

**Standards for the Growing, Harvesting, Packing and Holding of Produce for
Human Consumption: Draft Guidance for Industry 12/13/18**

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FOOD AND DRUG ADMINISTRATION (FDA) PUBLIC MEETING

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DRAFT GUIDANCE FOR INDUSTRY

Docket No. FDA-2018-D-3631

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267 Marietta Street
Atlanta, GA 30313

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A P P E A R A N C E S

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Samir Assar, Director, Division of Produce, Safety Center for Food Safety and Applied Nutrition, FDA

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Trevor Gilbert, Regional FDA Produce Safety Network (PSN) Representative

Adrianna Vargo, Regional FDA Produce Safety Network (PSN) Representative

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P R O C E E D I N G S

MS. McDERMOTT: All right. If everyone could take their seats, please. We're ready to start.

Welcome to today's FDA Food Safety Modernization Act public meeting, focused on the Draft Guidance for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. We understand this is a very busy time of year, and we certainly appreciate you taking time out of your day to attend this meeting.

My name is Cathy McDermott, and I'll be moderating today's meeting. I work in the Communications Division at FDA's Office of Foods and Veterinary Medicine.

I also want to recognize the large audience we have joining via webcast today. Thank you for attending. And please, please mute your phones so everyone listening via webcast can hear clearly.

Before we jump into the program, I just have a few housekeeping items. All of you should have received a folder at the registration desk that includes a number of handouts, including an agenda and biographies for all the speakers. So we'll be brief while we introduce our speakers.

For our web audience, you can also find the agenda on the FDA FSMA webpage.

Today's PowerPoints that are being used will all be posted to the FDA website FSMA page after the meeting -- not right after the meeting, but next week, probably.

If anyone here is a member of the media, if you haven't signed in, please do so at the registration desk.

For individuals who have signed up to make public comments, please see Juanita Yates in the back of the room to let her know that you are here and still doing so.

Everyone just take note of the exit signs, and the restrooms are on this level behind the room.

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This meeting is being webcast and transcribed. The transcript will be posted to FDA's FSMA website. Please note that, for all public meetings, if you are publicly speaking or in the auditorium, there is no expectation of privacy.

It is now my pleasure to introduce our kick-off speakers for this morning. We're very pleased to have Gary Black, Commissioner of the Georgia Department of Agriculture. He will provide the welcoming. And Samir Assar, the Director of the Division of Produce Safety at FDA's Center for Food Safety and Applied Nutrition.

Commissioner.

MR. BLACK: You all okay? Good morning.

AUDIENCE: Good morning.

MR. BLACK: It's going to be a good morning. Thank you. Welcome to Georgia.

Cathy, thank you.

Let me start by saying this. How many of you are from out of town?

How many of you have come from a place where traffic is worse than Atlanta?

I'm not -- I will debate that. I will debate that.

No, but it's good to see you today. I -- this is a very serious meeting. Perhaps on a couple of light notes as we start, I will guard against putting my iPad up against the laptop this morning. I did so at a meeting -- we had a meeting -- had a regional -- actually, a nationwide conference on rural stress here Monday with our University of Georgia. Many other land grants across the country were here. And of course, many of you -- I -- at least some of you may very well know how deep the fissures are in rural America now and the many challenges, both psychological, market-based, and other things. And quite -- actually, the things we will discuss today, I will submit to you that we've got to be careful that we don't contribute to that stress.

But what I did is I contributed to the stress, I think, at the beginning of that meeting because I

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laid my iPad down on top of -- without knowing, there was a notebook there. And when I did so, somewhere in the process, I touched the notebook and the screen came up. And I don't know if the people in the room could see it, but I could see it because the little slide counter was down here. And I don't care how bad a job I did -- and I'm sure the people coming after me did a pretty good job -- but I was looking down there. It said 1 of 96. I said, okay, when I get done, somebody's fixing to show 96 slides. If I just talk for a short period of time, everybody will be all right. So I'll try not to do that here. And I'm sure there are many slides that will be very good today.

Secondly, I will say to you, if you're from out of town, I will not go through the formal procedure, but I would just say to you that if you would like to shoot me a text after the meeting that, by having the meeting here, that if you will commit before the departure of this meeting to spend every dime in your pocket, I can help make you be an honorary Georgia citizen.

(Laughter.)

MR. BLACK: States sales tax dollars support this Department of Agriculture, and we welcome your investment in our future. But we are delighted that you chose and appreciate FDA, our partners, over the -- willing to choose Atlanta for this site. It's a very important topic we'll be discussing today.

Let me frame for you a couple of things about Georgia and our welcome. Number one, we are -- our -- we're very delighted that for the sixth consecutive year in a row, Georgia's been named the number one place in America to do business. We believe in jobs. We believe that our economy is literally on fire. We're excited about that. It comes with the challenges of more people, over 10 million Georgians now, and that's projected to continue to grow.

But we have -- we're uniquely situated in a very interesting market, a very strong transportation system, the busiest airport in America, the fastest-

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growing ports in America. And certainly the fastest-growing eastern -- on the eastern shore, our container ports at Savannah is just absolutely going to be a gateway for all of America.

Many don't know -- and you can debate some of these percentages year-in, year-out -- but it's a very important agricultural port. Even though we think of, you know, the raw commodities at New Orleans and the other places that are very vital, 40 percent of the poultry that is exported from America is actually exported from Savannah. And half of that comes from a farm in Georgia.

So it's just -- we're very proud of our poultry industry. We still lead the nation in poultry production. We lead the nation in peanut production. If the Lord will favor us at least for this coming 2019 year, we've had two years of 80 percent of loss of crop on blueberry. Other than that, we've been the number one blueberry-producing state in the nation. But that -- if those kind of matures -- and anybody from Michigan want to debate that? Okay. I saw you bow up a little bit. So ...

(Laughter.)

MR. BLACK: We -- due to the nature of our -- the age of our crop and those kind of things, we're -- if -- we kind of took that position about three years ago, but the last two years have been very, very tough.

I will tell you this. For generations, we have led the nation in pecan production. It's not likely to -- I don't know if it will happen ever again in our lifetime. Maybe. We're still suffering from the aftermath of Michael. When Michael hit the southwestern corner of the state, which I wish I could be with you all day long, but Natalie in our -- our team is here. But we will be back in Southwest Georgia today with the Weather Channel on trying to keep this in front of our people, I would ask you to continue to -- about 62 counties, about a little over a third of Georgia counties -- we have 159 counties in Georgia, but over a third of them Michael wreaked havoc. We

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have farm families that are suffering. We have rural economies. We have banks that are finding themselves in quite a bit of challenge, not to mention all the other service industries. And just the fabric of rural community has been ripped, and we're trying to keep it before the people.

So we'll leave here in a couple of South Georgia stops today, but we're looking forward to keeping that message out with Weather Channel today. But I'd ask you to keep them in your prayers as we move forward because it's very important that we work together to put those folks back on their feet.

But we had 27,000 acres of pecans that were either destroyed or mangled in such a way that productivity's pretty much going to be challenged. So we'll wait and see where our pecan numbers will go in future generations.

But we're a very important agriculture state. Fruit and vegetable has grown to be very important here, too, partly because some of the challenges of maybe some of the states in this room where we've seen some of the transition from Florida and from California and other producing areas that realize we have 265 frost-free days a year. We have a wonderful aquifer that is rechargeable. It's not one of those, you know, about a -- it's not a depleting resource. It's actually one that replenishes as the Lord provides every year. And it's amazing we go through a tremendous drought. But then in a matter of five or six weeks of rain, and our aquifers are back where they should be. And that bodes well for our future. But that's kind of the framework of this thing that we call Georgia, this place that we love and where we live.

But I want to -- we're very committed, and I -- we are very proud of our food safety team here in Georgia. We are thankful for the recognition from the American Association of Food and Drug officials. This past year has been -- with the recognition of being the number one food safety program. And we're -- Natalie and Brad and the entire team, so proud of y'all. And

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we've made that a goal.

The last eight years, we've worked incredibly hard. We've made sure that resources were available, that technical training was available in ways that we've never done. And see, FDA's a huge part of that. We wouldn't be -- we would not have been able to achieve those goals without your support. And every time you have a program offering, we're -- we try to be there. We want to be a reliable source to you. I know sometimes I'm pretty candid, but that's -- but I think that's good. I think that's healthy. We -- a healthy discussion about all these things is very important.

We were very honored last year to have Commissioner Gottlieb down. And Trevor, we had a great -- we had a couple of good days together to -- it's -- I think when I look at my life's journey or career journey, one of the -- it will be a mark to think of being at 8:00 o'clock on a Friday morning in a Waffle House me and the FDA commissioner and that's it.

And he -- y'all -- anybody know what Waffle House -- y'all know what Waffle House is? If I say scattered, smothered, and covered, do you know what that means?

(Laughter.)

MR. BLACK: Okay. Well, that has to do with hash browns. So he didn't know quite how to respond when I asked him what version he wanted. But then we had a very good, a very healthy discussion, and we were able to get him on the -- literally, on the farms of Georgia.

It's not just the land, not just the facilities, but something that we must all remember. All of us, wherever -- some of you say, hey, I don't work for you. That's -- but I'm -- you don't because you're in your state. But you have folks that you serve. And what we must always remember, when we make decisions, when we have public policy, whether driven by public health, which we all have a huge responsibility there, no doubt about it -- when we all make these decisions, they don't affect the facility.

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They affect a family. They affect the families who have invested their lives in being stewards of the land. And that's where I'll always be the -- be the strong advocate. I hope I'll be viewed that way because we must continue to improve.

We've -- we're a growing society. We -- and there are things that our mutual constituents want us to do. But we've got to find reasonable ways to do that. We've got to find ways to make sure that what we do to our producers that we expect the same out of those with whom we trade. And I think ever since the beginning of FSMA, that's one of the things we've talked about every time there's been a forum is to make sure that our producers are not put at a noncompetitive or a -- reduce our ability to compete on a global scale simply because we have rules that other people do not. And then as we establish our rules and we establish a commitment to make other people play by our rules, we must be in a position to make sure that is enforceable.

And I hope that as we continue -- I really appreciate that. And Dr. Gottlieb -- we've had several discussions on this both publicly and privately, and we've made a lot of progress. And that has to be noted, and I'm very grateful for it.

But I still think there's a lot of wisdom in this room. There's a lot of wisdom behind the camera and various places across the country. And I'm hoping that we can continue to put our wisdom together, our experience together with a servant's heart and mind that there is a family -- there are families we're affecting that affect the productive capacity of this country. And I want us to make sure that, as we move forward, that we continue to -- you know, to build these rules, to build these -- put these tools in place to make sure we can properly serve those families and still meet our responsibilities when it comes to public health.

We -- I want the Agency to know that, when you make an investment with us, we are going to be good stewards. I think we have been, but we recommit

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ourselves as we move forward to -- because I am -- we are very committed from a standpoint of how we manage our Agency, how we work together as a team that our team's going to know what they do and why they do it and then how we manage through those situations to serve people and be good stewards at the taxpayer dollar. And that's a big deal, too, because somebody's paying for all of this. And I never want us to ever get together without us remembering that back home or as a nation that somebody's paying for all -- literally for all of us to be here. And so we've got to be wise stewards as to that time, wise stewards of those financial resources. And I just -- I want you to know that when y'all make an investment in us, we're just going to pay dividends for the people.

So I am -- I wish you well today. I look forward to the proceedings and look forward as we are able to communicate back-ups for the administration on our needs, what are our needs, because -- I'm going to wrap up with that because we have a -- I'm thankful we got a farm bill this week, it looks like. Maybe they'll wrap that up.

I'm hopeful that we're going to see sometime in the next 48 hours at least some commitment on disaster relief, which is going to be very helpful to us -- it's -- and I know in other parts of the country as well.

But I -- we -- we're communicating some things at some pretty high levels today. We have a new administration -- and I'll just leave it at that -- that's -- be coming in here in July. And we're going to be communicating in some pretty important places today. We're going to -- I'm sure there -- part of that's going to be that we've had regulatory reform, and I'm thankful for a bunch of it. There's a lot of things that have helped American producers.

We want to continue to make sure that we have resources that are necessary for FSMA, but they've got to be balanced. They've got to be -- make sure that -- because there are other things like trade agreements

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that, quite frankly, when we're talking about produce, I'm real concerned about, particularly for our state because we've got to make sure we don't have a government-induced stress. And whether it's trade, whether it's regulations, those are the kind of things that we're going to continue to ask, continue to partner with you on. And as far as the State of Georgia, we're going to be committed in everything in our power to make sure that those things are always reasonable.

And so God bless you. I hope you have a merry Christmas. I hope you have a great meeting here today and always count on us to be your partner.

Thank you.

(Applause.)

MR. ASSAR: Good morning. My name is Samir Assar. I'm the director for the Division of Produce Safety. I want to thank Commissioner Black again for being here. We -- it's an honor to share the podium with him. And we appreciate everything he's done and everything that he's doing to make Georgia a very successful agricultural state and a leading state in certain sectors. So we appreciate that.

And I thank you for joining us today to talk about the Produce Safety Rule, compliance, and implementation guidance. And we're here today to share information with you and get your feedback face-to-face.

When we were -- as you know, the draft guidance is open for comment. It's available and open for comment. And yeah, we -- this dialogue that we're having today is really important to the process of making sure we're getting it right.

When we developed the Produce Safety Rule, we found meetings such as these and the conversations that we'll have today just incredibly invaluable to us. And we need to continue this dialogue as we move forward with implementing the Produce Safety Rule. It's incredibly important.

This draft guidance has been a long time in

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the making and longer, perhaps, than what we would have liked. But we wanted to be sure that it was as helpful to farmers as possible. We recognize it's a long document, and it's got a lot of information in there. We wanted to build as many examples into the document as possible that will help growers comply with the rule and also provide useful tools and, ultimately, develop a guidance that is going to be user-friendly. And we'll talk about some of the tools that we developed that will assist you later on in our discussion.

Is it the best that it can be? Well, that's what we want to hear from you. And implementing the Produce Safety Rule is new territory for all of us. And hearing from you -- we're looking forward to hearing from you about, you know, what you think, what changes need to be made to make it a resource that will truly guide farmers to their work to comply with the Produce Safety Rule and implement produce safety practices.

I'd like to touch on the big picture for a minute. The Produce Safety Rule is one of the foundational rules that will create the food safety system envisioned by the FDA Food Safety Modernization Act, one that focuses on prevention with safeguards based on science and risk.

The Produce Safety Rule advances our thinking on produce safety standards that began back when we worked on good agricultural practices all the way back in the late 1990s. That was 30 years ago, and it's been almost eight years since FSMA was signed into law.

But the importance of this mission has been driven home by a number of outbreaks that we've seen this year in produce. And these include at least 77 illnesses of salmonellosis in 9 states tied to precut melons, at least 511 illnesses in 15 states of Cyclospora infection and tied to packaged salads sold in restaurants, at least 250 illnesses in four states of cyclosporiasis tied to vegetable trays, at least 210 illnesses, including five deaths, in 36 states of E. coli 15787 illness linked to romaine lettuce grown in

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and around Yuma, Arizona. And we continue to deal with the challenge of E. coli in leafy greens, as evidenced by the most recent outbreak of E. coli 15787 linked to romaine lettuce.

It's been a tough year for all of us, and it really underscores the need to implement prevention-based standards, the ones that are included in the Produce Safety Rule. When we developed the Produce Safety Rule, we analyzed the root causes of the outbreaks that we've seen in the past and identified the avenues of potential contamination that include agricultural water, biological soil amendments, domesticated and wild animals, worker health and hygiene, and equipment buildings and tools.

And the draft guidance covers all of these areas with some exceptions. And as I'm sure you know, we're reconsidering the water standards and response to feedback that the standards that were in the final rule were too complicated to understand and to implement as well. So the rule-making to extend the compliance states for agricultural requirements for covered produce other than sprouts will soon be final. And we do not intend to enforce the agricultural water provisions in that sub-party of the rule for covered produce other than sprouts while we're going through this process of reconsidering the agricultural water requirements.

And in this process of considering this reconsideration phase, we're looking at how we might further reduce the regulatory burden, increase flexibility while continuing to protect public health. We know water is very important in produce safety. So we are absolutely focused on continuing to protect public health.

Additionally, we are continuing to do work on -- to develop a framework for evaluating the safe use in -- of untreated biological soil amendments of animal original, such as untreated or raw manure. We are involved in multiple research projects that will inform a risk assessment that will be the foundation for

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future policy decisions. And with both agricultural water and soil amendments, we've been and will continue to be actively involved and engage stakeholders throughout the entire process to make sure that we develop the most practical and effective standards.

There are a couple of points that I'd like to point out about the draft guidance. The draft guidance does contain -- this is something you'll hear over and over again all day today -- the draft guidance contains nonbinding recommendations that really provides a mean -- means for us to update our thinking on implementation and account for advancing science, so keeping the flexibility to account for new information that comes about and building that in as part of the process of a longer approach to issuing guidance and addressing implementation and compliance needs.

The guidance provides examples and clarifications and information to help farmers develop their own practices because the Produce Safety Rule generally includes enough flexibility for farmers to implement the requirements in a way that best fits their operation. And so there may be different approaches that will result in compliance.

Our target audience includes those engaged with the implementation on a farm, including the owner, the operator, or agent in charge of a covered farm and farm management personnel. And this also includes organizations that assist farms with implementations such as extension, trade associations, and academia.

