodity-specific training as necessary. I think Linda and her group have done a tremendous job of putting out some of that. Some of the commodity boards, Leafy Greens Marketing Agreement, does a good job of training, particular. Almond Board has their own training.

So we will look to those groups and try and partner with them and get to those specifics that address their needs in not such an overall general view at the 50,000-foot level here.

MR. GORNY: That's a great comment.

Walter, any thoughts on that?

MR. RAM: Yeah, I do. I mean, while commodity-specific guidelines sound like the ideal, they wouldn't be very practical. I can't imagine what it would be like enforcing them.

But I think that both the public health and the industry might be served if we were to create commodity groups based on the risk profiles. Example, we could have a half dozen, you know, four, five, six, seven, commodity groups like tree crops, leafy greens, ground crops, root vegetables, et cetera, that have similar risk profiles. And that way, we could actually -- without being commodity-specific, we could focus in on the hazards and the risk, you know, with that agronomic technique or how the -- you know, how these commodities are produced and really, really zero in more on better, more effective food safety systems without going through something as impractical as commodity-specific.

This is -- there's actually a precedent for this. USDA regulates meat -- what is it -- beef, pork, poultry, and shell eggs. And they've got four different programs set up for those groups that works extremely well. And this is something I think we could

do as a Stage 2.

We have to remember that we've only been doing this for 20 years. You know, GAPs didn't exist until 20 years ago, and we've come a long way in that period of time. But we have a longer way to go.

MR. GORNY: Yeah. So I think this is the long-term play with regard to we need guidance right now. And it is general. But what I'm hearing is potentially in the future -- and Linda, I'm sorry. I didn't mean to skip you because you're actually the expert in this. You're actually working with CAFF and other folks who aren't necessarily commodity-specific, but they need production practice-specific.

DR. HARRIS: Right. And I would also argue a little bit that -- I'll use the Almond Board example. In California, there are 6,000 almond growers, at least. And so I think, in that kind of situation, having a commodity-specific where the commodity board is providing guidance to those individual growers is useful. Most of those growers are also growing something else, so they can't just -- you know, they can't narrow down and ignore a more general guidance.

But -- and then, yes, I agree. When you have a smaller grower, often, they have constraints that are less commodity-related and more production-related. And so I think there is an area for both.

We're also -- one of my colleagues -- or a couple of my colleagues have recent funds to look at translation not only into Spanish, but Mandarin, Cantonese, and Hmong. So that's another layer of getting down to specificity where language might be a barrier. So …

MR. GORNY: So I'll go to Kurt and Mark. Just any thoughts on, you know …

DR. NOLTE: Just some quick thoughts, you know.

MR. GORNY: Sure.

DR. NOLTE: This -- the produce rule is certainly nimble enough to accommodate change. So as science develops, obviously, we can adapt to the -- to

new discoveries and to new opinions, new ideas as they develop.

MR. GORNY: Yeah. Mark, any thoughts? I think you have a tough job. I mean, you go for anything from artichokes to zucchini and everything in between. You have to be able to inspect that field, that packing house. Any thoughts on, you know, just going forward?

MR. CHEN: Right. I think from our standpoint in ORA it's very similar to Steve, you know. We don't know what we don't know. And so as we approach the first inspectional dates for this past year, we've been doing a lot of -- or we've been trying to do a lot of educational farm visits. And these are actually very useful for us as the regulators because we get a chance to see different farming practices for different types of commodities in a low-pressure, no-pressure-type situation, which, you know, we don't go out there with a regulatory eye. We go out there, really, to learn and to understand.

And you know, I think -- I might actually have one of the semi-harder positions within our cadre because I do have Hawaii, which brings in a whole new set of very unique commodities. I was really interested to see in this guidance that basically finally specified that algae and seaweed are not produce because we were getting a lot of questions about that from Hawaii.

And so I think that's -- again, this is part of we don't know what we don't know because we haven't been able to go out and see what's out there. And so again, as the boots on the ground, as we come back from these initial inspections, hopefully, you know, we've got about another four months or so. If you're willing to set up an educational farm visit and a farm tour for us for California for our state regulatory partners to see what you're doing out there, that's fantastic because we can take that information back, and we are able to send that up through Kurt or Steven or any of our CFSAN counterparts back to CFSAN and say, hey, we

can use some additional guidance on this type of information for these particular situations. So it's certainly what we're -- what -- how we hope that the guidance will also grow as we start moving into this direction.

MR. GORNY: Great answer. Thanks, Mark.

So I'm going to throw it back to -- we'll come back down this way, or if anybody wants to jump in, just any concluding thoughts that you wanted to put in there that you had thought about when -- that you were going to be on the panel and you didn't get a chance to express just, you know, one last time?

Linda, I know you're always never --

(Laughter.)

DR. HARRIS: No --

MR. GORNY: Or Walter or Steve? Don't be shy. If there's any last thoughts that you have --

MR. RAM: So my last thought would just be the relationship that we have with FDA, particularly with OFR and PSN both. Since the beginning, it's been a well-thought-out process. And any time government agencies start working together, there's always some trepidation about how -- whose lane's going to -- whose toes you're going to step on. And this has really been a very collaborative effort that we understand what PSN does. And we rely on Kurt heavily, and we rely on Steven Hughes. We've talked to each other. We've spoke in conventions together, you know. We've done a number of things. And Mark has certainly been assistance to our staff as well, and we hope that we have been to him. And it's worked out better than we could have expected, quite honestly.

MR. GORNY: Yeah, and I'd like to personally thank Secretary Ross for her leadership and support on this and supporting CDFA and really taking a leadership role here. It's very much appreciated.

Any other concluding remarks? Walter? Linda? All good?

(No audible response.)

MR. GORNY: Alright, then. I just -- let's

thank our panelists, and we'll move on --

(Applause.)

UNIDENTIFIED MALE SPEAKER: Test, test.

MS. BARRETT: Yeah, really, really nice panel. Thank you all. That was great.

We are now bringing up our FDA subject matter experts, folks that you have heard from this morning. And we're going to open up the floor for questions at this time. And we'd like to somewhat keep it to the content of what we covered this morning since we'll have another opportunity this afternoon to ask questions as we cover more ground through the guidance.

But we want to welcome anyone who would like to ask a question. There is a microphone in the middle of the room that you will need to come up to. If you can state your name and affiliation because, as I mentioned, we are having this transcribed, that would be -- we would ask for that. And then you can ask a question to our panelists. If you'd like to direct it to a certain person, feel free. If not, we will -- they will decide amongst themselves the best one to answer.

But really, this is a great opportunity to get further clarification in an area that you may be wondering about, and really just welcome your questions.

So great. We have someone coming on up.

MS. NORTON: Good morning. I'm Stephanie Norton (ph) from Community Alliance of Family Farmers.

My question is related to records management. So under most of the other parts of 21 CFR, if you do records management on -- in an electronic form, you also have to follow 21 CFR, Part 11 for electronic records and signatures. Will the records management underneath this law be carried over to ensure that we have to follow 21 CFR, Part 11 as well?

MS. TIJERINA: I don't believe so.

MS. NORTON: Okay.

MS. TIJERINA: I will have to double-check on that just to be absolutely sure.

MS. NORTON: Okay.

MS. TIJERINA: But I think only under certain -- yeah, certain circumstances would you have to follow that.

MS. NORTON: Okay. Thank you.

MS. TIJERINA: But if you'd like to catch up with me a little bit later and I can get your contact information, I will get back with you on it.

MS. NORTON: Thank you.

MS. BARRETT: Thank you for the question.

Other questions?

MR. FRANKLE: Hi. My name is Lee Frankle (ph). Hopefully, the question isn't too off topic, but kind of following up on the records requirements. And maybe it has to do with some of the people on the last panel.

But you know, are there kind of areas for improvement of just exactly how we should be keeping records or ways to make it more transparent when you're trying to do an outbreak investigation? Or it seems like there is maybe some missing link or something that's not quite working right in the present system that, you know, might help lead to potential causes or even forces of different issues if we just knew how to organize our records a little bit better or maybe in a different format or -- and we're not measuring the right things. I just kind of wanted to get some feedback on that.

MR. ASSAR: Yeah, I'll just say real high level. I appreciate your question and comment.

So the Produce Safety Rule doesn't include, you know, requirements for the traceability records that I think you were referring to in your question or comment. However, obviously, we're looking at the situation that we're dealing with now, that we're all dealing with right now, in terms of the outbreak. And that -- you know, the -- essentially, the outcomes of our exploration of the outbreaks will inform -- could inform other efforts in that regard. It may not be part of the Produce Safety Rule or guidance, but it

could be a separate effort all together.

It's an important area that we are focused on and in -- particularly in view of this outbreak. So we -- it -- yes, it's something that we're active on.

MS. TIJERINA: Just to add on to what Samir was saying is that -- have you had a chance to possibly have someone do an On Farm Readiness Review, possibly? That may help answer some of your questions and to make sure that you are in compliance with the rule as far as your record-keeping. That may give you a better idea of where your farm sits as far as the required information, and it could possibly give you more information on what you could add on as far as information in the case of an outbreak.

UNIDENTIFIED FEMALE SPEAKER 1: Yeah. And maybe it would be helpful to go through some of the actions related to record-keeping and frame it in the way that Jim presented, kind of the steps of progression as we move towards implementation today because I appreciate your question and interest in enhancing your record-keeping and management system. And it is a process as you move forward with developing a record management system. So the first step, as Mary pointed out, is to review the requirements of the rule and make sure that you understand those requirements and then look at how your current record-keeping system aligns with the requirements and make sure that you're ready for compliance.

And then of course, we understand that record-keeping is not always viewed as a favorite activity of farm personnel in some cases. And so it's important to go through and look to see the procedures that you develop with respect to record-keeping. Are they being implemented in a consistent fashion? And that kind of rounds out the verifying that you are managing your records the way you think you are on a regular basis.

So thank you for the question.

MS. BARRETT: Okay. Other questions?

Yeah, come on up.

MR. VILLANEVA: Mike Villaneva, California

LGMA.

And a question on training. And as an organization, we take it very serious. It's one of the cornerstones of the LGMA. And I'm really pleased that FDA took the stance they did on training -- the specificity, the supervisors -- I mean, those levels.

And I guess my question would be: How is FDA going to -- when you're out looking and evaluating those training requirements, how are they getting done? Is there some measurement that we can use or -- to say that, you know, we're hitting the mark as far as those specific training requirements?

I know it's kind of a general question -- I just -- because, you know, we're trying to bring our folks up to a higher level. And I don't know if we -- if anybody can give me anything specifically that an investigator would be looking at to say, yeah, that supervisor is training in their levels and responsibilities. I'm just getting questions like that from our folks. So --

MS. NAIR: Right.

MR. VILLANEVA: -- I'll throw that at you.

MS. NAIR: Can you hear me? So as Mark pointed out earlier, the investigators can only do the inspections to what's required in the rule. However, when it comes to making sure that all of those requirements are implemented correctly, it's really going to depend on what they observe on the farm. So you know, taking into context what their observations are and knowing what the requirements are is really going to help them to gauge.