Implementation is a long-term process, and we'll be all learning from each other throughout this entire process. And this is the case for both the regulators and for those who are regulated. It's about awareness and changing behaviors and practices as needed and ensuring that the implementation is consistent across the diverse landscape of growers no matter where they're located around the world. And obviously, as part of this process, as part of our regulatory approach, we not only have to think about production here in the United States, we also have to

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think about farms outside of the United States that are offering produce for import into the United States, which is quite a challenge.

Let's talk about moving forward with implementation. Larger farms had to comply with Produce Safety Rule provisions by January 26, 2018. Small farms face a January 28, 2019, compliance date for most provisions. Commissioner Gottlieb did convey that inspections for larger farms that are subject to the Produce Safety Rule will begin in spring 2019. And this was designed to give states and FDA additional time to prepare and also provide opportunities for education and outreach. So FDA also plans to begin its inspections of large operations in foreign countries in spring 2019 as well.

Also, in addition to this draft guidance, there are other resources and tools available to help prepare farmers for inspections, and we continue to collaborate with our partners to advance our produce safety efforts in a coordinated way, which is incredibly critical. And certainly, USDA has a major stake in produce safety. And we've been working closely with the states as well, including the National Association of State Departments of Agricultural in the development of On Farm Readiness Review program. The OFRR program is a voluntary opportunity for farmers to get specific feedback from a team of state regulators, FDA regulators, and other educational partners about how to prepare and how to meet the requirements of the Produce Safety Rule. And so more information about this OFRR program and how to sign up can be found on NASDA's website about On Farm Readiness Review.

FDA has also added staff and tools to engage with our stakeholders. FDA's Produce Safety Network is made up of produce safety experts located throughout the country to provide stakeholders with localized, regulatory, and technical assistance to support compliance with the rule. A network directory of the PSN can be found on FDA's website, and stakeholders are encouraged to reach out to their local PSN

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representative. And we'll hear from a few of them later on today during the panel discussion.

Also, FDA's Technical Assistance Network is available through our website, the FDA website. And it's a central source for information related to the Produce Safety Rule and other rules for regulated or mandated by the FDA Food Safety Modernization Act. I certainly encourage you to take a look at that site because it -- we've heard so much great feedback about how useful of a resource that really is.

And also, I want to point out that our educational partners have made great progress in delivering training programs. FDA and USDA are collaborating to address a wide range of training needs through establishing partners that are aimed at training different audiences, including the tribal, sustainable agricultural, and the international community, as well as small- and medium-size growers, which is critical.

And the Produce Safety Alliance training is an instrumental partner and have implemented over 1,000 grower training courses that have been conducted domestically and internationally. And through these programs, almost 19,000 U.S. farmers and more than 8,000 farmers in other countries have been trained.

We also continue to work with USDA AMS on important farming issues. And FDA formally recognize the USDA's Harmonized Good Agricultural Practices program as aligned with the FDA Produce Safety Rule. And growers have expressed this as a result of -- the activity was really informed by the fact that growers have expressed concerns about facing both market access audits from buyers and inspections for compliance with the Produce Safety Rule. While this recognition does not exempt farms covered by the Produce Safety Rule from state or federal inspections, it is intended to help farmers meet the requirements as efficiently as possible.

And I'd just like to close by saying we've come a long way since the GAP's guidance -- again, 30

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years ago -- and we still have a lot to do. We've advanced produce safety, and we'll need to continue to get ahead of and stay on top of emerging produce safety issues.

And one thing I've learned in all of the meetings that I've attended -- and I think I share my thoughts with my colleagues that are here today -- we all -- we really all want the same thing. And it's about -- we -- consumer confidence because they deserve the safety of fresh fruits -- deserve, really, an understanding and recognizing the safety of fresh fruits and vegetables that are on the marketplace. We want people to eat fresh fruits and vegetables. That's what we are about. We just, again, need to make sure that those fresh fruits and vegetables are safe, which will, again, instill consumer confidence and support a robust market.

And we can't really -- we can't accomplish this on our own. We recognize that. We recognized that from the very beginning. There's a big landscape out there that is -- influences and has been involved with produce safety for a long time before we really came into the picture with FDA's Food Safety Modernization Act. And it's just critical for us to be able to work with our partners to move the ball forward in the right direction. We recognize that, and we've shown that through the establishment of partners as we've moved forward this -- throughout this process. And we will continue to show it, even past the rule-making and the guidance development. Throughout implementation, it's critical that the community and FDA as a whole really stay together and connected on food safety, on produce safety.

So thank you again for joining us, and thank you for your commitment to food safety.

(Applause.)

MS. McDERMOTT: Okay. Thank you, Samir, for your comments. And again, thank you so much to Commissioner Black. I know he's a very busy man, and we certainly appreciate him coming to the meeting today

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and taking time out of his busy schedule.

So at this point, I'd like to invite our first set of speakers, our FDA produce safety experts, up here.

Great. Thank you.

I just want to remind everyone. I forgot to ask that if you could silence your cell phones during the meeting or put into vibrate or something.

As well again to the webcast audience, please mute your phones.

We'll now begin to hear from a number of our FDA produce safety experts. To begin, we have Karen Killinger, Consumer Safety Officer from the Division of Produce Safety at FDA's Food Safety -- sorry -- FDA's Center for Food Safety and Applied Nutrition. Karen will provide an overview of the Produce Compliance and Implementation Guidance.

Following Karen will be Dave Ingram, Consumer Safety Officer, Division of Produce Safety, again, at FDA's Center for Food Safety and Applied Nutrition. He'll be providing an overview on the general provisions, which is Chapter 1 of the draft guidance, and records, which is Chapter 8 of the draft guidance.

Karen.

MS. KILLINGER: Thank you, Cathy.

Good morning, everyone.

All right. The coffee hasn't kicked in yet.

In the back, can you raise your hands if you can hear me okay, please?

Okay. Looking good.

Well, again, I'm Karen Killinger from the Division of Produce Safety, and it's a pleasure to be with you today to share more information about the draft produce safety guidance for industry. I know that many of you have looked forward to the release of this draft compliance and implementation guidance, and we really look forward to having a discussion with you today about the draft guidance and hearing more of your initial thoughts about the draft guidance.

I'd like to take a moment to thank our

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guidance project team for their hard work and commitment to addressing numerous issues. This was truly a team effort within the Division. We had over 16 staff who worked on the draft guidance document. And we made an effort to consider not only the diversity of the farming community domestically, but also internationally as we worked on the draft guidance.

This is an important step as we continue to educate before and while we regulate. And we've received input from state partners, stakeholders, educational partners, and other agencies as we continue with our process towards implementation.

So let's review what that process has looked like to date. The Food Safety Modernization Act, or FSMA, was passed into law in 2011, and FDA was directed to issue a rule to establish science-based minimum standards for the safe production of harvesting and producing fruits and vegetables.

We published the original proposed Standards for Growing, Harvesting, Packing and Holding of Produce for Human Consumption on January 16th of 2013 for comment. Based on initial stakeholder input, we decided to release a supplemental notice, which was a limited reopening of the docket to discuss our current thinking on specific aspects of the rule, and we received additional stakeholder comments through that process.

Then in 2015, on November 27th, we published the final rule, Standards for Growing, Harvesting, Packing and Holding of Produce for Human Consumption, which we'll refer to as the Produce Safety Rule.

The Produce Safety Rule represents minimum standards for the safe production and harvesting of fruits and vegetables. In many cases, the rule is flexible to have requirements that allow ways to account for specific conditions on farms and to reduce risk.

The first compliance date for larger farms, unless they produce sprouts, was in January of this

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year, and the next compliance date is January 28th of 2019. We've delayed routine inspections, as Samir mentioned, until 2019 in the spring to give farms and state regulators more guidance, training, and technical assistance to help ensure they have the tools they need.

Releasing this draft guidance is a step to help farms implement the rule and, when finalized, will describe our current thinking. Similar to the rule-making process, the draft guidance is open for comment, and you may submit comments at any time. But we encourage your comments to be submitted by April 22nd of 2019 so we can take those comments into consideration as we finalize the guidance.

I'd like to note that our efforts with the guidance will continue. We intend to continue to update the guidance because we do anticipate advancing science to influence our current thinking. And also, we fully recognize that we will continue to learn from each other as we move forward with implementation. And we want to account for that in our current thinking as well.

At every stage of this process, we have engaged with stakeholders through public meetings, listening sessions, educational farm visits, and other activities. And we intend for this to continue as we move forward with implementation. This process of communication is essential as we move forward together to achieve our food safety goals.

So let's start talking more specifically about the draft guidance. And on this slide, you can see the chapters that are covered in the draft guidance. They closely follow along with the subparts in the Produce Safety Rule, and we'll have presentations on all of these chapters today, except Chapter 9 on Variances.

I'd also like to mention some topics that are not covered in the draft guidance. At this time, we're choosing not to release guidance related to Subpart Q on Compliance and Enforcement; Subpart R, Withdrawal of a Qualified Exemption; and Subparts E and B with

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respect to agricultural water and alternatives.

As mentioned earlier, with respect to agricultural water, we do not intend to enforce the agricultural water provisions in Subpart E for covered farms -- for covered produce other than sprouts. Farms should continue to use good agricultural practices to maintain and protect the quality of their water sources and 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 draft guidance last year to help primarily sprout operations to comply with the sprout-specific requirements of Subpart M in the Produce Safety Rule. The recommendations in this draft guidance are applicable and may be helpful to sprout operations to take into consideration regarding several other subparts of the Produce Safety Rule.

Finally, I'd like to note that this guidance does not address the farm definition. And the guidance for industry titled Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and Foreign Supplier Verification Programs was issued to state our intent not to enforce certain regulatory requirements, including aspects of the farm definition and written assurances.

Before we move in to talking about the draft produce safety guidance for industry in more detail, I'd like to take a few minutes to review the purpose and content of an FDA rule and the purpose and content of an FDA guidance document, which is summarized on this slide. So as you can see in the first two columns, an FDA rule is comprised of the codified and a preamble.

So let's start by discussing the codified, which is in the first column of the table. The codified includes the specific legally binding requirements. And in many cases, the legal requirements use the word "must." More specifically, the final Produce Safety Rule provides science-based

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minimum requirements, or standards, to reduce risk associated with biological hazards. In many cases, an FDA codified section of the rule provides definitions of terms.

Moving on to the next column, the preamble, the preamble is often the bulk of a rule document. And the purpose of the preamble is to outline our thinking as we develop the rule, the rationale for certain provisions. And for a final rule, we also include responses to comments that we received on the proposed rule.

Now let's move on to talking about an FDA guidance document, as summarized in the third column on the table. Guidance documents contain nonbinding recommendations to assist in understanding how to comply with the rule requirements. Guidance documents, when finalized, represent our current thinking, and, in some cases, we update them from time to time.

Our recommendations in the guidance often use the word "should" or "recommend." In a guidance document, use of the word "must" or the citation of a specific provision number indicates it specifies a rule requirement.

As mentioned earlier, we typically release a draft guidance first and seek comments, and that's the very important stage that we're in right now with respect to this compliance and implementation draft guidance. So we again encourage you to submit comments 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 to our approach as we developed the draft guidance and also highlight some information from the introduction and background of the draft guidance documents.

Regarding our overall approach, we made an effort to keep in mind the diversity of the farming community as we worked on the draft guidance. We understand that there are operational differences that need to be accounted for as well as differences in awareness of food safety topics.

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As a starting point, we reviewed the comments that we received in the preamble of the rule, and we also took into consideration recent scientific literature as appropriate. We also considered what information and materials are available from industry and educational groups. We made an effort to communicate with other groups within FDA as well as other agencies to take into account areas where the rule impacts or can be impacted by the rule to assist in the development of consistent approaches across the board. We also worked with a group of commissioned state representatives that were appointed by ASDO (ph), AFDO, and NASDA to receive feedback on the draft guidance.

We continue to value our engagement with stakeholders as we move forward, and we learned a lot through opportunities to attend meetings, listening sessions, and educational farm visits. And that was really helpful to us as we worked on the draft guidance.

Another important way to communicate with us since the rule has been released has been the Technical Assistance Network, or TAN. I understand that some of you may be frustrated with our response time with respect to TAN inquiries. We've worked to streamline our process, and our response time continues to improve. But please keep in mind that those TAN inquiries allow us to review questions and understand farm-specific scenarios. The TAN inquiries were an important source of information to us as we worked on the draft guidance.

Moving on, there's some key concepts in the introduction and background of the draft guidance that I'd like to highlight. First, I'd like 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, so there may be many ways to comply with a given requirement. You can use an

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alternate approach as long as it satisfies the requirements of the applicable statutes and regulations.

We made an effort to include many examples in the draft guidance to illustrate one or, in some cases, more than one way to comply. In some examples, they illustrate changes that are needed in practices, processes, or procedures based on the requirements. Please keep in mind we did not intend to capture every possible scenario in our examples.

Moving on, in the introduction, the draft guidance states that it's intended to help the owner, operator, or agent in charge of a covered farm -- in other words, you -- as defined in the rule. So many of our recommendations are framed as "you should" to indicate that something is recommended but not required.

I'd also like to mention that many of the definitions from the rule are not listed in the draft guidance, so it may be helpful to review the definitions of the rule as you go through the guidance language. The definitions are found in the codified numbered section of the rule. And for those of you with us today, a copy of the definitions in the rule from the Code of Federal Regulations is included in your packet for your convenience.

Now I'd like to talk about some concepts that are common across many of the chapters. As mentioned previously, many of the rule requirements are flexible, so there may be more than one way to comply. In many cases, the first step is a recommendation to evaluate your procedures, processes, and practices, keeping in mind the framework of the rule requirements to assist you in -- to identify a way to comply that best fits your operation.

The draft guidance also mentions that it's important for you to consider the extent of your practices, including any infrequent practices and how your operations change over time, to ensure that these practices or changes are accounted for with respect to

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the rule requirements.

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

As mentioned previously, we tried to include numerous examples in the draft guidance to illustrate specific concepts, and there's over 51 examples in the draft guidance that use a numbering system within each chapter. There's even more examples embedded in the narrative text of the draft guidance.

With respect to these examples, we generally identify a specific type of covered produce for illustrative purposes. And in several places, we note that, even if you use similar practices and the specific type of covered produce mentioned in an example, you should perform your own evaluation of your farm's specific conditions and practices. In a few places, we also include visual aids, or figures, to help summarize certain information, and these will be introduced throughout the presentations today.

We'd appreciate your comments on these overall approaches to understand if they're helpful to emphasize key points and examples.

So you may be wondering where can I find more information. We have a draft guidance webpage, and that's listed here in the upper, right-hand corner of the slide. At that draft guidance webpage, you can download a copy of the draft guidance.

And we also developed At-a-Glance overviews that are summaries of each chapter of the draft guidance. And these overviews summarize important aspects of each chapter, and we also provide a series of key terms. So these At-a-Glance overview documents are also available for download at our draft guidance webpage, and we hope you'll take a look at those as well.

Moving on, at our final rule webpage, also

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provided here on the slide, we have two fact sheets available, one related to rarely consumed raw produce and one related to everyone's favorite new acronym, biological soil amendments of animal origin, or BSAAOs.

Next, an important way to communicate with us continues to be the Technical Assistance Network, or TAN. If you have questions about the interpretation or applicability of the Produce Safety Rule related to your farm and your specific practices, the TAN is a helpful way to receive information and for us to provide a response to your inquiry. So more information is also available on how to submit a TAN inquiry here on this slide.

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

And I'd like to take some time to introduce a couple of our PSN staff members with us today. We have Trevor Gilbert with the Division of Produce Safety and PSN staff. We have Adrianna Vargo from the Produce Safety Network and Diane Ducharme with the Division of Produce Safety and PSN staff as well.

So thanks for being with us, and we'll look forward to hearing from a couple of you on the panel later today.

In addition to other resources, we have some guidance documents that are available. We've released other guidance documents related to produce, and three of them are listed here on this slide.

First, we have the Small Entity Compliance Guidance, which is intended to help small entities comply with the Produce Safety Rule. And this guidance provides a summary of definitions as well as requirements related to the Produce Safety Rule.

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As I mentioned earlier, we released a draft guidance related to assisting sprout operations to comply with the sprout-specific requirements of Subpart M. And we also recently issued a draft guidance Guide to Minimize Food Safety Hazards of Fresh-cut Produce that discusses how fresh-cut processes may comply with requirements for current good manufacturing practices and requirements for hazard analysis and risk-based preventive controls.

We also intend to publish 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 related to alternate curricula. We also intend to post new and updated questions to the TAN Frequently Asked Questions on the Produce Safety Rule.

So what are next steps for the draft guidance and implementation guidance? This is the fourth public meeting related to the draft guidance, and we really appreciate the opportunity to be here and share information with you today and look forward to hearing more of your thoughts throughout the day on the draft guidance.

Most importantly, you have the opportunity to share information with us on the draft guidance by submitting comments to the docket. For the -- for your comments to be considered, they must be submitted to the docket, and we encourage those comments to be submitted by April 22nd of 2019 for us to take them into consideration as we work on the final guidance.

There are several ways to access the docket to submit a comment, so I'd like to highlight those. One way is to go to the Federal Register Notice, which is available at this website on the slide. And there the Federal Register Notice provides additional information on submitting electronic comments as well as how to submit written or paper comments and provides more information if you want to share confidential information in your comment.

I'd also like to note that in the Background

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section of the Federal Register Notice of Availability, we provide questions where we seek additional information, data, or comment. And we'll mention these questions as we go through our presentations today in Chapter 5 on Domesticated and Wild Animals and Chapter 7 related to Equipment, Tools, Buildings, and Sanitation. And for those of you with us today, in your packet, there is a copy of the Notice of Availability in the Federal Register so you have access to those specific questions where we're looking for more information.