Now, on the farm side, when it comes to, you know, making sure that things are implemented in a way that they're meeting the requirements of the rule, again, start with the codified. Go to the guidance as kind of a measure of things. And you know, if your farm wants to go above and beyond and put in additional measures, of course that's, you know, something that we look forward to farms implementing voluntarily. But you know, as far as we can, you know, recommend ways to

comply, again, we're sticking with the rule pretty closely and our recommendations in the guidance.

I hope that helps.

MS. TIJERINA: And to add on to Amber's response, please keep good records of your training activities.

MS. BARRETT: And I would say, too, I mean, as we solicit comments on the draft guidance, if there are measures of training that you would suggest as examples, I think that they would certainly welcome hearing in that regard, too.

Other questions? We covered a lot of ground this morning. Any additional thoughts? Any comments on anything that you heard?

MS. SMITH: Michelle Smith from FDA. And one of the things, having seen two public meetings of what keeps coming up in my mind, a statement that Mary made, because the sprout part of the produce rule went effective prior to other produce farms, we have had some experience through our inspection. She cited the experience with records from those inspections as something that has been a learning experience for us, some of which is in the current draft guidance.

Are there any specific examples of what we learned from the sprout inspections that could help inform the implementation part of Jim's four-step process and everybody else for guidance and things like that?

Thanks.

MS. TIJERINA: As far as record-keeping?

MS. SMITH: Any part of the rule that --

MS. TIJERINA: Okay. There were some challenges that were noted in some of the sprout inspections with record-keeping. And it was found that some things weren't quite as well understood as what was required. And so the sprout guidance coming out and in the sprout inspections being done, that has informed us that, even though record-keeping isn't the fun part of the guidance or the Produce Safety Rule, if you can consider any parts to be fun, but it's a very

important part. And so we want to emphasize that records are extremely important because, if you don't have it recorded, it didn't happen. So please keep in mind that record-keeping is very, very important, and the sprout inspections did help inform us of that.

UNIDENTIFIED FEMALE SPEAKER 1: And to follow up, I think Amber will be mentioning this afternoon at another topic area that we've seen in sprout inspections that has presented some challenges, particularly with respect to equipment and tools and some of the provisions around buildings. So both of those are areas that folks might want to take a look at with respect to both the requirements and some of the recommendations of the guidance to help with implementation.

MS. BARRETT: Okay. Thank you.

Another question?

MR. ISOM: Yeah, good morning. Roger Isom with Western Agricultural Processors Association and California Cotton Ginners and Growers Association.

My question has to do with the required employee training. Right now, it speaks to that it has to be FDA-approved or equivalent, which is right now the Produce Safety Alliance. Do we know when that equivalency will be determined? Is that soon, or is that several months down the road?

MR. ASSAR: So right now, what we put out -- just as you point out, what we have is a standardized curriculum that is recognized by the Food and Drug Administration that, if taken, would meet the -- would help meet the requirement of the rule.

There -- we are working on a guidance, actually, around, you know, recommendations for developing equivalent curricula. And hopefully, that will be issued as draft very soon. And again, there will be a comment period associated with that.

To date, we're not aware -- we have not officially recognized any other curriculum as being equivalent or, you know, alternate to the standardized curriculum that we have recognized and was developed

through the Produce Safety Alliance process, although certainly there is an ability to do that. And we are very flexible in that regard.

And as long as -- again, I would say the guidance will be very meaningful in that regard for those that are looking to go in that direction because it will provide the principles that can be followed in developing such a curriculum.

MS. NAIR: I just want to add on to that that FDA does not have to recognize an equivalent or alternate curricula for it to be considered as such. But the guidance will provide principles that people can determine if their curricula is equivalent to that provided by the Produce Safety Alliance.

MS. BARRETT: Thank you.

Other questions?

MR. MALDONADO: Robert Maldonado, Northgate Markets. We're here in Anaheim.

First of all, I'd like to commend you guys on the great job you guys did on that 40-minute video on the Produce Safety Rule. That was an excellent job. I think you guys really hit home on that. I would like to see it in Spanish, if there's any way possible. But you guys did an excellent job on that. It covered everything.

And then also, you know, Linda Harris and Dr. Sesslo (ph), they do an excellent job on providing all the resource materials for a lot of the farmers, an excellent job on the material you guys publish. I've taken a lot of post-harvest classes from you guys at UC Davis, and they're excellent.

I guess my question would be: How are we going -- since about 70 percent of our produce comes from Mexico, how are you guys going to handle the -- you know, the farmers out of Mexico? And I guess that would be my question.

MS. BARRETT: Sure. Thank you.

MR. ASSAR: Okay. I'll take that one. So as was noted in one of the first discussions, it's really important that there is a uniformity and consistency

with respect to our regulatory approach that impacts domestic farmers as well as farmers outside of the country that are offering for import into the United States. That's hugely important. We recognize that.

One thing that we will be doing is foreign inspections of those farms that are outside of the U.S. We didn't really talk about the plan domestically, but it -- I think it was alluded to, initially, that the states will play a huge role with most of the inspections that'll happen here in the U.S. And FDA will play a role in -- with those states that are not under a cooperative agreement with FDA. And then so on top of that, again, on the foreign side, you'll have our FDA investigators doing foreign inspections.

We'll also be relying on one of our keystone verification -- foreign verification rules, the foreign supplier verification program, where there is a requirement that importers essentially ensure that an audit -- and this is a very base-level and very simplistic way of describing what the rule actually requires. But essentially, there is a requirement for the importer to have an audit or have an -- audit records or audits conducted of foreign farms that are offering for import into the United States. And there are flexibilities around that. There are equivalencies around that. You don't need to have an audit based on the Produce Safety Rule as long as there is something equivalent at play.

And then there are other cases where an audit isn't necessarily needed, but other type of activities that would be equivalent to an audit could be utilized by the importer to satisfy the requirements of that rule.

So we've got two different types of verification. One is through our own foreign inspection program by FDA. And then we'll also be relying on the foreign supplier verification program, which is really targeted towards importers. And -- but the importers are responsible for making sure that the growers are producing food, the suppliers are producing

food under the standards that are equivalent to the Produce Safety Rule.

MS. NAIR: Also, to add on to that, we are participating in efforts to provide various materials in Spanish language for those producers and various stakeholders who are Spanish-speaking to understand the rule and how to comply. So that's another --.

MS. BARRETT: Okay. Additional questions?

(No audible response.)

MS. BARRETT: I'm just going to do a quick check on time. What we can do is, given that I'm not seeing anyone come to the microphone right now, I just want to give out one more shot. Okay.

Are there other questions? No. Okay.

Why don't we break for lunch and come back early. I'm just going to look to our team here. 1:00 o'clock? 1:00 -- okay. So we're going to start up again at 1:00 o'clock.

Thank you.

(Applause.)

(Lunch break.)

MS. BARRETT: Alright. Well, welcome back, everybody. And we are going to work our way through some additional chapters of the draft guidance.

We're going to start with our first speaker, Michelle Smith, who is a Senior Policy Analyst in our Division of Produce Safety in the FDA Center for Food Safety and Applied Nutrition. Michelle is going to discuss the Biological Soil Amendments of Animal Origin and Human Waste, Chapter 4, as well as the Domesticated and Wild Animals chapter, which is 5.

And then Amber, who you met this morning, will follow Michelle. And she's going to speak on the Growing, Harvesting, Packing, and Holding Activities, Chapter 6, as well as the Equipment, Tools, Buildings, and Sanitation, Chapter 7.

So with that, I'll turn it to Michelle.

MS. SMITH: Thank you, Kari. And welcome back from lunch, everyone. I hope you had a pleasant lunch.

As Kari said, I'm covering two chapters this

afternoon. The first will be an overview of Chapter 4, Biological Soil Amendments of Animal Origin, also known as BSAAO, for short -- and I use that word loosely -- and Human Waste. The requirements of Subpart F are the minimum standards for BSAAOs, including agricultural teas that are BSAAOs and human waste. Chapter 4 provides draft guidance to help determine the applicability of Subpart F to you and your farm as well as recommendations and examples related to BSAAOs.

Next, there will be an overview of Chapter 5, Domesticated and Wild Animals. Wild and domesticated animals on or near your farm include feral, grazing, and working animals, livestock, and pets. Chapter 5 provides guidance to help determine the applicability of Subpart I along with recommendations and examples.

Now, this slide -- whoops. My computer doesn't show the same thing, but that doesn't matter because you can't see it.

Okay. This slide shows the sections covered in Chapter 4 of the draft guidance. Again, we've listed the section titles and the numbers of each section to help you navigate through the guidance itself and look things up.

As we worked on this chapter, like the others, we considered information from a lot of different sources. For this chapter, we again looked back at comments from stakeholders received during the rule-making processes, TAN inquiries, as well as our experience on a variety of farm tours and, in addition, attending three soil summit meetings.

This presentation is a brief overview of the topics covered in Chapter 4. The sections that are listed here are designed as a series of steps for you to go through step-wise, determining the applicability of the requirements in Subpart F to your farm and to provide recommendations and examples related to this topic. This chapter also has several figures, summarized lists, and additional examples, as appropriate.

Now, in Section 1, the first step is to

determine whether your soil amendment, including an agricultural tea, is a biological soil amendment of animal origin. There are several definitions provided in the Produce Safety Rule that are important to understanding the terms in this chapter.

In your package, for your convenience, there is a four-page handout copied from the section of the codified that has the definitions in it. So the date at the top of this handout is the date of the final rule -- November 27th, 2015. And the definitions start in Section 112.3. So you should refer to the definitions in the Produce Safety Rule. Some of the definitions or defined terms are listed on this slide, and many of them are covered in this chapter of the guidance.

Section 1 provides several examples of biological soil amendments of animal origin, including treated, stabilized compost, compost ingredients, or intermediary composting materials that contain materials of animal origin, worm castings, and animal bedding material that contains animal excreta. As shown on this slide, the draft guidance provides a figure -- this is Figure 4a on page 58 -- to help with this determination.

Section 2 is designed to help you determine whether your BSAAO is treated or untreated. The draft guidance reviews the requirements for a BSAAO, including an agricultural tea to be considered treated. Note the Produce Safety Rule does not require you or your supplier to conduct microbial testing of BSAAOs.

The draft guidance provides several examples of untreated BSAAOs, including stockpiled or aged manure that is not processed to completion, treated BSAAOs contaminated by untreated manure runoff after treatment and agricultural tea made from raw manure.

The draft guidance also lists a number of options for managing untreated BSAAOs. One option is to use it as an untreated BSAAO for growing covered produce in accordance with the applicable rule requirements. Another option is treating or retreating

it in order for it to classify as a treated BSAAO in accordance with rule requirements.