I'd like to take a couple of minutes to tell -
- to talk about information that's particularly helpful to include in comments. We welcome comments both on what you consider positive in the guidance as well as changes that you think are needed so that the final guidance can be balanced and applicable to a variety of circumstances. Commenting on positive aspects of the guidance is helpful to us to know that certain concepts or language should be retained.

We encourage you to submit substantive comments that thoughtfully describe your position on changes that should be considered. Please submit your comments with enough specificity or examples to help us understand any challenges associated with specific farm conditions or practices.

Another way to access the docket to submit comments is to go directly to this website on the slide, www.regulations.gov. And you can either enter the docket number or select a link to go to the site to submit a comment electronically.

So I hope you find that helpful and definitely encourage you to submit comments. And we really look forward to our discussion today with you about the draft guidance. Thank you for being here.

If you have questions related to this presentation, please hold on to them for the morning Q&A session prior to lunch. We'll look forward to those questions.

And we'll now move in to some of the

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presentations for the specific chapters in the draft guidance. Please keep in mind that these presentations are overviews. We don't have time today to discuss all of the chapters in detail. And thanks again for the opportunity to share more information with you, and we look forward to the discussions today.

(Applause.)

MR. INGRAM: Thank you, Karen.

Good morning, everybody. It's a pleasure to be here. I'm glad to see you all.

And my name is David Ingram, and I am a subject matter expert for soil amendments and animals and wildlife intrusion. I work with the Division of Produce Safety Fresh Produce Branch.

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

Now, 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 with which they are 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 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.

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

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Generally, the Produce Safety Rule applies when three conditions are present -- covered produce, covered farm, and covered activities. Note that under the Covered Produce section, there are subsections that discuss produce that is not covered, which we will discuss today 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 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 a 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, and this figure is available on page 8 of the draft guidance. And the link to the PDF version available on our draft guidance webpage is also provided.

I don't have time to walk through each step today, but this is an updated figure summarizing the steps in the order recommended in the draft guidance. We hope you will find this as a useful tool, and we 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 the food that is covered by the rule. And we've received numerous TAN inquiries on these topics.

Thanks to those of you who submitted TAN inquiries on this topic and -- so we can understand your farm's situation and your question. While we cannot address every scenario, we include a discussion of some types of produce that are not subject to the

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rule. We mention 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, such as grains, saps, and algae. 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. 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 removable -- 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 recommend some specific examples of produce RACs and activities that change them into a processed food. 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.

First, 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 to 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 comment on the draft

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guidance.

We determined that these products are almost always eaten cooked. The draft guidance provide some additional clarification on this topic, and we have a fact sheet available online that reviews some information about the rarely consumed raw list.

Produce grown for consumption, personal consumption, or on-farm consumption is also not subject to the Produce Safety Rule. The draft guidance provides some additional information on this topic.

So moving on, we discuss three conditions that you must meet to be eligible for the commercial processing exemption. First, the produce must receive commercial processing that adequately reduces microorganisms of public health significance, such as processing that meets requirements of the low-acid canned food regulation, juice HACCP regulation, or validated processes to eliminate spore-forming microorganisms.

We recognized through stakeholder comments 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 some of your produce is also 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, bills 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.

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You must also maintain documentation of your disclosures. You can keep records of your disclosure statements in several forms, such as by keeping a sample disclosure and a list of associated shipments or copies of documentation for each shipment.

Finally, as indicated on the slide, we announced we do intend to exercise enforcement discretion regarding the written assurance requirements that means -- which means we do not intend to enforce the written assurance requirements while we consider options for these requirements.

So let's move 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 related to what sales to include in your calculations, so we 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 sales sold, not just covered produce, in the applicable three years. Produce sales at farmer's markets, produce sales direct to consumers, or produce sales online would also be included.

Keep in mind the calculations include the previous three years. If 2018 is the applicable year, total produce sales for 2015, 2016, and 2017 would be included in your calculation.

Next, 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 mention that livestock sales are included in food sales as well as sales of hay, grains, wine, and other foods. In the draft

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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 comments on these topics and illustrate -- to illustrate how to perform these calculations. Note that farms that are eligible for a qualified exemption remain subject to modified requirements under the Produce Safety Rule.

And 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 composts a biological soil amendment of animal origin, or BSAAO. The farm needs to implement the relevant rule provisions applicable to this activity.

So this concludes our overview of Chapter 1. And let's move on to Chapter 8.

The topics on this slide list the sections covered in the draft guidance, and the section titles generally align 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 inspections of sprout operations, we observed some challenges with keeping records required by the Produce Safety Rule. It is 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

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Rule that are applicable to your farm.

So let's start with recommendations associated with general requirements for all records. The topics listed on this 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 buildings and fields.

Required records must include actual values and observations. These records should be accurate without rounding, without generalization. For example, records stating "pass," "okay," or "greater than six" should not -- do -- they do not accurately reflect the actual value or the actual observation. These types of records do not ensure that the required measures were taken to minimize hazards and do not allow you to determine trends in the recorded information.

So moving on to another 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 a 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 of the records, and then any necessary corrective measures are performed.

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The draft guidance recommends that supervisors should look for any unexpected results and then follow up as needed. Generally, we believe record review should occur within one week after the record is created. In some cases, shorter or longer time frames could be more appropriate.

Next, the draft guidance describes some examples of ways to comply with the requirements of records storage and format in Sections 2 and 5. We also discuss use of existing records in Section 3. Regarding record 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 these records at the individual growing sites or consolidate them at a single site, such as a 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. Paper or electronic records, or a combination of the two, can be used.

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

Section 7 reviews specific records requirements. There are four chapters of the draft guidance that provide 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

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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.

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

So thank you for your attention. We look forward to hearing from you. Thank you.

(Applause.)

MS. McDERMOTT: Thank you, Karen and Dave. Appreciate that.

At this time, we'll take a 15-minute break, and we'll resume at 5 after 10:00.

Thank you.

(Break.)

MS. McDERMOTT: Hi, everyone. Welcome back. We'll begin again. We'll now here from Karen Killinger again, Consumer Safety Officer, Division of Produce Safety in FDA's Center for Food Safety and Applied Nutrition. Karen will be speaking on Personal Qualifications and Training, which is Chapter 2, as well as Health and Hygiene, which is Chapter 3 of the draft guidance.

Karen.

MS. KILLINGER: Thank you, Cathy.

Let's try this again. Good morning, everyone.

AUDIENCE: Good morning.

MS. KILLINGER: Oh, that's awesome. Thank you. We're waking up.

Well, it's truly a pleasure to have the opportunity to share more information on Chapter 2, Personnel Qualifications and Training, and Chapter, Health and Hygiene, this morning.

So let's start with Chapter 2. This slide lists the sections of the draft guidance related to

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Personnel Qualifications and Training. And we don't have time to discuss all of these sections today, so we selected a few to highlight in more detail. And we do have the section numbers provided on this slide and on later slides to help give you a sense of where the information is located in the draft guidance.

And before we move in to talking about these chapters in more detail, I'm just curious. How many of you have had a chance to look through some of the draft guidance?

Great. That's about 70 percent of the room. That's awesome.

How many of you have looked specifically at Chapters 2 and 3?

All right. Well, as we worked on these draft chapters, we targeted providing recommendations and examples to describe options for implementation on the farm. We considered stakeholder comments, TAN inquiries, and our engagement with 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 in 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 we've received as well as stakeholder comments.

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

As a reminder, all personnel who handle

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covered produce or food contact surfaces or those 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 help 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 this draft guidance provides some examples of those situations.

Moving on to Section 8, 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, part-time, temporary, seasonal, or contracted personnel. The assigned personnel play an integral role in ensuring food safety on the farm.

The operator, agent in charge, or owner 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'll next move into some of the recommendations related to personnel qualifications covered in Section 2 of Chapter 2.

For personnel that handle covered produce or

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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 necessary 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 be able to apply their knowledge and experience while performing their assigned 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 that they have appropriate qualifications for their assigned duties.

Now that we've discussed some of the recommendations for personnel qualifications, let's move in to talking about some of the general recommendations for training. This slide discusses content for Section 3 and Section 4 related to training frequency and easily understandable training. In these sections, 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 that 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 at least once annually. Factors to consider when determining timing of training include the type, number, and timing of your crops and the

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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. In some circumstances, you may choose to deliver training more frequently to target specific topics or activities, such as providing training prior to the growing season and prior to harvesting.

Moving on to Section 4 of Chapter 2, Easily Understandable Training, the slide reviews some of the recommendations around making sure that 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 covered.

In some cases, delivering training at or near workstations can be useful to connect with specific job duties, add demonstrations, 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.

On this slide, we cover training recommendations in Sections 5 through 7 of the draft guidance in Chapter 2. For these sections, we were aware of stakeholder comments from the rule as well as information from our educational partners. The draft guidance discusses that 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 affect food safety of covered produce and food contact services. Further, the training should help personnel understand the roots of contamination so they can recognize how on-farm practices could result in contamination.

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Training should also include your farm's procedures so personnel are aware of your food safety procedures.

Next, the draft guidance discusses recommendations and examples related to the required minimum training content. 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; roots of contamination, such as humans, animals, or pests contaminating covered produce or food contact surfaces or holding an untreated -- handling an untreated BSAO in a way that it contacts covered produce during an application. Other recommended topics include preventive and corrective measures.

Training on health and personal hygiene should ensure that personnel understand they have a 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 that they become aware of that could result in contamination.

Another training requirement specifies that, at a minimum, at least one supervisor or responsible party 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 and is offered as one way to meet this requirement. We'll hear more from some of our educational partners as a part of our panel discussion later this morning.

And this wraps up our overview of Section 2 -- or excuse me -- Chapter 2, and we'll now move on to talking about Chapter 3. Chapter 3 discusses

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recommendations related to health and hygiene. And in this chapter, we were aware of stakeholder comments and expanded on some of these concepts and provided examples to illustrate options for compliance.

The chapter is divided into three main sections, which are listed on this slide. And again, the section numbers are provided on this slide and in 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 summary of some recommendations for each section. So we hope you find these helpful to become familiar with the content of these sections.

In this chapter, communication 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, Chapter 3 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 contamination through hygienic practices.

Now let's talk about Section 1 in Chapter 3. The main bullets on this slide and the next slide list the subsections for Section 1. 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, as well as volunteers or

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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 a 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 who have symptoms of an applicable health condition, and informing personnel who to notify if there is a reasonable possibility that they have an applicable health condition.

Moving on, let's review more of the content related to preventing ill or infected persons from contaminating covered produce. The role of supervisors or 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 hygiene requirements of the Produce Safety Rule.

Now let's discuss some of the content in the section 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

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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 an applicable health condition.

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

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 with certain hazards must use hygienic practices to the extent necessary to protect against contamination. This requirement is not limited to personnel who handle covered produce or 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 the section to help identify steps towards implementation, and these 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, such as avoiding contact with animals other than working animals and wearing jewelry.

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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 personnel are following hygienic practices.

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

Moving on to the role of supervisors, the draft guidance recommends that supervisors and other responsible parties should ensure that personnel consistently follow hygienic practices on your farm. As mentioned on the previous slide, these supervisors or responsible parties 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 on Required Hygienic Practices, the draft guidance provides recommendations and examples related to each of these requirements. And those of you who have looked at the draft guidance know that this is a significant section in the draft guidance with a fair amount of narrative to describe these recommendations and examples on the required hygienic practices and relevant recommendations. The requirements that are covered are included in 21 CFR 112.32(b) and include maintaining adequate cleanliness, thorough handwashing, and using gloves, among other topics.

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 from the rule. Please keep in mind that the term "visitor" is a defined term in the codified of the

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rule.

And the draft guidance recommends that the owner, operator, or agent in charge of a covered farm evaluate the different types of visitors and their interaction with covered produce and food contact surfaces to determine appropriate approaches. There's flexibility in these 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 the location of these accessible toilet and handwashing facilities.

This concludes our overview of Chapters 2 and 3, and we look forward to your questions later this morning as well as your comments on these chapters.

Thank you.

(Applause.)

MS. McDERMOTT: Thank you for that, Karen.

I'd now like to invite our external stakeholder panel to the stage. And I'll be handing the program to Karen Killinger, who will be moderating our upcoming panel with external stakeholders.

Thank you.

MS. KILLINGER: All right. Well, first, I'd like to thank all of our panelists for their willingness to share some of their thoughts about the draft guidance. And we have representatives today from academia, industry, state regulatory partners, as well as members of our Produce Safety Network.

So their bios are provided in the packet, but I'd appreciate it if we could start off by having each of you introduce yourselves and provide a little bit of a summary of your role and your organization's role with respect to the implementation of the Produce Safety Rule, particularly with respect to outreach education and training.

And for our Produce Safety Network panelists, if you guys could take a few minutes in your introduction to describe the role of the Produce Safety

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Network CFSAN staff in comparison to the Produce Safety Network ORA staff, I'd appreciate that.

MS. DANYLUK: You want me to start?

MS. KILLINGER: If you'd like.

MS. DANYLUK: Okay. I'll start.

I'm Michelle Danyluk. I'm an Associate Professor and Extension Specialist, the University of Florida and the Institute of Food and Agricultural Sciences, and I've been at UF since 2007.

So before the rule came out, we were actively involved in training GAPs and HACCP and a lot of focus put on our tomato good agricultural practices within Florida and TBMPs.

Since then, we've transitioned to do a lot of PSA trainings, and I was involved with PSA in some of the early development of the curricula. And I'm currently a PSA lead trainer and a trainer of trainers for the curricula.

For the last three years, I was the PD, project director, on the Southern Regional Training Center for FSMA, which a lot of you in the room have been involved with, involved in working with folks in the states within the southern region to do produce safety and preventive controls trainings targeted at the produce industry.

At the University of Florida, we are also a subrecipient in the CAP funding through our Florida Department of Agriculture and Consumer Services. So we partner very closely with them to do PSA and other important grower training produce safety workshops and On Farm Readiness Reviews in Florida. And I was part of the On Farm Readiness Review team, working with NASDA that was previously mentioned that started back in October of 2015 to develop the On Farm Readiness Review program. And I'm currently involved with training assessors.

MS. ADAN: Nice. I'll bring this down.

I'm Natalie Adan. I'm with the Georgia Department of Agriculture. I am the Food Safety Division Director. We have a farm safety program that

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consists of a program manager. We have a grants coordinator as well as two training and outreach specialists and six field inspectors.

Our focus has been on efforts to collect inventory development. We have received the FDA grant funding to fund our program, which has allowed us to get our staff in place as well as provide the training and outreach programs.

We do have one lead trainer for the PAS -- PSA training course, and we've educated over 700 growers through this course. We work with UGA as well to develop and deliver this course.

We're conducting On Farm Readiness Reviews, and we've received very positive feedback from those that have gone through this voluntary action. All our efforts are focused on preparing growers for the regulatory component that will begin spring 2019.

We work closely with the University of Georgia food science extension, the Georgia Fruit & Vegetable Growers Association, our Georgia Farm Bureau, various commodity groups, and FDA, our PSN staff. And we're actively working with NASDA on regulatory implementation tools to ensure consistency between the states.

MS. KILLINGER: Thank you.

MS. NUCKOLLS: I'm Kelly Nuckolls, and I'm a Policy Specialist at the National Sustainable Agriculture Coalition, or NSAC.

NSAC is an alliance of grassroots organizations from across the country that advocates for federal policy or forum to advance the sustainability of agriculture, food systems, natural resources, and rural communities. NSAC members have worked directly with small- and mid-size family farms, sustainable and organic farmers, and on-farm food processors who conduct activities within the scope of both the Produce Safety Rule and the Preventive Controls Rule for human food.

NSAC members across the country also provide food safety trainings, including PSA trainings and

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technical assistance for farmers and food businesses. NSAC members have also engaged in the FSMA process at the legislative rule-making and implementation stages, and we are very thankful for our continued work with FDA on the implementation stage of the Produce Safety Rule.

NSAC is also currently working on updating and continuing to provide educational resources related to the Produce Safety Rule. And specifically, we are working with AFDO through a cooperative agreement with FDA on developing an alternative curriculum to the Produce Safety Rule for smaller and diversified farms.

We look forward to using this guidance as we develop that curriculum.

MR. GILBERT: Thank you. My name is Trevor Gilbert. I work with the FDA Produce Safety Network.

We are regionally based, and we refer to us as a produce safety with boots on the ground for the FDA where we take the messaging of the Produce Safety Rule directly to our stakeholders and to the farming community.

We specifically provide technical assistance on the Produce Safety Rule. So therefore, we do answer questions relating to the rule, the codified, provide clarifications. We do so directly as we engage in various activities with our stakeholders through conference attendances, giving our presentations and updates on the Produce Safety Rules. And we also do so indirectly more so by email communication, phone calls, or assigned TAN inquiries that suits our specific line of work.

Our key roles also involves educational outreach. As was said earlier this morning, you know, implementation of the Produce Safety Rule is a team effort. So one of our key roles and responsibility is really establishing relationships with our industry partners and stakeholders and also to build on the existing relationships that has been there already to be as effective as we can be in spreading the educational outreach on the Produce Safety Rule.

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So one of the tools that we do use within the Produce Safety Network is educational farm visits where we, in collaboration with our stakeholders, we visit farms to also gain a better understanding of the unique growing practices that families grow within our assigned regions and to better understand the constraints that farmers may face in understanding the rule as well. So we have those opportunities to directly engage to provide those knowledge gaps.

And also, we identify resources that will be helpful in helping those farming communities and stakeholders better understand the implementation requirements to any unique circumstances.

Also, we conduct our educational outreach through On Farm Readiness Reviews, and we do so in collaboration with our stakeholders and also some led by us within the Produce Safety Network. And that - we continue to use that as a tool to help bridge the knowledge gap in understanding the rules and, you know, using the tools to help in getting into compliance and also to build those relationships with the industry as well.

Thank you.

MS. VARGO: Good morning. My name is Adrianna Vargo, and I am also with the FDA's Produce Safety Network. So I am based within the Office of Regulatory Affairs. I'm actually based in Virginia. But I'm one of four ORA PSN who is assigned to states and territories in the southern region.

So within ORA PSN, our focus is more on the inspection and investigation side of things. So that includes things like conducting inspections in states that haven't taken on that function through the cooperative agreement program. We'll be conducting inspections of foreign produce farms because they are held to the same standards as domestic farms. We also can act as a liaison between our state CAP grantees and the larger ORA division and district offices as well and participating in for-cause investigations.

So we do collaborate with our CFSAN PSN

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counterparts on education outreach as well. One area, in particular, has been On Farm Readiness Reviews, again, in those states and territories that aren't offering that program. So we work together closely to be boots on the ground and provide the different perspectives in terms of the rule interpretation questions that come in and the inspectional approach questions that come in as well.

MS. KILLINGER: All right. Thank you all for those introductions. And some themes that I'm hearing among your different roles are that you not only engage with growers, say, through training opportunities, but you also are really emphasizing getting out on the farms to observe specific practices and really understand at the regional level specific practices.

And I also heard that we have that collaboration going on in communication between academia, state partners, and the industry as well as with the FDA staff to help understand those regional differences. And that's really important to us as we move forward. And it's great to have our CFSAN PSN staff that can communicate that information back to us, those of us that work on the policy side within FDA, so that we have that communication in place.

So thank you for your continued efforts and hard work in those areas.

And now I'd like to hear about how you see the draft guidance fitting in with your current efforts related to education, training, and outreach.

MS. DANYLUK: So I'll start again. I got the unfortunate seat as the first one who gets to answer every time.

So we've already shared the draft guidance with our -- with a lot of our stakeholders. We maintain a list of everybody who's been through one of our PSA grower trainings and train-the-trainer courses. And as new information and new fact sheets come out from FDA, we do share those forward. And we often include sort of important tidbits that we took out of those guidance that might be important for them and

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questions we've heard in the past. So we have done that already with all the people we've historically trained.

As we move forward with our grower trainings and our different trainings, we are introducing them to the guidance document. But I think those of you who raised your hands earlier that have been through it know it's a chunk of material, right? It's a lengthy group of material. So we do point them a lot to fact sheets. And then we use the preamble very -- or we use the -- we plan on using the guidance very similar to how we use a preamble. Where there's a specific question, we can search a key word and then pull out what the current thinking is related to that key word. But we do intend to use it going forward.

MS. KILLINGER: That's good.

MS. ADAN: We like to -- we prefer to communicate with our growers face-to-face. But when we're not able to, we certainly use other methods as well as emails and phone calls and things like that. Our activities include the PSA training; On Farm Readiness; outreach events, such as the National Fair; Ag Expo; meeting with specific commodity groups and on farms, answering any questions, bringing awareness to the Produce Safety Rule. And this will be a great tool and resource that we'll be able to bring into that as well to help sort of bring a clear vision and what the expectations are.

MS. NUCKOLLS: NSAC has distributed this guidance document through our membership, and we have already received some answers to some of the questions our members have had related to the Produce Safety Rule, so continuing to answering those questions. And our members will use this as they continue to train farmers throughout the country on the Produce Safety Rule, specifically.

We also will continue to use this guidance as we create our alternative curriculum to the Produce Safety Rule, and it will help guide us, especially the specific examples that we can now provide to farmers

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related to their specific operations. And then we will continue to use the guidance to update the educational resources available on our websites for farmers.

And finally, I'd just like to thank the FDA staff for all the hard work that they put into this guidance. It already has answered several of our questions, and we're really glad that we now have this resource available.

MR. GILBERT: Well, thank you for that.

Just to follow up on your last comment, just to show how we within the Produce Safety Network, the draft guidance, what we visit farms, of course, not all of the practices, activities of a farm may be applicable to the Produce Safety Rule. So as farmers ask specific questions as to how to or what is the draft guidance, we immediately refer them to that -- as a tool, as a resource as to additional reading, simplified language of some these thought processes that they can consider in meeting the minimum requirements that may be specific to their operation.

So it really does give them examples of things they can think about rather than asking us directly, okay, what should we do or what should we not do. So it allows for that additional resource. So yes, we found it to be very effective to point them into that direction as well.

MS. VARGO: So in addition to using the guidance during those education outreach programs like an On Farm Readiness Review where growers are really looking for those specific examples and, you know, to help work through their own scenarios, it's also a resource that we would use once we begin inspections as well because when we're conducting inspections, we want to make sure that growers have all of the resources that are available so that they can meet compliance. So while we're not conducting inspections to the guidance, it's nonbinding. It's a helpful resource to make sure that a grower is aware of.

MS. KILLINGER: Okay. Thanks for that.

So it sounds to me like, in addition to

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distributing the guidance and providing the entire document to growers, which we definitely help appreciate getting the document out and in front of our stakeholders, it sounds like all of you also use the guidance as a way to get out and help farms answer specific questions.

And we appreciate that the document is a long document. And I think it's important to emphasize that the way you all are using the guidance as a tool and looking at where a farm is at what specific questions they have and maybe what practices they really need to focus on, using it as a tool to point them to specific topics within the guidance is really helpful. And we definitely appreciate your efforts to point them to the key information that they really need to help answer their questions and advance with their implementation of the requirements.

So thank you for that.

The next series of questions are really for Michelle, Natalie, and Kelly, as we'd like to hear in more detail about, as you've looked through the guidance, your initial reactions to the document.

And so first, I'd like to hear about some topics or concepts that, as you were looking through the guidance, you thought, wow, this is a really useful area that helps answer some of those questions that you've been getting and what you found to be particularly useful to farmers.

MS. DANYLUK: So I'll start again. I pulled out -- and again, I'll echo the thanks. There's obviously been a lot of effort put into the guidance.

So thank you, Karen, for working on it with your team as long as you did.

But I pulled out four things that, for me, are very, very helpful in the guidance that I've used right away as examples, the first of which is on page 9. And it's a definition of the harvestable portion of the fruit. This is a question we received a lot. What do they mean by the harvestable portion of the fruit?

And so this definition that the -- once the

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harvested or harvestable part of the crop is present, produce is present. And that ripeness or maturity level don't matter, sort of what the statement was in the document.

So when I translate that from FDA speak to how I would say that to a farmer, especially a lot of my growers that are growing perennial crops, I translate that to mean fruit sets. And if that's not what you guys mean, somebody pull me aside later and let me know. But that certainly is how I took that.

And so for a lot of our growers that are growing these perennial crops and have, I guess, fruit on the tree all year round, I can say to them, yeah, so it's fruit sets, and that means that you have fruit on your tree 12 months of the year so that you always have a harvestable portion on it. So I found that really useful.

Karen, you just spent some time walking through Chapters 2 and 3 in the grower training requirements in there, and that was another section that I know me and the team we work with in Florida found very useful.

(Background noise.)

MS. DANYLUK: And I'm sorry I'm not as exciting as the guys that are --

(Laughter.)

MS. DANYLUK: -- behind us.

So the slide starts on page 31 and goes through page 37. And it gives some great examples of what worker training should and shouldn't be. And you guys, even in that part of that document, go through information on looking for sources and roots of contamination, echoing very closely how I know you guys are training inspectors.

So for me, that sort of consistency amongst training was critical. And some of the why's behind the practices and why they're important for growers to do and the information there, again, very important. I like the suggestion of hands-on activities, giving examples of what those training activities could be.

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Things like, you know, actually mixing sanitizers and showing people how test strips work, not dragging hoses across food contact surfaces as examples were really good examples.

And I think, for us, one of the most important things that -- at least our translation, again, of it -- was, is that putting on a training video for half an hour once a year is probably not enough to meet the training requirements. So I thought that was good.

Animal intrusion chapter, again, was a chapter we really liked where your specific examples of what would be significant animal intrusion and what wouldn't be a significant animal intrusion sort of helped us draw a line for when we're teacher growers. And we thought that was really important. And I -- I'll reflect this in some later questions, but I wish we saw more of that in other parts of the guidance.

And then the last one I'll start with before I let Natalie and Kelly talk is, in Chapter 7, which is the Buildings, Equipment, and Tools part, where you guys give some examples of "as necessary." Something we struggled with a lot was where it says, "Clean and sanitize as necessary." And so there are some really good examples in there of when "as necessary" is -- some of the examples given starting on page 9 include every time you perform a wet clean, you should also sanitize; or after contact with animal or human excreta, contact with contaminated water, contact with contaminated produce, excluded produce, or contaminated hands. So I thought that clarification of what "as needed" was, was also a good thing that we could pull out of the guidance.

MS. KILLINGER: Thanks for the -- that, Michelle.

And I'd just like to say I like to think that the people in the other room are also strong advocates for health and hygiene.

(Laughter.)

MS. ADAN: I will echo some of those same comments. We really do like the At-a-Glance documents.

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This is a hefty draft guidance to get through. So for those growers and others that aren't looking to sit down and read a 150-something-page document all at once, they can at least read the At-a-Glance documents and then, in areas and chapters that they need to dig a little deeper, they can go to those specific chapters. So I thought that was really good and hits a lot of the highlights and the key points in those chapters.

The draft guidance helps clarify some areas, such as exemptions, domesticated and wild animal section, like Michelle was talking about, and the burden of responsibility related to training.

We also like the checklist. Checklists are always really helpful, another tool that isn't so in-depth, but that you can take a look at and better understand.

MS. KILLINGER: Thank you for that.

And I just want to ask -- be sure you're using the microphone. I think we're having some difficulty with people in the back and on the webcast. So don't be shy about pulling that microphone towards each of you as you're speaking.

And then if you could also identify yourselves as you begin speaking for our transcriber. I apologize for not mentioning that sooner.

So Kelly.

MS. NUCKOLLS: Kelly Nuckolls with NSAC.

And there are a number of things, specific questions, that we received that we were able to answer because of the guidance. Two specific things that I'd like to mention -- the first one was the clarity around how often growers should monitor for animal contamination. We really appreciated that there were examples in there and that these examples are currently written in a way that's not overly burdensome for growers, but based more in the unique realities of that farm, including the examples for when wild animal occurrence noticed weekly, then you should monitor for that contamination weekly, and if it's seasonal, that you should monitor for it seasonally when appropriate.

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The second big thing that we really liked and we're glad that we could clarify in the guidance was on record-keeping for biological soil amendments of animal origin and that treated BSAAOs from a third party only require annual documentation, such as a certificate of conformance. And we like to see that, you know, it's only required annually. That was a good clarification that we like to see in the guidance.

MS. KILLINGER: All right. Well, thanks to all of you for providing some positive feedback on things that you found helpful. And again, it's really helpful to hear what you like in the guidance.

And now I'd like to hear a little bit more about areas that you found that might need more clarification or things that need to be changed. Or perhaps if there's topics that you found missing in the guidance that you'd like to see considered to be added.

MS. DANYLUK: I don't think this mic is on.

MS. KILLINGER: That could be part of the problem.

MS. DANYLUK: So I'm going to go for this one.

MS. KILLINGER: Oh, great.

MS. DANYLUK: There's no light on that one, so I will talk here. And I'm sorry if you couldn't hear me earlier.

Michelle Danyluk from the University of Florida.

So we did identify some areas where we think there's more opportunity to put more information in the guidance document. And that -- we'll talk a little bit about the soil amendments chapter.

So we spent a lot of time with Dave here in the southern region at two soil summits that went on here. And we were hopeful to have seen more information from the discussion and outputs of the soil summits in the guidance document and, specifically, in that section.

And for example, we spent a tremendous amount of time especially in Texas at that summit talking about agricultural teas, agricultural extracts,

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additions of different nutrients, holding times before application. And we didn't see any specific examples related to that. And we thought we had really good examples at that soil summit, and we wish that some of those could make it into a next version of the guidance.

I'm going to channel now my extension colleague at the University of Florida, Travis Chapin, and talk about worm castings. We left that Texas soil summit with a pretty good thought that a worm was not an animal. And that -- so a worm casting that came from maybe all pre-consumer vegetative waste going into those worms wouldn't come out as a biological soil amendment of animal origin. They -- based on some of the folks up in Vermont, we like to call that a BSAAO now, is how we're choosing to pronounce that -- your acronym.

And the way that the guidance reads is that that worm is now an animal. And so those castings, regardless of what starting material they are, becomes an animal. And those worm castings, regardless of what material started out in there, is that biological soil amendment of animal origin. And that was not what we understood from before, so I think some more clarification around that.

What else am I going to say? I think that there was some more examples in some of the chapters we're going to discuss this afternoon. So Chapter 6, Growing, Harvesting, and Equipment Tools, stuff that begins on page 82, and then in Chapter 7 on the buildings, that starts on page 93. We were hoping for something in these chapters more similar to what happened in animal intrusion where there was sort of a clearly delineated this is okay, this is not okay. We didn't see that as much.

And there's a number of lists of things to consider in those chapters. But exactly what needs to be considered of them maybe was a little bit challenging for us to figure out, or we thought would be challenging for some of our grower stakeholders.

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And so I'll give you an example. There's an example in there where celery is being put into a single-use plastic bag. And it goes through -- and then the example afterwards is honeydew melons being put into fiberboard boxes with wax on them. And they're -- and again, both of those I think are pretty good examples of reusable -- single-use or reusable -- actually, both of them are single-use examples of packing equipment. And in that case, those are the only two examples.

And you give us seven points to consider for these single-use packing containers. But something like an RPC or another reused type of packing container there wasn't an example of. And so it would be great if we can see, for these reused packing containers, what should or sort of logic pattern and thought pattern be for those, similar to what you had laid out in a lot of detail for those single-use packing containers, which I think are the easier of the two for the growers to go with. So we would loved to have seen more example there.

And then again, that sort of -- those long lists of things to consider continue into Chapter 7. And again, not as many example with that clear-cut this is okay, this is not okay decision that was in that animal intrusion chapter. So we'd like to see more around that, particularly around the examples starting on page 101 where you start talking about some of the challenging packing equipment and packing houses, like carpet and foam use, you know. So we'd like to see some more example -- examples there about what's okay and what's really not okay and conclusions to make. Yeah, so we'd like to see more of that.

And then probably my favorite one in the guidance is you guys list on page 10 swamp cabbage as an example of covered produce. So here in the south -- and I'm speaking at least for Georgia and Florida here. Folks in Alabama in the back row, correct me if I'm wrong. For us, swamp cabbage is the heart of a sable palm tree, and it's typically foraged. And then it's

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cooked with a lot of bacon and -- it is really good. And there's a town in Florida called LaBelle where they have an annual swamp cabbage festival. But it's all about this heart of palm.

So when I saw that, I thought I don't think this is what you mean. So I Googled swamp cabbage, and it can also mean -- something that -- on the internet told me it was called Thai water spinach. So I'm curious if you could delineate to us which of these swamp cabbages you really meant by putting it in there as an example.

MS. ADAN: Natalie Adan with the Georgia Department of Agriculture.

When we were looking at this draft guidance, we noticed, as you are providing additional clarity, there's also the opportunity for some possible unintended consequences, especially with so many different types of commodities, practices, and other variables that need to be considered in this. So we're certainly glad that we have the opportunity to not only have this listening session, but also to provide comments.

So I do encourage everyone as you're reading this to provide those comments. Everyone has those different concepts and different ideas. Swamp cabbage is a great example of that where you're thinking of possibly one commodity, but it also includes another one.

Just some examples that we had in the draft guidance on page 19, it appears the way that it's written that you can sell to a bordering country without that 275-mile radius, whereas you cannot -- you're not able to do that in-state. And I think that was just really -- I've got some people shaking their heads. So yes. I think it's just a statement that was not included in the draft.

And just keeping in mind with some people may just be reading that draft. While we will be regulating towards the regulations, a lot -- well, I shouldn't say a lot -- just some people may not be

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reading the actual regulations. And when they read that, they'll be performing in accordance with that.

Another example is, in the draft guidance on page 22, it describes the \$25,000 threshold, includes sales of produce that you purchase that you're selling. This would, the way it's written, also include transfer stations, transfer markets. We have a lot of produce brokers and produce distributors. And I don't know that that was the intent of this. It doesn't appear to be in the final rule. So that's another area that may need to be revisited as well.

We do need more clarity on what the expectation is for harvest containers -- can they touch the ground during harvesting -- just sort of giving some examples in that respect. And definitely with the clarification on what is considered in that 25,000 qualified exemption, we saw that it includes hay. And that was eye-opening for us as well, especially since there's also peanut hay. As you're harvesting the peanuts, you can also harvest the hay and sell that. So is -- are you counting both those commodities in this?

So those are just some of our thoughts.

MS. KILLINGER: Okay. Thank you.

MS. NUCKOLLS: Kelly Nuckolls with NSAC.

One big piece that we thought was missing from the guidance was any guidance on Subpart R, Withdrawal of Qualified Exemptions. We work with a number of farms that will fall within this category, and we would really like some sort of guidance on the thousands of farms that will be impacted by this section, specifically. We'd like some specific examples and conditions that FDA would consider that it's necessary to withdraw the exemption from a farm based on certain conducts or conditions that they think could be a very big concern for the safety of covered produce.

We'd also like clear examples within that section on actions taken by the farm to address circumstances of concern FDA would take into consideration to not withdraw a qualified exemption, so

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any corrective actions that FDA will later decide not to withdraw that qualified exemption.