Section 3 is meant to help you determine the appropriate treatment process and associated microbial standards for your treated BSAAO. There is flexibility for you in determining a treatment process for your biological soil amendment of animal origin. You can use a physical, chemical, or biological process or any combination of these.

If you want to consider a BSAAO to be treated, it must be processed to completion using a treatment process that is validated to meet the relevant microbial standards described in the produce rule.

Now, as noted in the draft guidance, FDA does not expect farms to perform validation studies for BSAAO treatment processes. However, farms should ensure that the treatment process they use has been validated to meet the Produce Safety Rule microbial standards.

Key recommendations for processing your BSAAO to completion include establishing procedures to ensure delivery of the scientifically valid controlled process throughout the BSAAO, administering the treatment process in a controlled manner, to ensure that the treatment parameters established during validation are, in fact, achieved throughout the entirety of the BSAAO -- for example, proper blending or turning as necessary, monitoring time, temperature, moisture content, or pH as appropriate to the process.

Finally, you should ensure that the treatment parameters are managed in such a way to achieve delivery of that treatment even in the most challenging areas, such as the edges and the bottom of the pile.

Section 4, Determine How to Apply Your BSAAO. This section begins by providing a list of factors to consider, many of which are listed on this slide. I'd like to review a few of these in more detail.

First, the application restrictions are based on whether your BSAAO is untreated or treated. There are two different levels of treatment that is microbial

standards specified in the Produce Safety Rule. The level of treatment impacts the application restrictions. The draft guidance recommends that you consider the application methods that you could use and the likelihood of contact between the BSAAO and the crop both during and after application. For example, a broadcast application method would be very likely to contact the crop during application and after.

This section expands on our current thinking for application of untreated and treated BSAAOs, providing several examples. It also provides a figure -- next slide -- summarizing the requirements relating the microbial standards to the application requirements for treated BSAAOs.

And this is that slide. I don't have a lot of time to cover this in detail, but I would like to draw your attention to it because it is very important. It's Figure 4f on page 70 of the draft guidance. It was created as a visual aid to assist with connecting the relevant microbial standards and the application requirements in the Produce Safety Rule. This figure reviews the relevant requirements for treated BSAAOs, including the standards for different levels of treatment.

We also created a figure to review the application requirements and minimum application intervals for BSAAOs. This portion of the figure focuses on the application requirements and minimum application intervals for untreated BSAAOs. The entire figure, Figure 4b, is located on page 59 of the guidance. Note that FDA reserved the provision represented in this upper-right box that provides the minimum application interval of untreated BSAAOs applied in a manner that does not cover contact-covered produce during application and minimizes the potential for contact with covered produce after application.

As discussed in Section 4, we are deferring action on an application interval while we can pursue certain steps, including a risk assessment and further research. What this means is that, while we had

proposed a longer interval for untreated BSAAOs where the grower would have to minimize contact after application, comments and other things have caused us to put this on hold while we conduct the risk assessment and research to determine what the appropriate interval is.

So at this point in time, we do not have a different requirement for untreated BSAAOs applied in these two different ways while one of them is reserved. However, we would not object to the use of national organic program standards of 90- or 120-day application intervals for untreated BSAAOs applied in this manner. We do believe that adherence to a 90- or 120-day interval or some other similar program, while voluntary, would be a prudent step towards minimizing the likelihood of contamination while the risk assessment and the research progress.

Note, also, that while we have reserved the requirement for this particular provision, all of the other requirements for untreated biological soil amendments of animal origin, things like storage, handling, transport continue to be in force and apply.

Okay. Section 5 covers recommendations for determining the requirements for handling, transporting, and storing your biological soil amendment of animal origin. The owner, operator, or agent in charge of a covered farm should carefully evaluate your handling, storage, and transport practices for both treated and untreated BSAAOs for the potential to contaminate a variety of areas shown here, including your growing area of water source distribution system, potential to contaminate other biological soil amendments, including ones that have been treated, areas where you conduct covered activities, covered produce, and food contact surfaces.

Remember that untreated BSAAOs include incomplete or partially treated BSAAOs and BSAAOs that have become recontaminated. The draft guidance expands on recommendations and examples related to BSAAOs, storage practices and location, personnel and equipment

and tools involved with handling and transport of BSAAOs.

Finally, Section 6, which is on page 72 of your guidance -- it's not listed on this slide -- covers recommendations for determining what records to keep for your treated BSAAOs, and we look forward to your comments on this chapter.

This concludes the overview of Chapter 4.

Chapter 5, Domesticated and Wild Animals. In developing Chapter 5, we also considered stakeholder comments from the rule, information from other agencies, scientific literature, outbreak investigation information, and inquiries that we have received to our Technical Assistance Network.

Let's start with a little bit of the review of the background information and some of the rule requirements. Domesticated and wild animals are sources of pathogens that can transmit foodborne disease by contaminating produce. The Produce Safety Rule requirements are the minimum standards to address the potential for biological hazards to be introduced by your domestic animals, domesticated animals near the farm, and by wild animals.

The requirements of Subpart I apply only when covered activities occur in an outdoor growing area or in a partially enclosed building. Also, this section applies when, under the circumstances, there is a reasonable probability that animals will contaminate covered produce. We support the colocation of animals and plant food production systems in agriculture and do not prohibit animals from covered farms.

For this chapter, there are three main sections listed on the slide, again, with the section number and title. For each topic, we describe factors to consider, and we include several examples for illustrative purposes. Please keep in mind that even if you have similar circumstances listed in the examples, you should still perform your own evaluations based on your farm-specific conditions and practices.

Section 1 of Chapter 5 covers determining

whether, under the circumstances, there is a reasonable probability that animals will contaminate your covered produce. The draft guidance provides several recommendations -- first, that you should identify outdoor areas and partially enclosed buildings where covered activities occur during the growing season on the farm. These are the relevant areas that may be subject to the requirements of Subpart I.

Next, you should determine whether, under your specific circumstances, there is a reasonable probability that animals will contaminate covered produce in the identified outdoor areas and partially enclosed buildings. To do this, the draft guidance recommends that you should evaluate your farm's covered produce conditions and practices. This should also include an evaluation of the types of animals that could contaminate covered produce based on available historical observations of animals and other factors, such as the presence of animal attractants and habitats. The draft guidance expands on some of these factors a little further.

Wild and domestic animals, including your own domesticated animals and those from nearby areas, could be sources of contamination. Your evaluation should include land features, land use, and the presence of existing measures or structures on or near your farm that could affect whether or not animals or their waste will be present on your farm. Again, more details are provided in the draft guidance.

You should also periodically reevaluate your farm's conditions and practices. Changes on or near your farm could impact the probability that animals will contaminate your covered produce.

This section also provides examples related to a farm evaluating covered produce, conditions, and practices to determine whether there is a reasonable probability that animals will contaminate produce. As noted in the Federal Register Notice of Availability for the draft guidance, we are specifically seeking comments, including information and data, about factors

or conditions that would affect the likelihood of contamination of covered produce by animals.

Now, if you have not seen that yet, there is a copy of the Federal Register Notice of Availability in your -- for the guidance in your package. It's a single page, front and back. It's dated October 22nd, 2018, when we made the guidance available. And if you flip it over to the back, you can see a statement that we're looking for comments on all parts of the guidance. But there are two specific areas where we're especially looking for comments. And this is one of those two areas.

Now, I want to emphasize that FDA does not expect, suggest, or recommend that farms eliminate animals from outdoor growing areas, and we do not require the application of practices that may adversely affect wildlife, such as removal of habitat or wild animals from the land adjacent to the fields.

If you determine that there is a reasonable probability that animals will contaminate your covered produce, you must take the next step and assess the relevant areas for evidence of potential contamination of covered produce as needed during the growing season. And this will be the next section covered here.

Whoops. I need to go backwards.

Okay. Section 2. Section 2 covers assessing the relevant outdoor areas and partially enclosed buildings on your farm for evidence of potential contamination of covered produce by animals. The Produce Safety Rule provides flexibility in developing your approach to assessment, which could vary, depending on the types of animals and other factors you identified in determining whether there is a reasonable probability that animals will contaminate your covered produce in each relevant area of your farm. It may differ between different areas. In addition, you should periodically evaluate your approach to assessment and modify it as needed.

This section expands on factors to consider in developing and modifying your assessment approach, some

of which are listed on the slide, including personnel responsible for monitoring, timing and frequency of monitoring, and the details on reporting observations of evidence of potential contamination.

The draft guidance expands on factors to consider related to types of animals and their potential activity on your farm. It also includes examples of how a farm could assess relevant areas for evidence of potential contamination after they made a determination that there is a reasonable probability that the contamination would occur.

The owner, agent, or operate -- the owner, operator, or agent in charge of a covered farm should determine which personnel will conduct monitoring, how they are to perform the monitoring, including visual exam for evidence of potential contamination by animals in the relevant areas.

Finally, Section 3 covers evaluating significant evidence of potential contamination of covered produce by animals to determine whether or not harvest can occur. If there is significant evidence of potential contamination by animals, you must evaluate whether the covered produce can be harvested in accordance with the requirements of the rule and take measures reasonably necessary during growing to assist you later during harvest when you must identify and not harvest covered produce that is reasonably likely to be contaminated with a known or foreseeable hazard.

The draft guidance recommends that the owner, operator, or agent in charge of a covered farm should consider the extent of the evidence of contamination and expands on these concepts. We provide several examples to illustrate approaches for determining whether significant evidence of potential contamination by animals exists, including scenarios involving monitoring observations that likely are significant evidence and other scenarios that likely are not significant evidence.

So this concludes the overview of Chapter 5, Domesticated and Wild Animals. Thank you for your

attention. There will be time for questions at the end of these presentations. And again, we look forward to your comments on the rule and, in particular, comments on wild and domesticated animals.

Thank you.

(Applause.)

MS. BARRETT: Okay. Last talk of the afternoon. Take a stretch if you need it.

MS. NAIR: Okay. So again, I'm Amber Nair from the Division of Produce Safety, Fresh Produce Branch. And I'll present the overviews of two chapters in this presentation. These will be brief overviews highlighting selected recommendations. We will not have time to cover all of the content of these chapters. They're quite lengthy.

First, Chapter 6 provides our current thinking and recommendations related to the requirements of Subpart K. This subpart is applicable to growing, harvesting, packing and holding activities, including the transition points between those phases. Then Chapter 7 provides draft guidance related to equipment tools, buildings, and sanitation associated with the requirements of Subpart L.

In both of these chapters, we recommend evaluating your relevant procedures, processes, and practices periodically to consider the breadth of your practices, including any infrequent or unusual practices as well as any changes that have occurred and how this relates to the requirements of the Produce Safety Rule.

We included numerous examples to illustrate how a farm could use the principles and recommendations discussed in both of these chapters. We hope you find these useful and look forward to your comments.

To reiterate, even if you have similar circumstances or produce crops mentioned in these examples, you should perform your own evaluations based on your farm's specific conditions and practices.