We would also like some examples on how a farm that has had their qualified exemption revoked can resolve those problems and then be reinstated qualified exempt and also a timeline on when farms could expect for a reinstatement to possibly happen if they have had their qualified exemption withdrawn and exactly what an inspection will look like for a qualified exempt farm.

So that was the big piece that we saw missing. There were two or three pieces, several other pieces that we thought could use more clarity, and I'll talk about two of those. The first one, we would like additional clarity on accredited guard, guide, or service animals. We want the guidance to clearly state that farmers should be in compliance with the Americans with Disabilities Act, or the ADA, and that the Produce Safety Rule does not conflict with the ADA and just that the guidance, if it could add an additional language that this applies to all service animals, not just service dogs. It seemed like service dogs were referenced throughout the document, but there wasn't a clear reference to all service animals.

The second piece that we would like additional clarity on is the potential contamination from grazing animals and if FDA is considering grazing animals as an application of raw manure and, if so, if this could be clearly stated in the guidance. We would like the guidance to have several examples of the recommended time intervals based on the risk factors, including the methods of grazing. And we would like to see examples of how to monitor for animal feces or litter in the potential for contamination at the pre-harvest, harvest, and post-harvest stages.

So those are just a few areas of clarity that we would like to see more examples on.

MS. KILLINGER: Okay. Well, thanks for those thoughts. And I think several of you hit on specific areas where regional practices and terminology are very important. So again, that level of specificity and

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comments so that we understand the details around the scenarios that you'd like to see considered and added to the draft guidance are particularly helpful. So specificity, details, and examples are all really good things to include in comments. And we appreciate you sharing some of those with us today.

So one more question for the three of you with respect to -- did you see any areas of research that really stood out as you looked through the draft guidance that you think we need to move forward with in the future?

MS. DANYLUK: So Michelle Danyluk again from the University of Florida. And as a researcher, I could talk to you all for two hours probably, but I will hold my comments to not that long so we can all have lunch at a reasonable time.

Yes, I saw opportunities for research opportunities. I also just wanted to point out more funding opportunities for research are also really critical. Moving forward, I think I have to say that, somebody who relies on federal research dollars for my work.

We know there's a lot of great work going on, on biological soil amendments of animal origin with the risk assessment that's going on now. We think that there could be additional work going on related to practices and how soil amendments are used. So we know a concern that we've had is, well, what happens if you put your soil amendment under plastic mulch and then punch a hole in the mulch. Does that punching a hole in the mulch really expose that plant to those soil amendments, or are they still mostly noncrop contact? So we think there's a number of areas in soil amendment.

Nobody on the panel's mentioned water yet because it's not included in the guidance document. But we really -- I -- we really believe that agricultural water, production water comprises some of the greatest concerns and confusions with regard to the rule. And we know you are looking at it again, and we

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think there is significant opportunity to look at sampling schemes and indicator organisms and water treatment and transfers of pathogens to crop and survival on crop and that, at a regional level and a national level and an international level, there's a tremendous amount of work that still needs to be done in that area to really make a science-based recommendation.

And also, questions remain about equivalent levels of public health protection under various water management scenarios. I think there's a lot in ag water to research.

Production practices I think is another area where there's a tremendous amount of work that still can be done. One of the areas that I'll point out -- and Samir mentioned it when he spoke this morning about issues that have happened during that last year are the parasitic risks and the Cyclospora risks. And we know very little about Cyclospora survival in farms. When we're composting material, you know, how long do those spores survive? You know, if we've pulled all our plants or (inaudible) all our plants because of the potential for Cyclospora, what's the -- what do -- how long do we need to wait, or how do we even need to clean surfaces that those products might have gone over to really reduce those areas?

Issues, again, of animal intrusion and appropriate buffer zones, depending on issues, still, really, we need more data to make good science-based recommendations on those.

Natalie mentioned harvest containers. I mentioned post-harvest surfaces. Again, understanding that cross-contamination and movement amongst those surfaces along the chain is an area we still don't have a lot of great data. And being able to come up with some sort of a checklist or a prioritized list to be able to say, look, these are the real problem areas in your facility or on your packing house, these are the ones you should prioritize to sort of phase out first, understanding that our growers can't make major

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changes, million-dollar changes, and they really need help to sort of implement smaller changes as they can and guidance on what the most risk-reductive change could be in those post-harvest facilities are just a couple of things that come to mind when we talk about research needs.

MS. KILLINGER: Thanks, Michelle.

MS. ADAN: I really don't have a whole lot to include after that. That's excellent.

I mean, really, developing these science-based regulations and the guidance along with it, that's just so important to have that research. And those are excellent areas.

MS. NUCKOLLS: Yeah. I would like to just echo what Michelle said earlier related to worm castings and if that is considered a soil amendment. We'd like more research on how that could be considered treated and what would be considered treated and, specifically, just as the risk assessment continues to go on, considering other types of soil amendments like worm casting and that research just to make sure that there's a risk-based approach when it comes to those types of soil amendments.

Another area of research that we could see that would be useful for the guidance document, specifically, is any risk-based research around how much produce must be or should be discarded based on either the type of animal first and then, second, the type of animal contamination, so whether it's fecal contamination or saliva and the differences and the risks based on that and how much produce should actually be discarded.

And then related to the Produce Safety Rule, in general, we would really like more research -- or more surveys related to the rarely consumed raw list and, specifically, surveys that would take into consideration any traditional and cultural crops and surveys that would target the population that actually consumes those traditional and cultural crops instead of representation based on the entire population that

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may not consider what the actual population that's consuming those traditional and cultural crops use those products for.

MS. KILLINGER: Okay. Thank you for that.

So there's definitely a lot of opportunities for research. And again, I think that's why we continue to feel that we'll need to take into account advancing science as we move forward. So although we will provide a final guidance version 1, we certainly hope to continue to follow on with that with additional versions so that we can account for these areas of growth within the scientific literature and be able to account for advancing science.

So thanks for raising some of the key areas that may be needed in the near future.

One final question, and this is mostly for Natalie and for Adrianna. But could you speak a little bit as we move forward with implementation to the standards that will be used to evaluate a farm for compliance, and would a farm ever be cited for not following the guidance documents, specifically?

MS. ADAN: This is Natalie with the Georgia Department of Agriculture.

We -- and I think I mentioned this earlier -- we are regulating against the actual regulations, not the guidance. In Georgia, we're adopting -- we're in that process right now -- we're adopting the FDA produce safety regulations. So that's what we'll actually be regulating against. We will be using this guidance document as well as some other tools and resources to help the grower better understand what those requirements are. Maybe some examples that have been described in this guidance documents will be helpful as well. But we certainly wouldn't be regulating against the guidance document. We wouldn't be documenting any observations towards that.

MS. KILLINGER: Okay. Thank you.

MS. VARGO: Oh, and I would just echo that. You know, farms will be inspected to the codified section of the rule.

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This is Adrianna Vargo with FDA.

And we would use the guidance as a resource for the grower for questions and help with examples. But the inspections would occur -- would be towards the regulations themselves and not the guidance.

MS. KILLINGER: All right. Well, thank you again for clarifying and emphasizing that point. And thanks again to all of you for your willingness to share some of your thoughts with us today. We really appreciate it, and we look forward to hearing more from you throughout the day.

So this concludes our panel, and I'll invite Cathy to come back up and take us through the rest of the morning session.

(Applause.)

UNIDENTIFIED MALE SPEAKER: Test, test.

MS. McDERMOTT: Thank you again to our panelists. That was very insightful, and we really appreciate them participating in the meeting and for taking the time out today to do so.

We're now going to open the floor up to questions, and you can approach the podium. There's a mic there. So please feel free to ask a question. When you do, if you could please state your name and your organization because, again, the meeting is being transcribed.

MS. ROGERS: Okay. My question has to do with Section 8, Records.

MS. McDERMOTT: Give your name and your --

MS. ROGERS: Okay.

MS. McDERMOTT: -- organization.

MS. ROGERS: My name is Elena Rogers, and I am with NC State University.

MS. McDERMOTT: Thank you.

MS. ROGERS: Okay. So my question has to do with the addition -- or the requirements that should be in every record. And okay. So specifically, you would have to list the name and location of your farm and then the location of growing or other area relevant to the record and an adequate description of covered

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produce.

So should that information be in every piece of paper? Or should it be -- could it be provided at the -- I guess the first page of your notebook?

MS. KILLINGER: Thanks for that question. And I think --

MS. ROGERS: It's all, you know, information that, I guess, would kind of hone down on where the fields are and what produce is being grown. But when you look at the records required, it's more about, like, you know, we're looking at the qualified exemption, looking at cleaning and sanitation, or looking at your biological soil amendments. So ...

MS. KILLINGER: Yeah. And so I think that's a great question. As you mentioned, there's several areas where you -- a farm could be keeping records. So they may have an area where they're handling and managing their BSAAOs. And they may have another area where they're working on specific equipment and tools that are clean and sanitized, so there would be records associated with that.

And so unfortunately, I think the answer is likely it depends on how an individual farm is choosing to manage and manage their records because they may have multiple locations where the records are being created. And in that case, the individual records would need to have the farm name and location as well as the location of the growing area or activity area on them.

So again, some of this is really going to depend on the farm's choice of procedures to meet the requirements. I'm sorry that I can't be more specific. But you know, I think we really want these rule requirements to be flexible in this case to allow for a variety of records management strategies. And we definitely encourage farms to consider how they are going to manage their records because, as Dave mentioned earlier this morning, that is an area where, in our sprout inspections, we are finding -- observing some challenges with records management. And so it's

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an important area to think about in advance of the coming inspections in spring of 2019.

MS. ROGERS: Okay. Thank you.

MS. KILLINGER: Thanks for the question.

MS. ROGERS: Thank you.

MR. ASSAR: I was just going to say, again, if you have specific thoughts or scenarios that you wish to bring forward in the comments for us to weigh in on through the finalization process, please do that. I mean --

MS. ROGERS: Okay.

MR. ASSAR: Yeah, if -- wherever you think there's a gap or a need and you have some potential solutions or a way to address those gaps and needs, in view of the framework, in view of the existing guidance, then please feel free to provide that.

May name is Samir Assar, by the way.

MS. ROGERS: Okay. Thank you.

MR. ASSAR: Yeah.

MR. McREYNOLDS: Good morning. My name is Roland McReynolds. I'm Executive Director with the Carolina Farm Stewardship Association.

We heard several comments in the last panel, in particular, related to inspections being based on the rule and not on the guidance. Now, for many months, years, inspectional protocol documents have been under development by FDA and the National Association of State Departments of Agriculture to guide inspectors in how they apply the rule when they're going out on farms.

To the extent that there is any daylight between those protocols and this guidance, it creates a huge potential for farmers to be caught with going by the guidance and inspectors thinking -- expecting to see something else. Those inspectional protocol documents were discussed at the On Farm Readiness Review rollout event that was hosted in Raleigh, North Carolina, back in August, and they were promised to be shared soon.

So will they be shared before the April

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deadline for comments on this guidance?

MR. ASSAR: And you're -- my name is Samir Assar, and you're referring to the inspectional approach documents --

MR. McREYNOLDS: That's correct.

MR. ASSAR: -- that are being created by the Food and Drug Administration in collaboration with the National Association for the State Departments of Agriculture.

MR. McREYNOLDS: That is correct.

MR. ASSAR: I can tell you that the inspectional approach documents are very, very, very close to release, and we recognize the importance of those documents. I think the stakeholder community is certainly anxious to see, you know, what -- how are these going to be -- these inspections going to be carried out and implemented. So we want to get that information out there as soon as possible, and both NASDA and FDA understand that and are aiming to do that. I -- yeah. So

(Crosstalk.)

MR. ASSAR: -- specific timeline.

MR. McREYNOLDS: Yeah.

MR. ASSAR: But yes, it's very soon. We're --

MR. McREYNOLDS: Certainly, the opportunity for folks to review those documents and inform their comments on this guidance is of paramount importance.

MR. ASSAR: Absolutely. Thank you for that.

MR. McREYNOLDS: Thank you.

MR. STOECKEL: Good morning. My name's --

MR. ASSAR: Good morning.

MR. STOECKEL: -- Don Stoeckel. I'm with the Produce Safety Alliance. We're a cooperative supported by FDA and USDA through Cornell, and we support 2,000 - - or actually, more than 2,000 trainers. And as such, we get a lot of questions.

So we're really grateful for this document, this guidance document, that helps us answer those questions. But we're also aware, because of the people that we -- the folks that we have trained and folks

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that we support, that, as soon as you answer one question, there's a follow-up question.

So I wanted to take a moment to thank you for this interface because, as we make incremental steps toward clarity, I think having these conversations can help us help you move forward and answer the follow-up questions that get raised on these questions.

So after that, you defined "produce" very nicely, and that helps a lot. I just want to confirm -- and something that could work in the document is that covered produce includes produce that is not exempt or excluded for other reasons, grown on a covered farm that is grown but not sold, not consumed on farm, for instance, for donations. Is that true?

MS. KILLINGER: Yeah. I think we've got some information on produce that is donated and --

MR. STOECKEL: And I apologize if it's in there.

MS. KILLINGER: -- in current document, actually. So yeah, I'm trying to find the page number it's on.

MR. ASSAR: So do you have it? Okay.

MS. KILLINGER: You can go, if you'd like. I think I do have it, though. Sorry.

MR. STOECKEL: So maybe -- I guess I just -- if it is -- assuming it is covered, a clear statement that produce that is grown not for sale would be covered produce still.

MS. KILLINGER: Yeah. So we've got on page 16 in the draft guidance under the 25,000 threshold, it does not include produce for which you do not receive payment or anything else of value in exchange for the produce. For example, produce held without sale or produce donated or given away.

MR. STOECKEL: Right. That doesn't count into your calculations. But is it covered produce?

MS. KILLINGER: So you're --

MR. STOECKEL: Does it have to be grown in accordance with the Produce Safety Rule?

MS. KILLINGER: Are you ask --

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MR. ASSAR: If it's exempt, then it would not need to be -- so if it meets the exemption or the exclusion, then it would not need to be produced in accordance with the Produce Safety Rule.

MR. STOECKEL: So if it's grown for donation, it's not covered produce? Apples?

MS. KILLINGER: I think what you're asking is kind of an intersection between covered produce and determining if you're a covered farm.

MR. ASSAR: Right. Yeah.

MS. KILLINGER: So -- and both. And I think Dave mentioned this morning that, for the Produce Safety Rule to apply, generally, you have to have all three conditions -- covered produce, covered farm, and covered activities.

MR. STOECKEL: Correct. So I was having a conversation with a person in the back of the room. Some farms will grow 10 percent specifically for donation. They are covered farms, they're growing covered produce, and they're doing covered activities, but they're not selling 10 percent of their produce. Is that 10 percent covered produce? And this leads to a question about gleaning.

MR. ASSAR: So I don't think we explicitly expressed that or specifically addressed that scenario in the guidance.

MR. STOECKEL: Right.

MR. ASSAR: So that's an area that we could potentially cover again if --

MR. STOECKEL: Yeah, I would encourage that to be covered.

MR. ASSAR: -- providing comments. Yeah.

MS. KILLINGER: Yeah. And I think it would be helpful to, again, have kind of the details here.

MR. STOECKEL: Yeah.

MS. KILLINGER: So again, the specifics would really help us to --

MR. STOECKEL: Right.

MS. KILLINGER: -- understand the scenario. But we absolutely appreciate you --

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MR. STOECKEL: Yeah.

MS. KILLINGER: -- raising it because it does sound like, particularly, a lot of the topics in Chapter 1 are complex topics. And so having those farm-specific scenarios to help us understand those that need to be described in more detail in the --

MR. STOECKEL: Right.

MS. KILLINGER: -- guide -- in the draft guidance would be really helpful.

MR. STOECKEL: So the follow-up question: If it is covered produce and -- could we get into whether a gleaner who is a person who is on your farm with your permission, not being paid, but is doing a covered activity on covered produce picking up covered produce for the donation, is that gleaner personnel or a visitor for purposes of educational requirements?

And I don't know whether there is an answer today, but it -- that follow-up question would be lovely to include in further guidance.

MS. KILLINGER: Yeah, no. I think we'd love to see a comment in the docket for clarification related to that topic. But thanks for raising it.

MR. STOECKEL: Thank you.

MS. McDERMOTT: Thank you for your question.

MR. INGRAM: I'd like to add a little bit to that, just a general comment. This is David Ingram, FDA.

So just a general overview that our rules associated with the Produce Safety Rule really do contain the minimum baseline provisions that we would expect growers to comply with in order to maintain the safe production of fruits and vegetables. We fully expect a lot of growers to be exempt from the Produce Safety Rule, but we would very much appreciate those growers to also apply these rules. We don't expect these rules to be overly burdensome for most growers. And even if you are exempt, we would appreciate growers to look at the rules and apply them to all commodities grown, even those that are exempt from the rule.

Thank you.

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MR. DE LOS SANTOS: How are you doing?

Richard De Los Santos here with the Texas Department of Agriculture.

And as we move forward with all of this, I really want to thank you all for trying to help make this, you know, the least amount of questions as possible for producers and for those of us who are trying to enforce it because the more questions out there, the more confusing it can be.

The comments that I want to make, not necessarily a question, more of a comment, in Chapter 4 under Covered Farms, you know, we're trying to establish the farm size and require -- it says a three-year average thing, but it also allows for one and two years as well. But maybe there should be some more clarity within those little statements there because -- just so that the growers themselves because they -- well, do I submit just one year, or do I have to wait for two? Just a little bit more clarity on that portion of it.

The other one is the number of employees and projected farm sizes and how do we go about establishing. Those are an example because we're -- because there's some farms with two or three employees that are extremely successful and where others that are not. So is -- it -- the number of employees really doesn't reflect on that farm size.

The other -- Chapter 5 under Covered Activities, the guidance document talks about gift baskets and how you can put covered produced in the same basket of produce that's not covered by the rule. And in Texas, a lot of our gift baskets include grapefruits and pecans, and there's so many different ways to harvest those pecans that are -- definitely are not compliant with the rule if they were to be covered. So that leaves a lot of room for cross-contamination there as well.

And then the last comment on Chapter 8 on modified requirements for qualified exempts is -- I'd like to see if they're going to be required to put the

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-- you know, they have to put the address down. But I'd like to be -- if there is a P.O. Box, that they also include a physical address and not just a P.O. Box.

Thank you.

MS. KILLINGER: Thank you.

MR. ASSAR: Yeah. And I think the range of the questions that we received so far are really reflective of how diverse, you know, the industry is, the sector that's being covered by this -- by the rule and by this guidance really is. And our challenge is to address as many of those scenarios, as many of those cases, the nooks and crannies of coverage, if you will, to the extent possible, to provide clarification, to draw the lines where lines can be drawn.

It's easier for everyone if there is a clear understanding of what's in or what's out or what's -- what you should do or not do or what we -- yeah, you don't do or do. So it's -- where we can do that, we will do that, absolutely. Unfortunately, the challenge with produce is that there's a lot of gray, and I think everyone in this room recognizes that. And so we really need your help to address the gray.

And so the more insights and information that you can provide to help us help you, the better off we'll be in implementing this Produce Safety Rule. When I say "we," I mean (inaudible) we. So ...

MS. ROGERS: Elena Rogers with NC State University.

I have another, I guess, question and concern. When -- I work in training, so I do a lot of Produce Safety Alliance trainings and GAP trainings, spend a lot of time with farmers and -- of all sizes. And one of the concerns that came out when the -- or that I've noticed since the draft came out is the increased responsibilities for supervisors, crew leaders at the -- obviously, at the farms.

And so one of the issues that I have been trying to think about how can we better address is the need for training for those middle management, I'll

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say, or, you know, these crew leaders that may -- sometimes, even though the Produce Safety Alliance training might be a very good piece to introduce or to reinforce food safety concepts, it might not be adequate for crew leaders. It might -- it actually a lot of times goes over their head.

And when you look at all the responsibilities that are assigned to them, this is a huge area of concern. I just feel there could be farm owners that are knowledgeable of basic food safety concepts but that can't really -- they're not educators, so they can't go and really communicate and elaborate on all the expectations that are outlined in the rule, especially when it comes to personnel qualifications and training and to health and hygiene. I mean, and those are just two of the, you know -- everything in the rule rolls down back -- or goes back to who's supervising it, how often are they supervising that things get done correctly, and, you know, ultimately, who's responsible for these things. So I feel there's a gap there in training to really help farm supervisors or crew leaders.

The other thing is that, as I read that whole section and look at the responsibilities, I feel a lot of farms would have to probably hire someone, that that's what they do -- all they do part time and full time. And maybe as we look at, you know, farms that are making over a million dollars, that might be easy to build into their business plan. But when you look at farms that are probably grossing half a million dollars, that really cuts into their, you know, profitability and sustainability. So that's a comment.

MR. ASSAR: Yeah, two very good points. And throughout this process, we've tried to minimize the burden. And we recognize that, obviously, there will be a burden. And yeah, to the extent that we can further minimize where we are now, we'd be more than happy to hear that through the comments.

Also, the -- our rules are certainly -- I mean, that -- those are what we're requiring, and we

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will be, you know, working with the community to foster compliance around. It doesn't mean that operations or commodity sectors or regional groups can't institute practices on top of what we require that will help facilitate the knowledge, the education to the workers that need to know what to do and how to do it.

So we lay out a framework, and it's a bare minimum, or we -- what we say minimum standards. And there is, I would say, an expectation that that will be kind of the starting point for other groups to work from in instituting their own produce safety programs that might be more effective to address the situations, the various contexts that they face on a day-to-day basis. So --

MS. ROGERS: Okay.

MR. ASSAR: -- appreciate both comments.

MS. ROGERS: Thank you.

MR. ASSAR: Thank you.

And the -- and this was Samir Assar.

MR. STOECKEL: I'll take another crack at it. This is Don Stoeckel from Produce Safety Alliance. This one's for Dave.

Records. The guidance did a very nice job of saying that electronic records could be used so long as they held to the same general expectations as written records. But one of the requirements of written records is indelible. Several farms that I have been on keep their records, their log sheets, as spreadsheets, which are a very handy and efficient way of keeping those records, except that you can edit them afterward.

Can you comment on how to maintain electronic records in a way that they meet the indelible requirement?

MS. KILLINGER: Yeah, that's a great question, Don. And we do, again, try to provide flexibility in how folks can keep records. And we understand that electronic records in some cases are more convenient for some farms. And so we definitely want to be able to allow that flexibility.

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And I agree that there may be some challenges around indelibility, but there are programs that can be used to help lock records once they've been maintained. So if you'd like to see more detail around that in the draft guidance or if you see challenges with that record-keeping requirement related to indelibility in electronic records, we'd definitely like to see some comments on that in the docket so we can take that into consideration to add more detail around that particular topic.

Thanks for raising that.

MR. McREYNOLDS: Roland McReynolds, Carolina Farm Stewardship Association.

I would like to go back to Michelle's question just to get verification. The onset of the harvestable portion of the crop with respect to fruit is when the fruit sets; is that correct?

MS. KILLINGER: Yeah. So that's a great question, Roland, and we appreciate Michelle for raising that as well.

So currently in the draft guidance, we talk about the fact that the harvestable or harvested part of the crop, that, essentially, ripeness or maturity does not matter. And so I can see based on your comments that there's some room for additional interpretation. So if you'd like to see more language around fruit sets specifically, again, we'd like to see some comments in the docket --

MR. McREYNOLDS: No, no. I was asking you a question.

MS. KILLINGER: All right.

MR. McREYNOLDS: Yes or no?

(Laughter.)

MS. KILLINGER: I understand. And --

MR. McREYNOLDS: Yeah.

MS. KILLINGER: So -- but what we have in the draft guidance is our current thinking, and it's open for comment. So we really can't provide --

MR. McREYNOLDS: So you do not consider that the current -- that what you represent there addresses

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the question of fruit set.

MS. KILLINGER: I think -- again, I think that you can interpret that language, but we can't really speak to that interpretation until we have final --

MR. McREYNOLDS: Right.

MS. KILLINGER: -- guidance language --

MR. McREYNOLDS: Okay.

MS. KILLINGER: -- because, again, we're looking for more input from all of you on what you'd like to see.

And so we took a step towards interpretation of harvested and harvestable part of the crop in this draft guidance because we were aware that that would be a question that many of you would have. And what I'm hearing is that you'd like to see some additional language or interpretation around this topic because maybe there's still some lack of clarity on how to interpret that language.

MR. McREYNOLDS: Okay. Thank you.

MS. KILLINGER: Thank you.

MS. McDERMOTT: Are there other questions?

MR. STOECKEL: Don Stoeckel, Produce Safety Alliance.

And this refers back to -- I think Roland had mentioned the daylight that sometimes appears and between different sources of information. And in particular, some of the language that we hear sometimes from sources is -- has ambiguity built into it.

And as an example, I want to use the requirements rule in 12.6 for modified labeling requirements. And when we submit questions to the TAN, background information, sometimes our farms are selling -- they're qualified exempt. They're selling at a farmer's market. They don't grow all of their produce themselves. They purchase some of the produce from a neighbor, from a co-op, from a store, or from an auction.

So the question is: What farm where the produce was grown needs to be prominently displayed on a placard, et cetera, et cetera?

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In response to the questions to the TAN, we get the language the relevant farm for the purposes of 112.6 is the farm that is eligible for the qualified exemption. But then it goes on to say and the farm -- or the farm where the produce was grown.

Can you clarify or include in the guidance clarification a qualified exempt farm that is selling produce from multiple farms where it was grown whose name should be labeled? Because that language, the relevant farm is the farm that has the qualified exemption puts a lot of ambiguity into that question.

MS. KILLINGER: Yeah. Thanks for that, Don.

And we do understand that there's a lot of unique scenarios that are specific to certain farms. And we did try to address some of those scenarios in Chapter 1. But again, we may not have included all of the scenarios of interest. So it sounds like you have hit upon one here where you'd like to see more information in the draft guidance.

And I definitely understand where you're going with that question. So I would encourage a comment to the docket that you'd like to see more guidance in the document relative to that specific scenario. And I think that's a great illustration of the level of detail that we need to understand the farm-specific scenario so that we can help craft the language that would be helpful to clarify those particular scenarios.

So again, the more detail you can provide in those comments, the more helpful it is to us.

MR. ASSAR: Yeah. And just to add -- this is Samir Assar -- it's not only, you know, asking the question as you have with TAN. It's also providing your perspective. Where do you think, you know, and who do you think should label? And you know, those are the things that we're looking for as well in the form of comments. We want your -- this is the opportunity to provide your thoughts about where we should draw the lines. And we talk about harvestable portion. You tell us what you think the line should be.

And you know, what we're looking for is

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certainly your comment, your base comment. But to the extent that you can provide a justification for that comment, scientific information, or other information that could support your position on it, that's something that we can use and cite as part of our guidance.

So just please keep that in mind, is we're kind of -- certainly, we were challenged with and did a lot of addressing the TAN questions through that process. I think we were limited, to some extent, as to how we could respond. And some of those questions we did respond in the guidance.

I think this is really an opportunity -- the TAN portal does not really allow the opportunity to provide your perspective on where the line should be. That's really kind of a question-answer portal. The comment period is that opportunity to tell us what the line should be and to provide your justification for what you believe the line should be.

MR. MOSHER: Hi. I'm Mike Mosher with Wisconsin Department of Agriculture, Trade and Consumer Protection.

I've got a list, so I'm going to apologize in advance. But one of the first things that we saw with the draft guidance is the -- when we're talking about covered, you know, covered activities, covered produce -- and what was the third one; sorry for my memory -- anyway, it says that all three must be present but doesn't specify that they must be present at the same time.

We've been asked by growers that, you know, sometimes there is a covered produce present, but, you know, there are no covered activities going on or, you know, or so forth. I think it kind of needs to be stated there that those three conditions -- those three covered conditions must be present and at the same time for it to be considered something subject to the Produce Safety Rule, or at least somehow defined.

Second, when we talk about commercial processing and accompanying documents, the rule states

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that the -- that it should follow the common practices in the industry. Well, one of the common practices in the industry, at least in Wisconsin, is for a grower to actually be contracted by the commercial processor to grow the produce. They basically sign a contract. Someone comes in and plants the produce. The grower just, you know, maintains the produce, waters it, so on and so forth. Then someone else, a third-party contractor even, will actually come in and harvest the produce. And this harvesting activity can sometimes take place in the middle of the night while the grower is not present.

Now, the accompanying documents must go with the produce. The way the rule states and the guidance states, the accompanying documents must go with the produce to the commercial processor. But that's not always practical, especially if, as I said, a third-party harvester comes in, picks the produce, the farmer wakes up, looks outside, and says, oh, well, they've just harvested out of Field A and all the produce is gone.

One of the recommended -- recommendations we've gotten from growers is to have the accompanying documents as part of the contract when the growers signs with the commercial processor to grow the produce for them.

When we're talking about exempt produce and on-food consumption, the guidance mentions employees, but the Produce Safety Rule does not mention employees when we're talking about on-food consumption. So I can see where the guidance, you know, it makes reasonable sense. But it is common on some farms for employees to, you know, take some produce home, but it's also common on some farms for employees to purchase produce from their employer at a discount.

So when the employee does purchase produce or, you know, takes the produce, are they covered? Is that produce considered exempt, or is it still a covered produce?

MR. ASSAR: It would count towards the covered

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produce because it's a sale. Yeah.

MR. MOSHER: Yeah. Well, it might be an example to explore.

Equipment maintenance by third-party contractors -- the way the guidance is written and the way that we've interpreted it is that anybody that comes into contact with produce or food contact surfaces must be trained by the grower. Again, if a grower buys a piece of equipment and they're not qualified to do the maintenance on that equipment, if there -- if any kind of maintenance needs to be done, they'll have a third-party contractor or the person that sold their equipment come and do the maintenance on the equipment.

Well, the way the rules is, before that guy can come in, he had to have some kind of training to work on the equipment. Our recommendation is, is that, if that's a situation that occurs, instead of, like, mandating training for that third-party contractor, just state that the equipment needs to be cleaned and sanitized prior to use for covered activities. I mean, it's kind of a common-sense thing, but, you know, it should be kind of spelled out.

Another thing we were uncomfortable with, with the draft guidance was projected estimates for calculating coverage, whether or not you're covered. The draft guidance says you can estimate a third -- your sales -- or your next-year sales in order to determine whether or not you're going to be covered under the rule. The Produce Safety Rule does not state that anywhere at all. And we'd be very uncomfortable asking a grower to make an estimate, especially considering the -- you know, the great fluctuations in the market and whether or not they're going to be able to even, you know, make a profit from one year to the next. It's just unjustified in -- you know, in the order to ask them to do that.

It would be reasonable for a grower to just say zero; they're not going to make any profit in the next year or the next two years when trying to come up

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with a projected estimate. And there's no kind of enforcement. You know, I know that the draft guidance is a recommendation, but, you know, to make a recommendation like that when it's not explicitly stated in the Produce Safety Rule is going to cause confusion for the grower.

And who determines what qualifies as minimal training requirements? The draft guidance, you know, does make -- you know, state that there are minimum standards that the training -- for training that has to occur for employees, but it doesn't, you know, say who gets to determine what those minimum standards are. From one grower to the next, those minimum standards can vary quite widely to, like, yeah, I gave them a lecture on it this morning before they went out and harvested, especially if they're, you know, just buying day labor. You know, they might document that. But like I said, you know, who determines whether or not that training was, you know, meeting the minimum standards?

I think there must be some effort made to determine what those minimum standards are just so when an inspector gets on the farm he has some kind of basis in which to make it a, you know, adjudication.

And finally, the draft guidance and food safety programs for the supervisor -- it says in the draft guidance you can use other training programs that are equivalent to the PSA grower training class. But the Produce Safety Rule says you must use FDA-recognized -- you can only use FDA-recognized training, or the only FDA-recognized training counts is training -- as appropriate training.

So is there a list of training that's equivalent -- that the FDA would consider equivalent, you know, to cover this? For example, larger farms will hire someone with a degree in food safety. And then to come to that person, you know, he could even have a doctorate in food safety -- produce safety and say have you have your grower training class from the Produce Safety Alliance. You know, he's probably going

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to say, no, I don't think I need that. But according to the Produce Safety Rule, that's the only class that's -- course that's qualified or FDA-recognized. So he would still have to be required to have that. But the draft guidance here says, like, well, it may not necessarily be so.

MR. ASSAR: Okay. And I can provide some clarification, and Karen can weigh in. This is Samir Assar.

So there is actually more flexibility than you cite in the Produce Safety Rule around what the requirements are for training. And you are required to take a training that has been standard -- FDA-recognized standardized curriculum or equivalent. Basically, it offers the same level of public health protection. The rule actually says that. And that would be, of course, supervisors that are supervising those that are contacting who are -- yeah, contacting food contact surfaces.

In terms of is there a list -- and I'll just say the only curriculum that we have recognized so far is the Produce Safety Alliance curriculum. So that might be what you're referring to. That is the only one that we recognized so far.

We are working with groups to develop alternate curricula, which would essentially be -- and through a recognition process. And when that becomes available, we will certainly provide a list of that alternate curricula.

And then there's additional flexibility to -- for others to create equivalent curricula that's not -- it doesn't need to be recognized by FDA. It just needs to be equivalent. So -- and we are putting out a guidance. And that -- that's another one that should issue soon, hopefully, within the next -- in a few months on what our expectations are. It would be issued as a draft guidance, by the way -- what our expectations are, what our thinking is about equivalent curricula. So stay tuned for that.

Do you want to add anything?

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MR. MOSHER: Just a side note.

MR. ASSAR: Yeah.

MR. MOSHER: Last week, we were up at the Great Lakes Expo in Grand Rapids, Michigan. And we came across two vendors that were offering FDA-recognized training. The one that we saw basically did use the Produce Safety Alliance grower training material. The other one, you know, did not want to share what it was that he was basing his training off of.

MR. ASSAR: Interesting.

MR. MOSHER: But again, they were advertising their services to growers as training that they can get in order to comply with the Produce Safety Rule. And so that's kind of like one -- that's why I was wondering about this because it kind of --

MR. ASSAR: Yeah.

MR. MOSHER: -- just got my curiosity going if there were other FDA-recognized training programs out there.

MR. ASSAR: We -- no, so far, no other recognized programs.

MR. MOSHER: Okay. Thank you.

MR. ASSAR: Thank you.

MR. BALASUBRAMANIAN: Ramkrishnan, Florida Organic Growers.

What's the applicability of 21 CFR Part 11 in this guidance document?

MS. KILLINGER: That's a great question. And Part 11 has to do with electronic records.

MR. BALASUBRAMANIAN: Correct.

MS. KILLINGER: And so in the rule, there's a provision that talks about the applicability of Part 11 and that, for the most part, there's an exemption to the electronic records requirements. However, there's a statement, depending on the particular farm, there may be some circumstances where it's applicable. So again, the farm has to really evaluate what -- what's applicable to them with respect to Part 11. But I would point you to the rule for more clarification on

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that.