This slide provides an overview of the sections in Chapter 6. And we will only discuss a few

of these today, which are highlighted in bold. The section numbers and titles, as previously mentioned, the section numbers and titles are listed on this slide and are provided on later slides to provide a sense of where the information is located.

Each of these -- excuse me -- each of these sections directly relate to a specific requirement in the Produce Safety Rule. As we worked on this chapter, we were aware of stakeholder comments on the Produce Safety Rule and TAN inquiries.

This chapter covers diverse topics related to growing, harvesting, packing, and holding activities. In several of the sections, we provide summaries of key recommendations, requirements, or other information to highlight certain points. And we hope you find these useful to become familiar with the content of these sections.

I'd like to take a minute to point out that, in several of these sections, the draft guidance provides recommendations for personnel, supervisors, and responsible parties related to each of these topics.

The owner, operator, or agent in charge of a covered farm should instruct supervisors or responsible parties on specific procedures related to growing, harvesting, packing, and holding. Supervisors and responsible parties play an important role and should remind personnel about specific practices to prevent contamination. Additionally, personnel should understand procedures and practices to protect covered produce from contamination. Finally, as applicable, certain personnel must receive training related to some of these topics.

Starting with Section 1, Separation of Covered and Excluded Produce, at the beginning of this section, the draft guidance reviews the Produce Safety Rule requirements to help you determine the applicability of 21 CFR 112.111. The draft guidance recommends that you evaluate your farm's activities and produce to determine whether you grow, harvest, pack, or hold both

covered and excluded produce and how you handle any excluded produce. It's recommended to visually assess farm activities during this evaluation.

If the requirements of 21 CFR 112.111 apply, then the owner, operator, or agent in charge of a covered farm should evaluate the farm's practices related to separating covered and excluded produce. During the growing, harvesting, packing, and holding of covered and excluded produce, separation could involve location, time, or both.

You should identify the locations where activities for covered and excluded produce occur. Further, you should identify shared equipment and tools and personnel that are involved in both covered and excluded produce. The draft guidance expands on these recommendations and provides additional examples.

Now let's move on to Section 2. In this section, we were aware of stakeholder comments on the rule and expanded on several concepts. As a reminder, immediately prior to and during harvest activities, you must take all measures reasonably necessary to identify and not harvest covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta.

At a minimum, your efforts must include a visual assessment of the growing area and all covered produce to be harvested regardless of the harvest method. These are flexible requirements to allow appropriate steps based on your farm's conditions and practices.

The draft guidance recommends that, in addition to animal excreta, you should consider and address, as appropriate, the possibility of other sources of contamination, such as flooding, that could be relevant to your farm.

With respect to the required visual assessment, the draft guidance recommends that it should involve designated personnel visually examining

the entire designated harvest area, including areas that will be mechanically harvested. These visual assessments are most effective when performed as close in time before a beginning harvest as practical or during harvest.

The draft guidance also expands on signs that covered produce is reasonably likely to be contaminated, requirements and recommendations for harvest personnel and their training, and procedures when evidence of contamination is observed, including your expectations for supervisors and responsible parties.

Continuing on with Section 3, Handling Harvested Covered Produce, the draft guidance recommends the owner, operator, or agent in charge of a covered farm evaluate practices during packing -- during harvesting, packing, and holding to identify conditions that could increase the likelihood of contamination. This includes consideration of the personnel handling covered produce during and after harvest and the equipment, buildings, and tools used for covered activities during and after harvest. There is a great deal of flexibility in the relevant requirement to tailor practices that are appropriate for your operation.

The draft guidance recommends that the owner, operator, or agent in charge of a covered farm should establish procedures to ensure that harvesting, packing, and holding practices protect against the contamination of covered produce. Practices to consider include avoiding contact between the cut surfaces of covered produce and soil, reducing damage to harvested covered produce to the extent practical, and packing and holding covered produce in a manner that minimizes the potential for contamination.

There is additional information on these topics in the draft guidance. It's important to note that this topic is likely to involve personnel who handle covered produce or food contact surfaces or who are engaged in the supervision thereof. The draft

guidance in this section reviews training requirements and provides recommendations related to these personnel and handling harvested covered produce.

Now let's review some of the draft guidance content in Section 6 on food packing materials. So first, I'd like to point out how we addressed some overlap in content between Chapter 6 and Chapter 7 of the draft guidance related to this topic. Food packing materials, including food packaging materials, are subject to the requirements provided in Subpart K and Subpart L. To minimize redundancy on these topics, we provide draft guidance on the aspects of the materials themselves in Chapter 6.

The draft guidance reviews that pathogens can become established and grow in or be transferred from materials that have cracks, pits, rough areas, or other damage, which can increase the potential for materials to introduce contamination. Both porous and nonporous materials can facilitate contamination if they are damaged or the surfaces are not intact.

At the beginning of this section, the draft guidance lists recommended steps to help the owner, operator, or agent in charge of a covered farm determine whether a food packing material is adequate for its intended use, and these steps are listed on the slide.

First, you should identify the type of -- the types of food packing materials that you use and determine whether each type is reusable or for single use. Then determine whether your food packing materials are unlikely to support the growth or transfer of bacteria, taking into consideration your handling, maintenance, and storage practices. Finally, you should determine whether reusable materials can be cleaned, considering your handling, maintenance, and storage practices. In this section, other recommendations and examples are provided related to single-use and reusable materials.

And continuing on with Section 6 on food packing materials, the draft guidance expands on

evaluating your practices and food packing materials. The draft guidance recommends that the owner, operator, or agent in charge of a covered farm should periodically evaluate your practices, including handling, maintenance, and storage of food packing materials. This evaluation is important to account for changes that could occur over time, including the use of certain food packing materials or changes in your practices.

The draft guidance lists factors to consider, many of which are included on this slide, such as the type of material -- for example, plastic, wood, foam, cardboard; the nature of the material -- for example, whether it's smooth, coarse, absorbent, porous, or nonporous; the durability of the material -- how the material is constructed; the existing condition of the material, whether it's intact, scored, cracked, or otherwise damaged; maintenance practices -- for example, repairing or replacing worn or damaged components; and handling practices and storage practices, such as how the material is received and prepared for use, among others.

The draft guidance also provides examples to illustrate how a farm could evaluate food packing materials and their use, taking into consideration the factors described in the draft guidance. We hope you find these examples a useful tool.

We look forward to your comments on this section, and this concludes the overview of Chapter 6.

Moving on to Chapter 7 of the draft guidance, it includes four sections on equipment and tools, buildings, other sanitation measures, and records. Again, the section numbers and titles are listed on this slide and are provided on later slides to provide a sense of where the information is located. In this presentation, there is a slide featuring each of the three sections in bold that highlights the topics covered within each section to emphasize the extensive amount of information contained in this chapter.

As we worked on this chapter, we considered

stakeholder comments from the rule, TAN inquiries, experiences from our educational farm tours, outbreak investigations, and engagement with our educational partners. The topic in this chapter are important concepts for consideration.

Based on the inspections of sprout operations, the most frequent citations relate to the requirements of Subpart L, particularly, requirements for equipment, tools, and buildings so the content of this chapter may be useful to farms, including sprout operations, to assist with implementation of the requirements.

Let's start with Section 1 on Equipment and Tools. At the beginning of this section, the draft guidance summarizes key steps for equipment and tools based on the requirements. These steps follow closely with the subsections related to equipment and tools and Section 1 of Chapter 7. We will not discuss all of these in detail in this presentation, but will highlight some of the material covered in the steps highlighted in bold.

As mentioned earlier in this presentation, food packing materials, including food packaging materials, are subject to the provisions related to equipment and tools in Subpart L. So we provide recommendations related to some aspects of food packing materials in this section of the draft guidance.

Starting with the first recommended step, it's -- I'm sorry -- okay. Starting with the first recommended step, it's important to identify the equipment and tools subject to the requirements of Subpart L. You should visually assess your covered activities in your growing, harvesting, packing, and holding areas to identify the equipment and tools that are intended to or likely to contact your covered produce.

The draft guidance provides some examples to illustrate how your practices could affect whether contact is intended to or likely to occur. I'd like to highlight that, in the Federal Register Notice of Availability for the draft guidance, we believe

additional information would assist us, and we -- excuse me -- we seek specific comments, information, and data on the following: When acquiring equipment and tools, how do you engage with equipment and tool suppliers about the size, design, and construction of your buildings so that they can accommodate the equipment and tools?

Moving on to Step 2 in Section 1, let's discuss some of the recommendations related to design, construction, workmanship, installation, and maintenance for equipment and tools.

The draft guidance recommends evaluating the materials used to make your equipment and tools and the impact of the materials and their construction on adequately cleaning and properly maintaining them. You should also evaluate the design, construction, and workmanship of equipment and tools.

The draft guidance recommends considering several factors, including those listed on the slide. We recommend that you use equipment and tools made from nonporous materials to the extent practical. We understand that some farms use equipment or tools with porous materials. If you choose to use equipment and tools made of wood, fabric, foam, or other porous materials, the equipment and tools must be of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained. Equipment or food contact surfaces that can no longer be adequately cleaned or maintained should be repaired or replaced.

Next, I'd like to highlight some of the recommendations related to inspections. Periodic inspection of your equipment and tools can help you identify signs of potential contamination and determine whether maintenance, replacement, or cleaning or sanitizing is necessary. The outcomes of your inspections should guide your decisions about continued use of your equipment and tools.

The draft guidance recommends that the owner, operator, or agent in charge of a covered farm should

establish and communicate the following: Procedures for inspecting equipment and tools, including food packing materials; the frequency of these inspections; the personnel involved; conditions that should be reported to you, a site supervisor, or responsible party to determine appropriate steps to protect covered produce; and expected practices when personnel observe unclean, damaged, or worn equipment and tools, including food packing materials.

The draft guidance also provides a list of factors to consider when determining inspection frequencies. You could determine that different inspection frequencies should be specified for different types of equipment and tools. The draft guidance in this section provides other recommendations and examples as well.

I'd like to emphasize that there are several examples throughout the narrative of the draft guidance related to Section 1. As we developed this section, we were mindful of stakeholder comments on the rule, question that -- questions that we've received through the TAN, and our experiences on educational farm tours as we worked on this chapter, and other interactions with stakeholders.

There is a subsection in Section 1 focused on providing examples that use principles and recommendations discussed earlier in the chapter to illustrate how a farm could visually assess and evaluate their equipment and tools, conditions, and practices based on the requirements. In some of the examples, the evaluations lead to changes in the equipment or tools, practices, or procedures. And in others, the evaluations do not lead to a change in equipment or tools, practices, or procedures on the farm.

These examples help illustrate our current thinking related to the evaluation of food packing materials, including harvest containers and equipment and tools that are used for wood, foam, and carpet, among other topics. We hope you find the examples in

Section 1 helpful and look forward to your comments on this.

The draft guidance includes a great deal of information related to our current thinking on cleaning and sanitizing, and we can provide only a brief overview in this presentation.

Let's start with the key recommended steps recommended at the beginning of this subsection. The draft guidance recommends that the owner, operator, or agent in charge of a covered farm should evaluate equipment and tools by identifying food contact surfaces and non-food contact surfaces of equipment and tools and determining the cleaning practices and, as necessary and appropriate, sanitizing practices for each type of equipment and tool and the frequency at which you will perform these practices.

The draft guidance recommends visually assessing your covered activities to identify food contact surfaces during production activities. Several more specific recommendations are provided as well as examples to illustrate how to evaluate equipment and tools, practices, and conditions to identify food contact and non-food contact surfaces. This is an important step to understand the applicable requirements for your equipment and tools.

Moving on, there is a subsection that provides more detail on recommendations and examples as well as factors to consider related to cleaning and sanitizing procedures.

Next, there is a subsection that expands on the frequency of cleaning and, when necessary and appropriate, sanitizing. This section also provides more recommendations, examples, and factors to consider.

This is another topic where we seek specific comment, information, and data, as noted in the Federal Register Notice of Availability with the question, "What information or date can you provide about cleaning, sanitizing, and maintenance practices and procedures for equipment and tools that have wood,

foam, or other porous or absorbent materials?"

We look forward to your comments on this question. For your reference, the Federal Register Notice of Availability, as Michelle pointed out a little bit earlier, with this and other questions noted this afternoon is available in your packet of materials.

Now let's transition to topics covered in Section 2, Buildings. The subsections are listed on the slide, and we will cover some of the content related to size, construction, and design as well as pest control in this presentation.

First, I'd like to highlight an overall recommendation related to buildings. The first recommended step is to identify all fully and partially enclosed buildings that you use for covered activities. Many of the requirements related to buildings are designed to be flexible to accommodate a wide range of buildings where covered activities are performed on farms.

Now let's discuss a few of the recommendations on building size, construction, and design, some of which are provided on this slide the draft guidance recommends that the owner, operator, or agent in charge of a covered farm should evaluate whether your identified building's size, construction, and design are appropriate, considering the covered activities performed and operating conditions in each building. This includes an evaluation of the building materials. The draft guidance discusses several factors to consider, and many of these are listed on the slide. This section also provides further examples.

In the section on preventing contamination, including floors, walls, and ceilings, the draft guidance also recommends evaluating your buildings and their components, including performing a visual assessment.

Let's move on to the recommendations on pest control. This section of the draft guidance provides several recommendations, and some are highlighted on

this slide. The draft guidance recommends that the owner, operator, or agent in charge of a covered farm should minimize pest attractants and harborage areas in and around your buildings. This includes accumulated litter and debris; food scraps; unused equipment; waste; storage; and tall, dense foliage, leaves, and grass.

You should also visually assess potential points of entry and potential routes of pest movement. The first assessment can be used as a guide to develop pest-monitoring activities, and the draft guidance lists several factors to consider when establishing a monitoring frequency. There is another area where personnel responsible for pest control activities should understand your procedures for pest control and when personnel need to inform supervisors or responsible parties.

Oh, there we go. Moving on to Section 3, Other Sanitation Measures, this slide provides the topics covered in Section 3, and we will discuss them with the content for handwashing facilities in more detail.

This slide provides an overview of some of the recommendations related to handwashing facilities. The draft guidance recommends that the owner, operator, or agent in charge of a covered farm should consider personnel and visitor activities in growing, harvesting, packing, and holding areas to help determine the number and locations of handwashing facilities to accommodate typical numbers of people accessing these facilities.

The draft guidance discusses recommendations for accessibility for use, such as near interested -- entrances to packing or other work areas as well as access for servicing, maintenance, or disposal activities. The location of handwashing facilities and associated waste disposal is also important to prevent contamination.

The owner, operator, or agent in charge of a covered farm should establish monitoring, servicing,

cleaning, and sanitizing procedures and schedules for handwashing facilities. These activities should be performed at a frequency that ensures they maintain -- they're maintained in a sanitary manner.

The draft guidance expands on recommendations for solid waste disposal systems, including considerations for portable handwashing facilities. Your personnel responsible for maintaining handwashing facilities should understand your procedures, and your supervisors or responsible parties should be directed to ensure that these activities are conducted and make corrections as needed.

As a reminder, handwashing facilities must be furnished with soap, running water, and adequate drying devices. You may not use antiseptic hand rubs as a substitute for soap. The draft guidance discusses that hand sanitizers could be used as an additional measure after a handwashing with soap.

This concludes our overviews of Chapters 6 and 7. We're glad to have had the opportunity to discuss this with you today. We look forward to your comments on these chapters of the draft guidance, including our requests for specific comments, information and data on the questions mentioned earlier in the Federal Register Notice of Availability.

Thank you.

(Applause.)

MS. BARRETT: Alright. That was a lot to work through. I'm going to ask the -- our other FDA subject matter experts to come up now for our second Q&A session.

UNIDENTIFIED MALE SPEAKER: Q&A test. Q&A test.

MS. BARRETT: Alright. So much like we did before this morning, now is an opportunity for anybody who has a question that they'd like to ask of any of the content that we've covered today. Please feel free to come up to the microphone.

If you just want to even make a comment on something that you've heard, feel free to do that.

Again, the -- really, the purpose is to give clarity so that you have a greater understanding of what's in the draft as well as to, you know, hear from each other. There may be a question that you have someone else is thinking, et cetera.

So please, we'll go ahead and begin. And when you ask a question, just say your name and affiliation.

Okay. You guys are a tough crowd. There -- is there -- oh, great. Let's hope that this is the start of a few. There's got to be a few questions down here.

MS. NORTON: Stephani Norton, Community Alliance of Family Farmers. I actually have three questions.

MS. BARRETT: Alright.

MS. NORTON: Under kind of our morning conversation, we talked a little bit about sales and qualified end-users. And we're wondering if food hubs would be considered a qualified end-user sale.

MR. ASSAR: So that's a -- that is a particularly challenging question because food hubs come in various sizes and shapes. And it -- it's really about the activities. So I -- we can't really say blank -- in a blanket way that food hubs would be end-users. We would really have to look at the specific model to make a determination as to whether or not it's an end-user, whether or not it represents an end-user. So …

MS. NORTON: Okay. Thank you.

My next question is: Are pastured animals considered an application of raw manure? So if you're kind of moving your pastured animals through as a part of your kind of whole-farm plan, would that be considered an application of raw manure?

UNIDENTIFIED FEMALE SPEAKER 2: I think you're asking if pastured animals would be considered -- if their excreta would be considered a soil amendment.

MS. NORTON: Right.

UNIDENTIFIED FEMALE SPEAKER 2: And no. That would be considered animals in an area that's being

used for growing or harvesting. So that would be found more under Subpart I and --

MS. NORTON: Okay.

UNIDENTIFIED FEMALE SPEAKER 2: -- Chapter 5 in the guidance.

MS. NORTON: Okay. Thank you.

And my last question is: Is there any treatment process that's been documented as being sufficient for worm castings to be able to use them?

MR. ASSAR: I am not aware of any such treatments. And I'm looking across. And that's a prime area for, you know, if you have some thoughts about treatments that we should consider. We would love to hear about that. So --

MS. NORTON: Okay.

MR. ASSAR: -- yeah.

MS. NORTON: Okay. Thank you.

MS. BARRETT: Okay. Thank you for your questions.

MR. VILLANEVA: Mike Villaneva, California LGMA.

What's going on with the research on the -- on compost? Is there anything to report on that?

MR. ASSAR: I'll take this one as well. And Michelle, you can certainly add in.

Yeah. Obviously -- and Michelle talked about -- referred to our reserved and the work that's generally being done to fill out a framework with research, a risk assessment framework.

And so there is -- there -- we are wrapping up studies that would inform that framework. And obviously, the next step would be to take that framework. And that would be a model that would inform basically what we would consider our risk management decision, which we would propose through a rule-making process and, again, look for comment as to whether or not, you know, that model or the approach that we've taken to address manure or untreated biological soil amendments of animal origin, you know, get feedback on that.

So that -- I can't speak about any specific timelines at this point. But yeah, it's work where we've -- trying to -- it's among one of our highest priorities, is getting our -- a proposed rule out first -- a risk assessment out that would inform a proposed rule or risk management decision for feedback.

MR. VILLANEVA: You know, I think we just know it takes time.

MR. ASSAR: Yeah.

MR. VILLANEVA: Research is not something that --

MR. ASSAR: Right.

MR. VILLANEVA: -- snap your fingers and you get answers. So …

MR. ASSAR: And fortunately, we have incredible cooperative relationships with USDA, ARS. They've done a lot of great work for us.

MR. VILLANEVA: Yeah.

MR. ASSAR: We've worked with our Western Center for Food Safety. They generate a lot of amazing work that, again, feeds right into this framework. And we have an amazing staff, a risk assessment staff, that is working on this.

So yeah, we're very fortunate. We're looking forward to proposing a new standard to address this issue of raw manure. We know it's important. And you know, obviously, there are pathogens associated with raw manure.

MR. VILLANEVA: Sure.

MR. ASSAR: There's no question about that. So we need to address it, and we will.

MR. VILLANEVA: Alright. Good. Thanks.

MS. BARRETT: Thank you for the question.

MR. FRANKLE: Hi. My name is Lee Frankle.

It's kind of a follow-up on the last question. I guess, understanding that there hasn't been a kind of comprehensive side of research in terms of when kind of traditional composting methods render something as treated material as opposed to untreated material. But I guess maybe it's my wishful thinking. But it seemed

like, you know, if you do some testing of the product afterwards and it meets those microbial standards, that maybe that's a temporary safe harbor until there is a more formal rule to say my compost is actually a treated product instead of untreated or raw manure.

MR. ASSAR: And Michelle can provide you the details about our thinking. But you're essentially -- I believe what you were suggesting, which is the case, the composting and, really, the biological soil and then of animal origin standards are kind of performance standards. And there are micro-criteria that need to be met.

There's not -- one thing that we had to clarify through the rule-making process is that we're not requiring testing. It's just the process that you apply, you implement, must meet the performance standards that are in the rule.

And so do you have anything else to add about that, Michelle?

MS. SMITH: I would say that, in setting those micro-standards, those are the standards for a validated treatment process that can achieve those standards. And we provide a number of examples of processes we recognize in the rule.

MR. ASSAR: Right.

MS. SMITH: We do not require that you follow the processes and the rule, but you need to follow a --

MR. ASSAR: A valid.

MS. SMITH: -- a validated process. Now, simply testing material as verification is not the same as validating the process.

MR. ASSAR: That's right.

MS. SMITH: So there is some language in the draft guidance about our current thinking about validation, and that might be helpful.

MR. FRANKLE: Okay. Thank you.

MS. BARRETT: Thank you.

Other questions? Okay.

Again, if you'll say your name and affiliation.

MS. EVERHART: Melissa Everhart, Calavo Growers.

Should packing houses be registering wild farm definition as influx right now?