MR. BALASUBRAMANIAN: Okay. The other question I have is: What's the FDA's current thinking on outreach plan once the final draft -- once the final document -- guidance document is published?

MR. ASSAR: This is Samir Assar. You know, I -- we don't have an outreach plan around the final guidance document yet. But I can tell you what we typically do after we issue a final guidance.

There's generally a lot of interest for us to participate in stakeholder-led meetings. We won't have -- we will -- we're not planning to have public meetings around a final guidance that is usually almost in every case not part of our regulatory process.

So we would count on and rely on stakeholders to set up to lead meetings or -- and invite us to speak. And that just kind of happens organically, or it happens in collaboration with us. And we often get invited to scientific conferences to speak about guidances. And we fully expect that that will happen after the final guidance issues, is that there will be a lot of invitations for us to engage with the community further on the final thinking.

This -- it is important for us to continue to be out there. I mean, one thing that we've done throughout this rule-making process -- and I've mentioned it before -- is stay engaged with the community. We -- this -- we fully recognize that -- you know, you've heard this before, probably from us even -- that this is a marathon, not a sprint. And in our whole mode of operation or our approach to this rule-making has been incredibly measured, involving the proposal and then a -- you know, going back and addressing some of the areas that we heard a lot of feedback on through a supplemental rule, to get more comments on those areas, and then doing a final.

And then, you know, now we're in a position where we're revisiting certain areas based on feedback about implementing those final requirements. It became more real to the stakeholders. Okay. This is what we

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have to do. Wait a second. How are we going to do this?

And so we're reexamining those areas, including agricultural water that you heard about, farm definition, as well as the written assurances area. Biological soil amendments was kind of flagged as -- you know, in the -- you know, earlier on.

So we're -- we recognize that this is going to be an ongoing process. When we say "final guidance," it's final guidance edition 1.

MR. BALASUBRAMANIAN: Okay.

MR. ASSAR: And we'll continue to work on it. That's -- we fully expect we'll be in this mode of developing guidance for a while --

MR. BALASUBRAMANIAN: Okay.

MR. ASSAR: -- because we need to. Yes.

MR. BALASUBRAMANIAN: All right. Thanks.

MR. ASSAR: Mm-hmm.

MS. DANYLUK: So Michelle Danyluk from the University of Florida.

I have a question about tomatoes, specifically. And I think you've heard this one before. Tomatoes are used in the preamble as an example of dropped covered produce. Samir just said, for the record, so yeah, he's heard this one before. And you know, there's different varieties and types of tomatoes, including bush tomatoes that are grown on the ground the same way you'd grow a squash or a cucumber if it's not -- or trellised.

And so in the guidance document on page 88, tomatoes are still listed, along with peaches now, as dropped -- an example of dropped covered produce. And it is expanded to say and -- that drops to the ground before harvest is considered dropped covered produce even if the produce still is attached to the plant where it contacts the ground.

And I would encourage you to put some science, especially around tomatoes, and bush tomatoes, in particular, that if --

MR. ASSAR: Yeah.

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MS. DANYLUK: -- if the cases that you believe they're riskier, maybe we shouldn't grow bush tomatoes anymore, to please put some more science references in there around why.

MR. ASSAR: Yeah. That's -- this is Samir Assar.

That's a very good question, and we've received questions about that particular scenario and using that particular example, or those particular examples, quite a bit at every public meeting we've been to so far.

I can tell you there was a lot of internal discussion about that area, as you can imagine. And so you -- this is one that, yeah, we would definitely want to hear from you about, and we will also count on you to provide some science to say one way or the other -- it should or should not. So we would ask you to provide us some scientific information to say, okay, it shouldn't be this and this is why because the science says this.

MS. DANYLUK: And I would ask you to provide some funding so that somebody could do those studies.

(Laughter.)

MS. DANYLUK: It's Michelle Danyluk, University of Florida. Glad to accept funding.

MR. ASSAR: Yeah. Okay.

MR. DE LOS SANTOS: Richard De Los Santos again, Texas Department of Agriculture.

And I have to go with what Michelle said. For Texas grapefruits, we have the best grapefruits in Texas. They grow big. They touch the ground as they get more weight on them, on the trees. And as -- we're in the middle of a harvest season right now, and that's definitely something we need to be addressing.

MR. ASSAR: Thank you.

UNIDENTIFIED FEMALE SPEAKER: (inaudible - off mic).

MR. ASSAR: Okay.

MR. McREYNOLDS: Roland McReynolds, Carolina Farm Stewardship Association.

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And I will point out I have questions about soil amendments, but I'm going to save those until after we've talked about those.

MR. ASSAR: Okay.

MR. McREYNOLDS: But I did -- with respect to records and the list of the things that are -- that must be kept, as applicable with every record, I guess my question is: Did you all evaluate inclusion of examples where a particular item wouldn't be applicable and, you know, to clarify that for purposes of folks developing their records?

So for instance, if I am applying -- in the fall, if I'm applying untreated compost to a field which I'm going to be turning in to prepare the beds for next year, I may not have decided yet what crop I'm going to put in that particular field. So it would be impossible for me to associate the crop with the record of that handling of the untreated compost in that situation, you know.

So I give that as an example. Obviously, we're asking questions that you all are using to tell us what questions to ask. But I get -- you know, to -- that's kind of the context there.

MR. ASSAR: Yeah. That's --

MS. KILLINGER: Yeah. It -- I think this is a great example of a topic that kind of crosses over into multiple chapters because we have a chapter on records, and new also have a chapter on BSAAOs.

MR. McREYNOLDS: Right.

MS. KILLINGER: And so we'd love to hear if there are specific examples that you think kind of fall between those areas that we should consider including providing, again, that level of specificity in a comment to the docket would be helpful to understand where you see the need for additional examples for components related to records that may be unique to scenarios for BSAAOs or for, say, equipment and tools related to cleaning and sanitizing.

MR. McREYNOLDS: Yeah. Well, I mean, and that's a good point. I mean, I -- but I guess the --

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what I -- but I would want to raise is that with respect in providing guidance under Subpart O, providing examples of what you mean when a record -- you know, of when a record might not be applicable would be helpful for people's thought processes in developing their record-keeping systems for everything that happens on the farm.

Thank you.

MS. KILLINGER: Thank you.

MS. McDERMOTT: Any other questions?

MR. MITCHELL: Hey, y'all. How's it going? My name is Billy Mitchell from the National Farmers Union. A shout-out to my internet fans listening in.

I have a couple of questions for you all. One, I was -- I don't remember how Don put it. I'm individual one in Don's gleaner question. We were talking earlier. Do you want more specifics now? Or do you want those in a written comment? I'm a little confused --

MR. ASSAR: So --

MR. MITCHELL: -- the best process right now.

MR. ASSAR: So there -- written probably would be best. I mean, we have -- and I think it was mentioned -- it was definitely mentioned that the docket will be open until April 22nd, 2019. And so certainly provide your comments through that process.

There's also a comment period as part of this public meeting as well if you want to, you know, touch on that issue during that comment period, so both ways.

MR. MITCHELL: Okay.

MR. ASSAR: This is more of a question-and-answer period, although we've heard both comments and question-and-answers during this period.

MR. MITCHELL: Okay. Thanks.

Yeah, I guess I just have a couple of questions. In the guidance, it talks about liquid handwashing waste, but it doesn't seem to me to recognize that, in some circumstances, the water that you're using to wash your hands could drain into a ground or a pit -- for example, a gravel pit -- without

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causing a contamination issue. Is that something that I'm understanding correctly? Incorrectly? Does that ring a bell?

MS. KILLINGER: Without flipping to the page number --

MR. MITCHELL: Yeah.

MS. KILLINGER: -- exactly, I think we did talk about the need to capture liquid handwashing waste. And I think what you're saying is there may be some additional scenarios that could be acceptable. And so again, we'd appreciate a comment on other ways to capture handwashing waste that limits and minimizes the potential for contamination. So if you could provide a detailed scenario or example as a comment that you think a gravel pit could work to limit and capture waste without preventing -- or without causing contamination, that would be helpful.

MR. MITCHELL: Okay. Thank you.

MS. KILLINGER: Mm-hmm.

MR. MITCHELL: And as far as the qualified exemptions go, I think someone on the panel touched on it a little bit for -- but for, like, a qualified exemption inspection, if someone comes out to my farm -- and I'll be specific. I'm growing for a farm-to-table restaurant and for CSA and for farmer's markets. I know that I'm qualified exempt.

An inspector comes out. Do I just show them my record-keeping financial paperwork, my labeling, and then they say thank you and they go away? Or is there more that happens? I guess I'm wondering if there's going to be more guidance on what happens after I show them my paperwork for my qualified exemption, how that looks.

MR. ASSAR: So in terms of -- so that kind of addresses more of the inspectional approach as well, like, what -- how will we be doing inspections or what will we be looking for during those inspections. I believe that's what you're asking.

MR. MITCHELL: I think so, yeah.

MR. ASSAR: Yeah.

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MR. MITCHELL: Just wondering if, as a qualified exempt grower, if I'll have some guidance about what happens when somebody comes. Do I meet them at the fence line and we do a back-of-a-truck --

MR. ASSAR: Right.

MR. MITCHELL: -- office meeting? Or ...

MR. ASSAR: Yeah, no. That's a good question. And it's something that we can certainly account for as part of our guidance or developing an inspectional approach. As I mentioned, there's interest in the thinking around inspections. How are we going to -- so this guidance is primarily for the industry, targeted for the industry, helping them comply with the rule. But there's going to be a separate set of documents that will be aimed at the inspectors, but we're also making some of that information available to everyone so that they can see firsthand how these inspections will be carried out.

So I think that's an area that we -- that, if not already addressed through the inspectional approach material that we're developing, it can be potentially addressed so you'll have a better expectation and understanding of how this whole process will carry out at the farm level when those inspections are happening for potentially qualified exempt farms.

MR. MITCHELL: Okay. Thank you.

And one last one, I promise. Michelle had mentioned a little bit how it talks about how plastic bags can be considered a single use, and it talks about how produce -- wax produce boxes can be considered single use. And I'm wondering if there can be additional language that, if you're taking a plastic bag and putting it inside a produce wax box, can you continue to reuse that produce wax box. Does that make sense?

MS. KILLINGER: It --

MR. ASSAR: It does.

MS. KILLINGER: -- does --

MR. MITCHELL: Okay.

MS. KILLINGER: -- make sense. So I --

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MR. ASSAR: Yeah.

MS. KILLINGER: -- think what you're getting at is that the plastic bag is really used more as a liner --

MR. ASSAR: As a liner.

MS. KILLINGER: -- for --

MR. MITCHELL: Yes, ma'am.

MS. KILLINGER: -- the wax box. And so I think that's a great illustration of reusable -- you know, kind of the use of a single-use material along with a reusable material. That absolutely is a possibility.

And so we speak in Chapter 6 to both single-use materials and some recommendations around single-use materials and recommendations around reusable materials. And your example has both.

So yeah, that's a great example. And if you're interested in having us add that type of example, I guess -- I think what you might be asking is could the reusable -- or could the wax box be considered a reusable material rather than just a single use. And depending on the farm's practices, it could be. So if you'd like to see those kinds of examples in the guidance, please submit a comment, and we'll take that into consideration. But thanks for the great illustration.

MR. MITCHELL: Okay. And thanks, y'all, for your time. Appreciate it.

MR. ASSAR: Thank you.

MS. McDERMOTT: Well -- oh, Roland.

MR. McREYNOLDS: Roland McReynolds, Carolina Farm Stewardship Association.

Kelly brought up that -- on the panel that this guidance does not address Subpart R with respect to withdrawal of qualified --

MR. ASSAR: Right.

MR. McREYNOLDS: -- exemptions. Do you plan on giving guidance on Subpart R separately from this guidance, or is it something that we should be asking you to incorporate in this guidance?

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MR. ASSAR: Certainly feel free to -- and we welcome you to comment on that we should provide guidance on Subpart R. I would say we are looking to provide more information about Subpart R moving forward. So yeah, add your comment. That will be even a more compelling force to get us to go in that direction, yeah.

MR. McREYNOLDS: Okay. Thank you.

MR. ASSAR: Yeah.

MS. McDERMOTT: Thank you, everyone, for your questions.

We're going to break for lunch now, a slight change to the agenda. It will just be a one-hour lunch break. So we'll meet back here at 1:15, not 1:30 -- 1:15. I believe there are restaurants within the block here. I think there might be some food or beverages set up outside. That's for another meeting in the hotel --

(Laughter.)

MS. McDERMOTT: -- not us. So thank you all and enjoy your lunch.

(Lunch.)

MS. McDERMOTT: Would everyone please take their seats. We are about to start.

Welcome back, everyone. I hope everyone had a good lunch. We are going to continue going through the draft guidance. Going through Chapters 4 through 5 is Dave Ingram. He will discuss Biological Soil Amendments of Animal Origin and Human Waste, and Domesticated and Wild Animals. Dave will be followed by Karen Killinger, who will be discussing Chapter 6 and Chapter 7.

MR. INGRAM: Thank you very much, Cathy. Thank you.

Good afternoon. I am Dave Ingram from the Division of Produce Safety, and I am pleased to provide an overview of two chapters today. The first will be an overview of Chapter 4, Biological Soil Amendments of Animal Origin, or BSAAOs, and Human Waste, the requirements of Subpart letter F, including

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agricultural and human waste. Chapter number 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.

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

Sorry for the technical difficulty. Our computers seem out of sync. I will be looking over my shoulder. Sorry, folks. It must be my magnetic personality to synchronizing the system.

(Laughter.)

MR. INGRAM: Where's the subject matter?

(Laughter.)

MR. INGRAM: Okay. Back in business.

This slide provides an overview of the sections covered in Chapter 4 of the draft guidance. This section's numbers and titles are listed on the slides to provide a sense of where the information is located. As we worked on this chapter, we were aware of comments from stakeholders on the rule, TAN inquiries, as well as our experience on farm tours and participation in several summits.

This presentation is a brief overview of some of the topics in Chapter 4. We do not have time today to cover the entire chapter in detail. The sections in this chapter are designed as a series of steps to help you determine the applicability of the requirements of Subpart F to your farm and to provide recommendations and examples related to each of these topics. The draft guidance provides several figures, summarized lists, and examples, and we hope you find these useful.

The first step is to determine whether your soil amendment, including an agricultural tea, is a BSAAO. There are several definitions provided by the Produce Safety Rule that are important to understanding

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the terms in this chapter. You should refer to these definitions in the Produce Safety Rule. Some of the defined terms are listed on the slide and in the draft guidance.

Section 1 of the chapter provides several examples of BSAAOs, including treating 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 well as other examples. As shown on this slide, the draft guidance provides a figure as a tool to help with this determination. This figure can be found on page 58 of the draft guidance, and we hope you find it useful.

Moving on to the next step is determining whether your BSAAO is treated or untreated. The draft guidance reviews the requirements for a BSAAO, including an agricultural tea to be treated. I'd like to emphasize that the Produce Safety Rule does not require you or your supplier to conduct microbiological testing of treated BSAAOs.

The draft guidance provides several examples of untreated BSAAOs, including stockpiled or aged manure that is not processed to completion in accordance with the requirements, treated BSAAO compost contaminated by untreated manure runoff after treatment, and agricultural tea made from raw manure, among others.

Additionally, the draft guidance lists options for management of untreated BSAAOs, including using it as an untreated BSAAO to cover -- grow covered commodities in accordance with the applicable requirements and treating or retreating it in order to use it as a treated BSAAO to grow covered commodities.

Now let's discuss Section 3, determine the appropriate treatment processes and associated microbial standards for your treated BSAAO. There is flexibility for you to determine a treatment process for your BSAAO. You can use a physical, any chemical, or any biological process or in any combination you

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choose. If you want to consider a BSAAO to be treated, it must be processed to completion using a treatment process that has been validated to meet the relevant microbial standard, as described in the Produce Safety Rule.

The draft guidance notes that FDA does not expect farms to perform validation studies for BSAAO treatment processes. However, farms should ensure that the treatment processes they use have been validated to meet the standards of the Produce Safety Rule. The draft guidance has a section on validation studies to describe our current thinking. We were aware of stakeholder comments from the rule TAN inquiries and soil summit discussions as we worked through this section.

Another topic covered is processes to treat BSAAOs, and this slide provides some of the key recommendations for this topic. The owner, operator, or agent in charge of a covered farm should establish procedures to ensure delivery of the scientifically valid, controlled process throughout the BSAAO, administer treatment processes in a controlled manner to ensure that the treatment parameters established during the validation are achieved throughout the entirety of the BSAAO material. Examples of these parameters include proper blending or turning as necessary and monitoring of time, temperature, moisture content, or even pH.

Finally, you should ensure that the treatment parameters are achieved in areas where the delivery of the process could be more challenging, such as at the bottom or the edges of your pile.

Moving on to Section 4, Determining How to Apply Your BSAAO, in this section we were aware of stakeholder comments to the rule, TAN inquiries, and discussion with growers at soil summits and educational farm visits. The 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.

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First, the application restrictions are based on whether your BSAAO is untreated or treated. There are two different levels of treatments that is microbial standards specified in the rule. And the level of treatment also 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 harvestable or harvested part of the crop both during and after BSAAO application. For example, a broadcast application method usually results in contact with covered produce when the crop is present in the field during application.

In this section, we expand on our current thinking for application of untreated and treated BSAAOs, providing several examples. The draft guidance provides a figure to summarize the requirements related to the microbial standards and application requirements for treated BSAAOs.