MR. ASSAR: Say, that's a good question. So right now -- and really, the guidance, first of all, does not cover registration as it pertains to packing houses and whether they be subject to the preventive controls. Or -- you know, obviously, the packing houses that are covered by guidance are those that are covered explicitly by the Produce Safety Rule.

And so I would say that the enforcement discretion -- I would say just keep in mind what the enforcement discretion is. And are -- I am assuming that you are familiar with the options that are available in terms of if you are a packing house that's subject to preventive controls what you can apply, either the GMPs or the Produce Safety Rule. I would say that's as far as we've gotten in terms of what our expectations are of operations that are covered by the preventive -- could be covered by the preventive controls regulation but fall within that enforcement discretion scope.

So that's -- it -- does anybody -- do you want to add anything, Michelle?

MS. SMITH: Okay. I can add to that, but I tell you up front it's not going to be a definitive answer.

On the one hand, I would say that if you're a packing house that used to be required to register, my personal instinct would be to continue to register just to be on the safe side because the registration is itself a separate requirement.

You might also go to FDA's website, FSMA. You might search under Registration, specifically, and see if there is any guidance there. And if there is, it certainly trumps my advice.

One of the things that I'm wondering about, though -- we use that registration list partly to determine lists of facilities to inspect under GMPs.

And so I'm not sure how this enforcement discretion that says that, if you're a packing house, that would be a farm except for the ownership provision. You can choose between the GMP provisions of the PC rule or the Produce Safety Rule until we sort this out. I don't know how they're dealing with those kinds of operations in setting up inspections. That -- whether you register or not may put you on one list versus the other. So look for more official guidance.

MS. BARRETT: Okay. Thank you. Thanks for asking that question.

Yes, please come on up.

MS. FINKE: Hi. I'm Lisa Finke from Canine Detection Services in Fresno, California.

My question is about Chapter 5, Domesticated and Wild Animals, the last paragraph, which states that farms are not required to exclude animals from outdoor growing areas, destroy habitats, et cetera, and nothing in the rule should be interpreted as requiring or encouraging such actions.

And the food safety certifying bodies tell me that animals, including working dogs, must be excluded from the fields and the packing sheds. So my question to you is: Who has the authority in this, and how does your role interact legally with the food certifying bodies -- food safety bodies?

MS. SMITH: Okay. FDA is a federal agency charged with public health protection. We've established this Produce Safety Rule, Part 112. That is the federal requirement for produce consumed in the U.S. that's covered by the Produce Safety Rule.

Now, our standard is like the baseline that everybody who's covered needs to follow. It does not prohibit other groups from establishing more stringent requirements for their particular programs.

MS. FINKE: Okay. Thank you.

MS. BARRETT: Thank you.

Other questions?

(No audible response.)

MS. BARRETT: Okay.

(Side conversation.)

MS. BARRETT: Okay. I do want to be sure that if you have a question you have that opportunity to ask it. So please, if you do, just raise your hand or come up.

Okay. I don't want to move us too fast, but I also am getting the message that you'd like to move on.

So we are going -- excuse me -- going to go ahead into our open comment period. We do have a number of folks who have registered to give public comment.

What I will do is I'll call out the organization, and if the individual giving comment will come to the microphone to offer that comment. We have asked people to keep their comments to approximately four minutes. And we just ask if you can respect that time. And again, when you come up, if you will say your name and affiliation.

So we'll start with the Western Agricultural Processors Association.

MS. RODRIGUEZ: Good afternoon. My name is Priscilla Rodriguez. I am with the Western Agricultural Processors Association. We represent the tree nut industry -- walnuts, almonds, pistachios, and pecans.

First off, I want to start off by thanking FDA for bringing out this guidance. We have found that it is helpful.

I have a couple comments. First, in relation to Chapter 1 of this draft guidance where it specifically talks about contract harvesters, it states, "Contract harvesters that only perform harvesting operations for a covered farm but do not sell the produce are performing a covered activity on behalf of the covered farm. Those contract harvesters" would not be considered a farm -- "would not be a covered farm; the farm for which they perform the harvesting would be responsible for the compliance with the requirements of the Produce Safety Rule."

However, in previously released draft

guidance, the draft guidance for Classification of Activities as Harvesting, Packing, Holding, or Manufacturing Processing for Facilities -- for Farms and Facilities, specifically, on page 15, they provide examples of harvesting activities, in particular, Operation F, which is considered a primary production farm that harvests but does not grow or raise raw agricultural commodities.

This is the same scenario as the draft guidance we are discussing today. However, many of our operations and ag operations use FLCs and farm labor contractors, which would be doing these harvesting activities, but from previous guidances are defined as a farm, or what -- they say here a primary production farm that does not grow or raise the crops.

So what we're asking here is to provide some further guidance whether it's the one or the other. Personally, we feel, because they are considered a farm, based on their activities, it should be their responsibility to meet the requirements of the Produce Safety Rule and not fall on the responsibility of the actual farm itself. There's additional issues with that, but Roger (ph) will be speaking on that, which is a little bit later today.

Secondly, still in Chapter 1, this draft guidance addresses produce, covered produce, harvested and harvestable part of the crop. Specifically, it provides an example. The tree nut industry states that when the unit is in its entirety nut-hulling shell, the unit is considered the harvestable part of the product.

However, we feel that, because the tree nut is protected by the hard outer shell and is not exposed, the hull and shell, both inedible, should not be considered the harvestable part of the product. We feel FDA agrees with this decision, as there is supportive -- supporting comments to our theory on page 88 of this draft guidance. When discussing dropped covered produce, it states, "Some covered produce, like almonds, may be intentionally dropped to the ground as part of harvesting. This type of harvesting generally

occurs with produce that is inedible, a hard out layer, and relatively durable inner" -- relatively durable.

Therefore, the hull and shell should not be -- we feel should not be treated as a harvestable -- or not be defined as a harvestable part of the produce even when it's in its entirety hull and shell itself or any other -- are only the protective barriers and will not be consumed by the consumer.

Saying that, the nut and shell, when it's in its entirety, the harvestable part of the produce can cause confusion and undue hardship to treat it as the produce. Therefore, we ask FDA to consider removing this language from the draft guidance.

And lastly, in Chapter 3, when discussing health and hygiene, in particular, the workers, ill workers, removing ill workers from contaminated covered produce, we feel that it would be important to just include some kind of a comment, a clarifying comment, that mentions although workers who are not in direct contact with the covered produce are still able to work, we just feel like this would be a clarifying comment in there, just to remove any kind of guesswork from that.

Lastly, I would again like to thank the FDA and the California State partner, CDFA, for all their work on this draft guidance.

Thank you.

MS. BARRETT: Yes. Thank you for your comments.

Our next organization is the Almond Alliance of California.

MS. SALAS: Hi. Thank you. Can you hear me?

MS. BARRETT: Yes.

MS. SALAS: Thank you. My name is Sonia Salas (ph). I'm not with the alliance, but I have been asked to share the following comments on their behalf.

So the first thing I want to say is the Almond Alliance of California is a membership-based trade association that represents California almond growers, hullers and shellers, processers, and handlers.

The Almond Alliance is -- they're engaged in the implementation of the Food Safety Modernization Act. And it's very unique because it has a pasteurization rule, which is the process of using heat to kill microbes. So this enables these processors to maintain almonds' unique texture and flavor while they are also eliminating the safety risk.

The mandatory pasteurization program proves the industry isn't afraid to tackle food safety concerns. So the almond industry marketing order established a pasteurization rule in 2007 for almonds sold domestically. The alliance revisions that have been incorporated to date in the draft guidance are valuable, and they continue to make revisions.

So the recommended revisions will provide clarity to almond industry concerns and frustrations around implementation of the produce safety regulation, including the definition of farm. The alliance believe that there is need for more clarity in the guidance to successfully implement and comply with the regulation.

So here are some comments, and the first part is related to the definition of produce. Based on what is indicated in the guidance, produce is usually grown outdoors in soil with influences from weather and other environmental factors and often does not receive treatment after harvesting that adequately removes pathogens that can cause issues.

So for clarification, what the alliance wants to share today is the California almonds produce and market in the United States do receive treatment after harvesting. That makes a unique case. In fact, all almonds covered under the Almond Board of California Federal Marketing Order are required to be pasteurized prior to being sold in the United States, the District of Columbia, the Puerto Rico, Canada, and Mexico. For clarity, California producers market almonds in the -- all the United States.

So the second part related to the guidance is related to the words "processed food" because, under the regulation, it means transform a state. And that

doesn't make -- and okay, so -- let me go back up. Processed foods are not subject to the produce safety regulation. And so examples of these activities will change our RAC into a processed food and include chopping and cutting, irrigation, and pasteurization.

So in the case of the Almond Alliance, what they want to clarify is that U.S. almonds sold in North American markets are never sold unpasteurized unless they are sold for further processing to the Almond Board of California are proved, direct, verified users. Any produce that undergoes a minimum five-to-four (ph) log kills that process should be exempt from the produce safety regulation, as produce has been properly treated for microbial organisms. It is their belief that these should automatically place them on the rarely consumed raw list.

Currently, produce that fall under commercial processing exemption are companioned (ph) with certificates and full traceability as to the process they go through. Commercial processed produce should be held to the same standard as, yes, a processed product.

Commercial processed product is trusted in the hands of those that are doing this product process. And so that's the point I want to make about the whole industry.

The last one is related to the draft guidance "rarely consumed raw" term. And the use of "cook" is brought in often for interpretation because FDA has a term. And they -- almost always they will be eating only after being cooked when we're talking about rarely consumed raw product. So other commodities on that list are leaving the kill step to the consumer. The almond industry has applied a kill step prior to marketing to consumers, eliminating the food safety risk.

Lastly, almonds -- all almond huller shellers, no matter of the ownership, perform farm primary and secondary activities. However, they weigh the process -- they propose -- well, the actual Produce Safety

Rules are written. Hullers, shellers, depending on ownership, will fall under different rules and requirements, even though the hullers and shellers are using same methods, equipments, and processes.

There is no data to suggest that a huller-sheller processing company own produce that possess less risk of consumer illness versus a huller-sheller that processes other grown produce -- growers produce. Therefore, there isn't a risk-based reason for different requirements for each huller and sheller based on their operation ownership or location since the pathway for commercialization of the almond product is through the same processor, handler, or venue.

And let me see. It is mandatory under federal law that almonds be sent to a processor who is subject to these requirements, including a mandatory pasteurization pathogen reduction treatment in order to be put and sold into commercial channels. The huller and sheller is a custom farm service to remove hulls and shells from the kernel prior to being processed. For clarity, the huller-sheller simply provides a service to the grower prior to almond kernels being purchased by the processor. So the hullers and shellers do not take ownership of almond kernels.

Almond Alliance requests that almond hullers and shellers be placed under the definition of farm-based on the facts presented and that the huller and sheller sends all almond kernel products to processors.

The Almond Alliance extends our invitation to interest parties to -- who are not familiar with almond growing, hulling, and shelling and processing and also is happy to coordinate a tour and visits if that's needed.

The Almond Alliance will submit written comments to the docket and appreciates the opportunity to provide these comments. Thank you for the consideration.

MS. BARRETT: Okay. Thank you for sharing their comments.

MS. SALAS: You're welcome.

MS. BARRETT: Alright. The next organization is CUUSA (ph). Okay. We can come back to that if -- how about United Fresh Produce Association?

Again, if you'll say your name and affiliation. Thank you.

DR. GRIEP: Hello. Good afternoon. I am Dr. Emily Griep, Manager of Food Safety for United Fresh Produce Association. Again, thank you for holding public meetings in support of the draft guidance for the Produce Safety Rule.

United Fresh is the National Trade Association for the fresh produce supply chain, representing over 1,200 members, including growers, shippers, fresh-cut processors, wholesalers, distributors, retailers, food service operators, industry suppliers, and allied associations. We've offered many comments during the rule development process and appreciate that FDA continues to engage with industry regarding challenges and implementing the rule.

Again, congratulations on getting the draft guidance published. We do recognize and appreciate the amount of time that goes into both the development of the guidance as well as the time that you dedicate to these public meetings where you seek and actively encourage stakeholder feedback.

We appreciate the plain English tone of the guidance but feel that its length may deter some growers from actually reading it. We find there is a fair amount of redundancy in the draft guidance, particularly around training requirements.

We were anxious to gain insight on FDA's interpretation of dropped produce and produce harvests on the ground, but we still find the explanation confusing and seek additional clarity. We do appreciate that FDA clearly explains that the concern with dropped produce is the potential for bruising that could stimulate pathogen growth, as opposed to simply the fact that the produce was touching the soil.

However, the line is still blurry between produce that ordinarily grows on the ground and produce

that touches the ground but is still attached to the plant. The situation most concerning to our members is what's referred to as bush tomatoes, which are more common on the West Coast and are not staked as tomatoes often are on the East Coast.

United Fresh considers and recently stated in our updated guidelines to the industry that this type of production practice does not constitute dropped produce since the tomatoes ordinarily and expectedly grow in a way that they may touch the ground. However, since the FDA preamble and draft guidance use tomatoes as an example of something that would be dropped produce, it has caused confusion that we hope FDA will address.

United Fresh advocated for a rule that offers grower flexibility in meeting regulatory requirements, but we fear that some of the examples FDA has selected suggests that some practices could be appropriate when, in fact, research funded by the Center for Produce Safety and others demonstrates risk.

For example, Example 7m discusses the use of foam pads and states that they could be permissible if cleanable. Foam pads are extremely difficult to clean, and we discourage our members from using foam due to listeria concerns. We suggest FDA reconsider using this specific type of example, which is subject to misinterpretation and could trigger food safety concerns.

United Fresh will submit more detailed comments in the document and is happy to provide additional comments and information at any time.

Again, thank you for the opportunity to offer comment on this important guidance document.

MS. BARRETT: Okay. Thank you very much for your comments.

Okay. We're going to go on to Western Growers.

I know you're busy now, Sonia.

MS. SALAS: So again, good afternoon. This is Sonia Salas. I am with Western Growers and the Senior

Director of Science and Technology. And today I want to thank you for holding these public meetings and for allowing us to comment on the draft guidance document.

Western Growers represents local and regional family farms. For those in the audience here who are not aware in -- what we do is we work with these farmers. They grow fresh produce in Arizona, California, Colorado, and New Mexico where members and their workers provide over half of the nation's fresh fruits and vegetables and tree nuts, including nearly half of the America's fresh organic produce. Some members also farm through the United States and other countries so people have year-round access to nutritious food.

So Western Growers has been around since 1926. It has been always leading the development of several industry commodity-specific guidance. We have also been engaged in the development and implementation of FSMA. And so we also made more detailed comments to the docket that we want some general thoughts at this point today.

First of all, I want to say thank you again. And also, we appreciate the at-a-glance summaries you have created since they are helpful and convenient and also assist, considering the guidance, the document, is lengthy.

So here are some of the general thoughts that we want to share today. The first, when we seek additional guidance on training related to the rule and how companies can determine who is qualified to provide this training, it will be important to have. In addition, we appreciate FDA's statement on their current thinking of what principles of food hygiene and food safety mean.

However, this is less comprehensive than the eight principles listed in the Agency's 1998 guide to minimize microbial food safety hazards for fresh fruits and vegetables. So we wonder if this indicates a shift in FDA's thinking or if this is actually another explanation for why these principles were not -- or if

there is an explanation for why these principles will not carry over the new guidance document.

Also, the second point I want to make is that we appreciate additional examples because they're helpful and they have been provided through the document. But we also encourage additional examples and believe that selecting proper examples is key to avoid any confusion.

We also ask for further guidance to help the industry determine what means primary production farm and what is a secondary activities farm. This is a major area of confusion in the industry. It still continues to be, and it will have -- it will be very helpful to include more information, such as examples provided for determining qualifying exemption status and about the explaining the FDA's current thinking in those two listed farm categories.

We also ask for clarification regarding the farm mixed-type facility concept. We want to know who should -- how should companies distinguish activities covered by the Produce Safety Rule and the Preventive Controls Rule. How will this be addressed during FDA inspections? Adding more clarity, that will be helpful.

And a couple more points. The next one is we would like to request additional discussion and clarification regarding the farm definition in two areas. First, activities that are considered part of a farm that are also considered processing, such as dehydrating.

Requirements applicable to RACs that will receive commercial processing, if there could be additional explanation on that.

And finally, we recommend the use of consistent terminology. We notice, for instance, the guidance on occasions introduces new terms and phrases or ideas that are a little different than what has been already shared. And so we encourage the Agency to explain existing terminology or use that terminology in concepts to avoid confusion.

One clear example is the term "levels of treatment" under the biological soil amendments testing criteria. And I also want to say in the at-a-glance resource, we notice the lack of the term "validation." So a little more consistency with terms.

With that, I want to say thank you for the opportunity to provide some of these comments now, and we will be providing more detail in written comments to the docket.

Thank you.

MS. BARRETT: Okay. Thank you very much.

Okay. Our next speaker is from Driscoll's.

UNIDENTIFIED FEMALE SPEAKER: Actually, I'm going to (inaudible - off mic).

MS. BARRETT: Okay. Okay. Thank you.

Alright. That brings us to the California Cotton Ginners and Growers Association.

MR. ISOM: So good afternoon. Again, Roger Isom with California Cotton Ginners and Growers representing cotton growers and gins in over 30 commodities they also grow as well.

First of all, I want to also reiterate the appreciation to FDA for developing this guidance, and it has been helpful. And I look forward to seeing it finalized and put into use.

I also want to make a comment and recognize CDFA and the On Farm Readiness Reviews. I don't think there's anything that could be more helpful to growers in going through those. We've been -- our organizations have been through several of them, and our growers have found them extremely helpful. So I'd like to see that continue and thank CDFA for doing those.

My comments are going to be very specific. We'll put additional information in writing to them. But they really go to some suggestions. And understanding that we're in California where regulations are -- abound, I will say, a couple of them, and on in Chapter 2, speaks to the comment of FLCs and the situation where you might need to train

their employees. We would express a high level of caution in doing that. In that situation, you create a dual employer. It's a joint liability situation that could expand way beyond food safety just because you gave training on a specific topic. We'll provide some suggestions on -- and examples of how that could be construed and used against the farmer and other situation, but it's just some clarification needed there.

Similarly, if you go to Chapter 7 with regards to the location of toilets, in the suggestions or examples, one of the examples is put the toilet down a hill. Again, we completely understand you don't want it in the orchard or in the field where the commodity is. However, you potentially create a situation that has -- conflicts with other laws. For example, Cal/OSHA has a field sanitation standard that requires the toilets to not be more than a five-minute walk away. So down the hill might be 10 minutes away. That -- you would be in violation. And so we'll provide some more clarification and an example of how that might be worded. But it's just -- if we're wanting farmers to look at this and accept this and use this, we've just got to make sure we're not conflicting with other laws.

And then lastly -- and I think Dr. Harris or someone also made a comment similar to this. And that is, in Chapter 7, it talks about sanitizing when necessary and appropriate.

I would start by saying we appreciate that flexibility. However, to a grower who's just looking, hey, what do I need to do, when you say necessary and appropriate, it means -- it doesn't mean anything to them. They don't -- we need more specificity there.

We're working on trying to develop that, what that might be. It might be commodity-specific. It might need additional research. But I can tall you the growers' response to that is: What does that mean? So we understand the cleaning part, but that sanitation part of it is critical. And we just want to see that

maybe add some more clarification or specificity to that.

Thank you.

MS. BARRETT: Great. Thank you so much for your comments.

Okay. And we have Canine Detection Services.

MS. FINKE: Yes. Thank you.

My company is in Fresno, and our corporation is currently offering canine bedbug inspections and canine rat abatement services. I've been involved also with the Citrus Research Board in the evaluation of detector dogs for huanglongbing disease in citrus and also the ACP, which is a vector.

So as an individual who has become very ill from both E. coli and salmonella at different times, I have a very personal interest in what has been done in recent years to ensure the safety of our food supply. So I want to say thank you to all of you who have done that. Federal and state employees, producers, packers, everybody who's been involved in this effort, thank you.

MS. BARRETT: And I do want -- if you could just say your name again, too, for the record. Thank you.

MS. FINKE: Lisa Finke.

MS. BARRETT: Okay.

MS. FINKE: Yeah.

MS. BARRETT: Thank you, Lisa.

MS. FINKE: A few years ago, I became aware of a research project that a dog trainer friend of mine, Andy Falco Jimenez, was involved in to assess the usefulness of detection dogs trained to locate fecal matter in produce. It was published in 2014 in the Journal of Food Production.

I'd like to just give you some highlights about it, and the full article is on ResearchGate. And there is a link to it on my website if you can't easily find it. The title is Quantifying the Sensitivity of Scent Detection Dogs to Identify Fecal Contamination on Raw Produce.

I'm going to read just a bit from the abstract, the last part. "For the direct detection method" -- they tested the dogs on indirect and direct. Direct was much more successful. Indirect was using Pseudo Scents on a pad, not very successful. But in the direct method, the dogs exhibited over 75 percent sensitivity for detecting greater than 0.25 grams of feces on leafy greens, cilantro, romaine lettuce, and spinach and Roma tomatoes with sensitivity declining as the amount of feces dropped below 0.25 grams. "We determined that use of a scent detection dog to screen samples for testing can increase the probability of detecting less than 0.025 grams of fecal contamination by 500 percent to 3,000 percent when samples for fecal contamination are rare." So this, it was amazing to me, and I am very surprised why it's not in use.

The conclusion said that scent detection dogs appear capable of directly detecting low levels of fecal contamination on romaine, cilantro, spinach, and Roma, thereby, elevating the probability that an investigator, grower, or processor can successfully detect produce samples with fecal contamination before harvest -- for example, the use of scent detection dogs to identify contamination, contaminated produce using a Z-Pattern sampling approach in the field, as is used in pesticide residue sampling, may increase the effectiveness of pesticide monitoring methods.

If we assume that most of the microbial contamination on raw produce is the consequence of fecal contamination in the field, then the use of scent detection dogs will allow us to prioritize produce sampling for analytical testing and, thereby, optimize the detection of both feces and associated microbial pathogens that so many -- so often accompany fecal contamination.

As I've talked to growers and packers about this research, they're very interested. However, they're concerned their food safety certifying bodies won't allow dogs in the processing plant or the fields. I'm requesting your help in understanding how to

address this with those bodies.

I would like to hear from people in this group what role might be appropriate for fecal contamination detector dog teams, meaning a handler and a dog. Potential areas that may be helpful, from my perspective, are, number one -- and I'll be brief; don't worry -- canine detection for fecal contamination could be a part of a grower's assessment of relevant areas for evidence of potential contamination; two, assist the designated personnel responsible for visual examination of the entire designated harvest area prior to harvest -- canine handler teams would greatly reduce the time needed for this task and increase accuracy; inspecting restrooms and outdoor -- outhouse door handles, faucet handles, and other areas humans involved in harvesting or packing may touch after using the restroom.

Four, it is possible detector dogs could assist the clearing of other areas of the farm after contamination has been found in one section.

Five, the time needed to complete outbreak investigations may be reduced if the investigators had a canine handler team with them.

Could detection dogs be utilized to increase more quickly customer confidence in romaine lettuce? I find the strangest thing. When I walk into a hotel or a home with a bedbug dog, people have great confidence if the dog doesn't find anything that there is nothing there. And I tell them the dog is no more than 95 percent accurate. And they say, well, that's just so good. And they just -- they believe the dogs are perfect even though we inform them that it's not. And so it could help restore confidence in romaine lettuce.

Is it possible these specially trained and certified dogs could play a role in the importation of produce from other nations? Inspection of equipment and tools for fecal contamination residue could be another role for these dogs. Although that was not a part of the validation study, I'm sure they could do it. Dogs can find their target odor on anything. It

doesn't have to be produce.

Processed and packaged produce before it is shipped to customers -- in the research project, a dog found a very small amount of contamination inside of a palletized box of -- a bunch of boxes palletized that were set in a row. The researchers put contamination in one, and the dog hit on it accurately.

Processed and packaged produce before it is shipped to the customer -- this is something that has been validated already as successful.

Produce purchasers could also utilize detector dogs to inspect their shipment, if they desired, before they actually used it.

So these are my thoughts, and I'd love to hear from any of you if you have any comments to me later.

MS. BARRETT: Thank you. And please submit your thoughts to the docket as well.

I wanted to go back. CUUSA -- did we have someone who wanted to offer comment?

(No audible response.)

MS. BARRETT: Okay. Is there anyone else in the room -- you don't have to be registered -- that would like to make a brief statement?

(No audible response.)

MS. BARRETT: Okay. Seeing no hands, we are going to then move into the wrap-up. What we're going to do is we're actually going to sort of share thoughts as a panel to reflect on what we've heard today and to pull out some themes.

I am going to start with you, Samir. And then I'm going to go to Mary, Karen, Amber, and Michelle.

So I'm going -- and I'm going to sit down while you do this. So --

MR. ASSAR: Okay.

MS. BARRETT: -- please.

MR. ASSAR: Alright.

MS. BARRETT: Go ahead.

MR. ASSAR: Well, again, thank you so much for being here. We really appreciate it.

You -- we -- it's evident that you've read the

rule. And I asked the question. A lot of you raised your hand that you have, and we greatly appreciate that. And thanks for sticking in there. It was a long day. There was a lot of information. We've got a full room still, so that's very encouraging. We appreciate that.

I'm going to provide some high-level reflections, and my colleagues will certainly provide more detailed reflections based on some of the specific comments that we heard in the discussions that were held as well, also the questions that were asked during this public meeting.

I'd say that it sounds -- it sounded to me that there was a great appreciate for -- that the guidance was finally issued and that there was a lot more detailed thinking about how to implement and comply with the Produce Safety Rule. There were thoughts about how a -- future guidances could be potentially developed in terms of whether they be commodity category-type guidances or agro-ecological region guidances, but guidances that could provide a bit more clarification or tailoring to specific conditions, practices, or commodities.

And that's certainly -- again, we mentioned at the very beginning that's absolutely on our radar. We recognize the importance of providing as much detailed thinking as possible to help you understand where our heads are at. And all throughout that entire process, again, we are going to be engaging with you, and there will be opportunity to comment and refine and put out final versions that will continuously be updated over time as, again, information emerges and technology -- we become aware of advancing technology and so forth.

I did hear that there was a comment with respect to -- that the document was long and there was some redundancy. And that's something -- we were very conscientious over that in developing the guidance, and we will -- that's something we'll have to go back and look at again. We want to make it as streamlined and as user-friendly, as reader-friendly as possible. It's

not going to be meaningful to you if it's not, you know, in a format where you can readily access the information that is most useful to you.

The at-a-glance documents -- I heard in several cases that that approach was useful, that it does provide a kind of a brief overview. It effectively provides a brief overview of our thinking in the guidance, and we appreciate that. And those are things we will continue to build off of as we move forward.

And with that, I'll go ahead and pass it on.

Were you next, Mary?

MS. TIJERINA: I'd just like to say thank you again for everyone hanging in there and also for the questions on the Subpart O, the records. There were several related to records, and I appreciate the chance to answer some of them. And of course, there's a couple of questions that I will be getting back to those individuals that ask. I apologize for not being able to give you an answer today, but hopefully you'll be patient.

And again, thank you all for your interest and your participation. It's very helpful to us, and we appreciate, you know, you being here and giving us a chance to know your thoughts. So …

MS. KILLINGER: Good afternoon, everyone. And thank you for continuing to be with us this afternoon and to wrap up this discussion.

There were a lot of helpful comments and questions throughout the day. And it seemed like a theme that came through in the panel was that the guidance was likely to be used to help evaluate day-to-day practices on the farm, which I think is really positive. That's what we were aiming for, and we want to continue to improve that based on your comments.

Some of the helpful aspects that we heard -- and I thought it was very interesting that Walter pointed out the Table of Contents was a useful guide to help navigate the guidance. And as Samir said, we have a challenge in that we do have a long document. But we

acknowledge that, you know, everyone's really at a different point in their food safety journey. And that was a discussion point by the panel. You know, they talked about perhaps some farms are far -- further along in their food safety journey and have already implemented the practices, whereas I think Linda mentioned that some of the smaller farms are still starting out in their food safety journey. And so we're trying to balance that type of information that we provide in the guidance.

So perhaps that Table of Contents can be used to direct folks to specific information rather than maybe reading the document straight through but look at and evaluate where is this farm in their process and then point them to the areas of the guidance that would be most helpful to them.

It was wonderful to hear that those key summaries at the beginning of the chapters of the sections are helpful as well as the examples. And we'd certainly like to hear more from you in your comments on where we might want to consider expanding and adding other summaries and examples. And so again, the specificity of your comments to be able to provide that information will be particularly helpful, and we look forward to your comments on that.

Another key theme I think it was important to acknowledge in the panel today was the comment about the diversity of operations. And Natalie opened with some comments this morning about the diversity here in California with respect to the, I think, 400 -- over 400 commodities that are grown here in this state alone. And so it's very important that we continue to acknowledge the diversity of farms and acknowledge that this is a process, and we are going to continue to learn from each other as we move forward with implementation.

And so this guidance is in draft form. We'd really appreciate your comments to help improve the content of the guidance, and there are opportunities to continue to update the guidance as we learn from each

other and as we have more scientific information become available. And we appreciate the comments on areas of research that need to be expanded so that we can continue to advance our practices.

So again, please consider submitting comments to the dockets. And the more specific your comments can be, the more helpful it is to us to provide that information that you feel is important to include in the guidance.

Thank you again for all of your comments today.

MS. NAIR: So I think I'm going to volley back to something I heard on the panel discussion earlier today as well. One of the panelists had talked about getting active involvement from every level, and, you know, that creates employee buy-in and helps to, you know -- it facilitates the culture of food safety.

And I think what we're trying to continue to do with this guidance is continue to get involvement, active involvement, from every level as well. And I think we have had some very active involvement and have pulled information from various sources as we discussed during our presentations. We took from TAN inquiries, discussions with various educational partners, regulatory agencies to really build what we have in the guidance. And we want to continue doing that to make sure we continue to build some really meaningful policies and recommendations. So we're really thankful for that and hope that spirit continues.

I also want to talk about something else I heard today. And I really appreciate that there is a further research feed for sanitation of harvest equipment. We are definitely looking for more information on that. So I want to encourage, you know, any research articles or things that, you know, you observe on farms or within your industry groups that has -- have been a discussion item, please submit those because we are really interested in that and tying that into the research need on questions for which no data exists. And again, I'm bringing it back to sanitary

design. That's just one thing that is -- you know, sticks out in my mind.

So again, we look forward to hearing comments on several different issues, but for me at least, these two, specifically.

But thank you.

MS. SMITH: Okay. This morning's panel discussion was kind of like deja vu to presentations we were putting together when we were just earlier presenting our concept for effective compliance and implementation across the board for FSMA.

And one slide, in particular, had three bullet points. And the first bullet was to ensure that people understand what's expected of them. The second bullet is make sure they have the knowledge and the tools to be able to implement or to meet these expectations. And the third bullet point was to ensure consistency in evaluation of implementation and compliance, whether it's between companies, between inspectors, or whatever.

And I think guidance like this draft CNI guidance has the opportunity to help ring all three bills. If you see places in there where it rings the bell, let us know. If there is something that falls short, like some requirement in the rule that you still don't think the guidance has made clear what our intention or expectations are, feel free to tell us. If there are additional examples or tools that people might need that this guidance could help deliver, please let us know what's missing.

And keep in mind a lot of the comments on the panel referred to diversity, not just by commodity group, but by region, condition, practices, size of operation. So if there is something critical that you have an idea for a good example for that's not yet reflected in there, please let us know. And to the extent there are redundancies, let us know, too, so that we can make some room for all this new good stuff.

So thank you.

MS. BARRETT: I just want to give one round of

applause to our FDA panel and to all the people who offered public comment.

(Applause.)

MS. BARRETT: Thank you so much and thank you to everybody who helped pull these meetings together. There was a lot of work that I can't take credit for. But I just want to thank you for pulling this together.

With that, we are going to adjourn. Thank you for giving us your day, and I hope that you found this helpful. And again, we look forward to your written comments to the docket. So thank you again.

(Whereupon, the meeting was concluded.)

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I, Karynn Willman, do hereby certify that this transcript was prepared from audio to the best of my ability.

I am neither counsel for, related to, nor employed by any of the parties to this action, nor financially or otherwise interested in the outcome of this action.

December 12, 2018
DATE

Karynn Willman