While we don't have time to discuss this figure in great detail, we wanted to create a visual aid to assist you in connecting the relevant microbial standards with the application requirements. This figure can be found on page 70 of the draft guidance. It reviews the relevant requirements for treated BSAAOs, including the microbial standards for the different levels of treatment, the application restrictions, and the minimum application intervals. We hope you find this useful tool, and we understand -- we hope this tool is useful to help you understand the relevant requirements.

We also created a figure to review the application requirements and minimum application intervals for BSAAOs. This is a portion of the figure that focuses on the application requirements and minimum application intervals for untreated BSAAOs. The entire figure is located on page 59 of the draft guidance.

In Section 4, we discuss that FDA reserved a provision represented in the first red highlighted row

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of this figure that provides the minimum application interval of untreated BSAAOs applied in a manner that does not contact produce during application and minimizes the potential for contact with covered produce after application.

We are deferring action on an application interval until we pursue certain steps, including a risk assessment and further research. As a result, the requirements for the minimum application interval for untreated BSAAOs highlighted in red in this figure do not differ as of the date publication of the draft guidance.

We do not object to the use of the National Organic Program standards of a 90- to 120-day rule application -- day application interval for untreated BSAAOs applied in a manner described in the first red highlighted row of this figure. We believe adherence to a 90- or a 120-day application interval to be a prudent step toward minimizing the likelihood of contamination while the risk assessment and further research occur.

It is important to note that, although FDA reserved the provision, represented in the first red highlighted row of the table, several requirements related to untreated BSAAOs continue to apply, including those on handling, transporting, and storing your BSAAO and using application methods that prevent direct contact with your produce.

So next I'd like to cover some of the recommendations in Section 5 on determining the requirements for handling, transporting, and storing your BSAAO. The owner, operator, or agent in charge of a covered farm should carefully evaluate your handling, transport, and storing practices for both treated and untreated BSAAOs for the potential to contaminate your growing areas, water sources and distribution systems, other soil amendments, including treated BSAAOs, areas for covered activities, covered produce, and food contact surfaces.

You should remember that untreated BSAAOs

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include incomplete or partially treated BSAAOs and re-contaminated BSAAOs. Further, the draft guidance expands on recommendations and examples related to BSAAO storage practices and locations, personnel and equipment and tools involved with handling, transport, and storage of BSAAOs. Briefly, I'd like to highlight that Section 6 covers the recommendations related to determining what records to keep for your treated BSAAOs, and we look forward to your comments on this section.

I will now move on to discussing Chapter 5. In Chapter 5 of the draft guidance, we were aware of stakeholder comments from the rule, information from other agencies, scientific literature, outbreak investigations, and TAN inquiries.

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

The requirements of Subpart I only apply when covered activities occur in outdoor areas, in partially enclosed buildings, and when, under the circumstances, there is a reasonable probability that animals will contaminate covered produce. FDA supports the colocation of animals and plant food production systems in agriculture. We do not prohibit animals from covered farms.

For this chapter, there are three main sections which are listed on the slide. The section numbers are provide here and on later slides to provide a sense of where this information is located. We describe factors to consider for each of these steps, and we include several examples to illustrate how a farm could evaluate information related to these topics. Please keep in mind that even if you have

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similar circumstances mentioned in these examples, you should perform your own evaluations based on your farm-specific conditions and your farm's specific practices.

In the first section of this chapter, determining whether, under the circumstances, there is a reasonable probability that animals will contaminate your covered produce, the draft guidance provides several recommendations. First, the draft guidance recommends that the owner, operator, or agent in charge of a covered farm 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.

The next recommendation is that you should determine under your specific circumstances there is a reasonable probability that animals will contaminate covered produce in these identified outdoor areas or partially enclosed buildings during the growing season. 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 your covered produce based on the available historical observations of animals and other factors, such as the presence of animal attractants or habitats. The draft guidance expands on some of these factors further.

Wild and domesticated animals, including your own domesticated animals and those from a nearby area, 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 affect whether animals or their waste will be present on your farm. Again, more details are provided in the section of the draft guidance.

It is recommended that you should periodically reevaluate your farm's conditions and practices. Changes on or near your farm could impact the probability that animals will contaminate your covered

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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 covered produce.

I'd like to highlight that, in the Federal Register Notice of Availability for the draft guidance, it was noted that we seek specific comments, information, and data, about factors or conditions that would affect the likelihood of contamination of covered produce by animals. We look forward to your comments on this topic. And for your reference, the Federal Register Notice of Availability is available in your packet of materials.

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 the removable -- the removal of habitat or wild animals from adjacent lands to produce fields.

If you determine that there is a reasonable probability that animals will contaminate your covered produce, you must assess the relevant areas used for the covered activity for evidence of potential contamination of covered produce as needed during the growing season. This would be the second step mentioned in this chapter.

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. There is flexibility in developing your approach to this 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 on your farm. It is recommended that the owner, operator, or agent in charge of a covered farm should periodically evaluate your approach to assessment and modify it as needed.

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This section of the draft guidance 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 also expands on factors to consider related to the types of animals and their potential activity on your farm. Additionally, this section 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 animals will contaminate covered produce.

Moving on to performing monitoring activities that draft guidance recommend that the owner, operator or agent in charge of a covered farm should determine which personnel will conduct monitoring and how they are to perform monitoring, including visual examinations for evidence of potential contamination by animals in the relevant areas.

So let's move on to Section 3, Evaluating Significant Evidence of Potential Contamination of Covered Produce by Animals to Determine Whether Harvest Can Occur. In this section, we took into consideration stakeholder comments from the rule. As a reminder, 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 and take measures reasonably necessary during the growing season 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. Further, several examples are provided to illustrate approaches for determining whether significant evidence of potential

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contamination by animals exists, including scenarios involving monitoring observations that are likely significant evidence of potential contamination and scenarios that are not likely significant evidence of potential contamination. We hope you find these examples useful, and we do look forward to your comments.

So this concludes our review of Chapter 5. I thank you for your attention, and there will be plenty of time for questions later this afternoon. And I leave the floor to Dr. Killinger to cover the next two chapters.

(Applause.)

MS. KILLINGER: Thank you, Dr. Ingram.

Good afternoon, everyone.

AUDIENCE: Good afternoon.

MS. KILLINGER: All right. Can you guys still hear me in the back okay?

Awesome.

All right. Well, I'm looking forward to sharing more information about Chapters 6 and 7 with you this afternoon. These will be brief overviews of these two chapters, highlighting selected recommendations. We don't have time to cover all of the content in these two chapters this afternoon.

And just out of curiosity, how many you -- of you have made it through Chapter 6 and 7?

I even see some smiles. So I'm glad to see that. I know that there's a lot of material and definitely appreciate your follow-through in getting through those. And it's obvious from the discussion this morning that many of you have read these sections in detail. So thank you for that, and we'll look forward to more discussion in the Q&A session this afternoon.

Chapter 6 provides our current thinking and recommendations related to the requirements for Subpart K, and this subpart is applicable to growing, harvesting, packing and holding activities, including the transition points between those phases. Chapter 7

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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 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 chapters, and we hope you find these helpful and look forward to your comments.

Please be aware that, even if you use similar circumstances or produce crops mentioned in these examples, you should perform your own evaluation based on your farm's specific conditions and practices.

Now let's move in to discussion Chapter 6. And again, we're only going to select a few sections to highlight in more detail. So those sections are highlighted in bold here on the slide. And the section numbers and titles are located on this slide and later slides to provide a sense of where the information is located in the draft guidance. Each of these sections directly relates to a specific requirement in the Produce Safety Rule. As we worked on this chapter, we were aware of stakeholder comments on the rule as well as TAN inquiries.

This chapter really covers a diverse number of topics related to growing, harvesting, packing, and holding activities. In several 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 many 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

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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.

So let's move in to some of the sections in Chapter 6. Section 1 on 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 evaluate your 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 occur for covered and excluded produce. And further, you should identify shared equipment and tools as well as personnel that are involved with both covered and excluded produce. The draft guidance expands on these recommendations and provides additional examples.

Moving on to Section 2, Identifying and Not Harvesting Contaminated Covered Produce, in this section, we were aware of stakeholder comments on the rule and expanded on some of these concepts. As a reminder, immediately prior to and during harvest

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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 harvest method. These requirements are intended to be flexible 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 as practicable before the beginning of harvest 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.

Moving on to Section 3, Handling Harvested Covered Produce, the draft guidance recommends that the owner, operator, or agent in charge of a covered farm evaluate practices during harvest, 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 equipment, buildings, and

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tools used for covered activities during and after harvest. There is a great deal of flexibility in the relevant requirement to tailor your 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 activities protect against contamination of covered produce. Practices to consider include avoiding contact between 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 all of these topics in the draft guidance. And 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, and some of these topics have already come up in our discussion today related to food packing materials. First, I'd like to point out how we addressed some overlap in content for Chapter 6 and Chapter 7 of the draft guidance related to this topic, specifically. Food packing materials, including food packaging materials, are subject to the requirements of Subpart K and Subpart L. To minimize redundancy on these topics, we provide draft guidance on aspects of the materials themselves in Chapter 6.

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

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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 here on the slide.

So one of the topics that came up this morning is a first step is a recommendation to identify the types of materials that you use for food packing materials and determine whether those materials are 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. And 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.

Continuing on with Section 6 on food packing materials, the draft guidance expands on evaluating your practices and your food packing materials. The 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 can occur over time, such as the use of certain materials or your practices.

The draft guidance lists factors to consider, many of which are listed here on this slide. And some of them include the type of material -- for example, whether it's wood, plastic, foam, or cardboard; the nature of the material, whether it's smooth, coarse, porous or nonporous, or absorbent; the durability of the material -- how the material is constructed; the existing condition of the material -- for example, whether it is intact, scored, cracked, or damaged; your maintenance practices -- for example, repairing or replacing worn or damaged components; as well as

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handling and storage practices, such as how the materials are received and prepared for use, among others practices.

As we discussed this morning, there are also some examples to illustrate how a farm could evaluate food packing materials and their use specifically related to plastic bags and cardboard -- wax cardboard boxes, and we hope you found these useful to describe some of our current thinking and examples.

So this concludes our brief overview of Chapter 6, and now we'll move on to Chapter 7. This chapter has four sections, Equipment and Tools, Buildings, Other Sanitation Methods -- Measures, and Records. Again, the section numbers and titles are provided on this slide, and section numbers are included on later slides to help provide a sense of where the information is located.

We'll be covering three sections in this presentation, which are in bold on this slide. And as you know, there is an extensive number of topics in Chapter 7, and we can only cover some of them today.

As we worked on this chapter, we considered stakeholder comments from the rule, TAN inquiries, experiences from our educational farm visits, experiences from our outbreak investigations, and engagement with educational partners.

The topics of this chapter are important to consider. Based on our inspections of sprout operations to date, the most frequent area for citations related to the requirements of rule are citations related to Subpart L, particularly with respect to equipment, tools, and building. So the content of this chapter may be helpful to farms, including sprout operations, to assist with implementation of the requirements.

So let's start with Section 1 on Equipment and Tools. At the beginning of this section, the draft guidance summarizes key steps for implementation related to equipment and tools based on the requirements, which are listed on this slide. And

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again, we only have time to cover a few of these today, and those are 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 there are additional recommendations related to some aspects of food packing materials in this section of the draft guidance.

So I'd like to talk a little bit about this first step. It's important to identify the equipment and tools subject to the requirements of Subpart L. So the first recommended step is to identify equipment and tools that are intended to or likely to contact covered produce, including instruments and controls used to measure, regulate, or record conditions.

You should visually assess your covered activities and your growing, harvesting, and packing and holding areas to identify 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, we believe additional information would assist us, and we seek specific comment, information, and data on the following question: When acquiring equipment and tools, how do you engage with equipment and tool suppliers about the design, construction, and size of your buildings so that they can accommodate your equipment and tools?

I think I need to go back one, please.

UNIDENTIFIED MALE SPEAKER: (inaudible -off mic).

MS. KILLINGER: Okay. Okay. Great. Thanks.

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

The draft guidance recommends evaluating your

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materials used to make equipment and tools and the impact of these materials and their construction on adequately cleaning and properly maintaining them. You should evaluate the design, construction, and workmanship of the equipment and tools. And the draft guidance recommends considering several factors, and that includes the ones listed on this slide.

We recommend that you use equipment and tools made from nonporous materials to the extent practical.

However, we understand that some covered farms use equipment and 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 and 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 and properly 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, 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 packaging materials; the frequency of these inspections; the personnel involved; conditions that should be reported to you, a 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

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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 text in the draft guidance of Section 1 for Equipment and Tools. We were mindful of stakeholder comments on the rule, questions we've received through the TAN, and our experiences on educational farm tours as we worked on this chapter.

There is a specific subsection in Section 1 that provides examples that uses the 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 these examples, the evaluation leads to a change in equipment and tools, practices, or procedures. And in others, the evaluation does not lead to a change in equipment and tools, practices, or procedures.

These examples are intended to illustrate our current thinking related to the evaluation of food packing materials, including harvest containers and equipment and tools that use wood, foam, and carpet, among other topics, and we hope you find the examples helpful and look forward to your comments.

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

So let's start with the key recommended steps that are summarized at the beginning of this subsection, and they're listed here on this slide. 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 nonfood contact surfaces of equipment and tools and determining cleaning practices as necessary -- and, as necessary and appropriate, sanitizing practices for each type of equipment and tool and the

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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 nonfood 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. There is also 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 data 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 comment on this specific question. And for your reference, in your packets, you have the Federal Register Notice of Availability that includes these questions so you have access to them.

Now let's transition into talking about Section 2, Buildings. The subsections are listed on the slide, and we'll cover some content today related to size, design, and construction of buildings as well as pest control.

First, I'd like to highlight an overall recommendation for buildings. The first recommended step is to identify all full -- excuse me -- all full -- fully enclosed and -- excuse me.

The first recommended step is to identify all fully and partially enclosed buildings that you use for covered activities. Many of the requirements related

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to buildings are intended to be flexible to accommodate a wide number of buildings that are -- farms use for covered activities.

Now let's discuss some of the more specific recommendations related to 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 the operating conditions in each building. This includes an evaluation of the building materials as well. The draft guidance discusses several factors to consider, and many of these are listed on the slide, so I won't read through them. This section also provides examples.

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

Let's move on to some of the recommendations related to 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, weeds, 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 help develop pest-monitoring activities, and the draft guidance lists several factors to consider when establishing monitoring frequencies. This 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.

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Moving on to Section 3, Other Sanitation Measures, this slide provides the topics covered in Section 3, and we'll discuss only some of the content related to handwashing facilities in more detail.

This slide provides an overview 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 location of handwashing facilities to accommodate typical number of people accessing these facilities.

The draft guidance discusses recommendations for the accessibility for use, such as near 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, and cleaning and sanitizing procedures and schedules for handwashing facilities. These activities should be performed at a frequency that ensures they remain sanitary.

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

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

This concludes our overview of Chapters 6 and

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7, and we're glad to have had the opportunity to discuss these topics with you today. We look forward to your comments on these chapters, including our requests for specific comments, information, or data related to the question in the Federal Register Notice.

Thanks for your attention.

(Applause.)

MS. McDERMOTT: Thank you, Dave and Karen, for your presentations.

We'd now like to open up the floor again for questions and answers. Again, if you could approach the middle of the room, the podium, and state your name and organization before you ask a question.

MR. McREYNOLDS: Good afternoon. My name is Roland McReynolds, Carolina Farm Stewardship Association.

And with your all's permission, I have several questions related to soil amendments. I think I'll just go ahead and ask them all at once instead of the charade of one at a time back and forth, if that's okay with everybody else, too.

First question relates to -- and this is unclear if this is a domestic animals issue or a soil amendments issue, but that is the question of grazing animals that are integrated into the farm's production, where animals graze a field of one season of one year and at a future time there may be produce planted in that field. That situation does not seem to be squarely addressed in Subpart F or Subpart I.

However, Chapter 7, related to facilities, does specifically provide an example that calls for storing the animal excreta from grazing animals away from production areas and by using berms and so forth as a barrier. So that -- if that is the only time that you're talking about grazing animals, it actually creates an implication that grazing -- that there shouldn't be animals that graze in fields that grow in produce areas.

So I mean, I know you're all aware of this issue. I'm curious as to why it wasn't addressed in

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either Subpart F or Subpart I and what kind of guidance you might be looking for to allow that issue to get elaborated upon in this guidance.

MR. INGRAM: Testing, testing. Thank you, Samir.

So David Ingram, Division of Produce Safety and FDA.

Thank you. Yes, we are aware that grazing and the colocation of animals in general where produce activities occur are not specifically addressed in Subpart F. And the reason is mainly because Subpart F is associated with amending your soil specifically for the purpose of increasing the nutrient and soil properties, physical properties of the soil, specifically for growth of covered commodities under the Produce Safety Rule.

While we understand grazing operations and produce operations may be associated in the sense that there might be some time between the finalization of the grazing activities and then the preparation of those same fields for the growth of propagation of produce, we felt it wasn't appropriate to address directly in Subpart F because the grower is not concentrating that manure product and targeting that manure in specific areas destined for produce production.

So there's a difference in risk that I'm trying to get at in that that risk is not -- it doesn't support including grazing activities under Subpart F. Our risk assessment and research activities are ongoing right now. I don't expect those activities to change our approach.

And what I'm hearing is it would be very useful for FDA to consider coming forth with guidance documents that specifically addresses the colocation, grazing, and even draft -- use of draft animals during the production of covered commodities, which is we fully support as well.

So --

MR. McREYNOLDS: Okay.

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MR. INGRAM: -- I hope that helps clarify.

MR. McREYNOLDS: Yeah. Well, and not to the draft animals point, but in terms of the rotational grazing piece, at least. I mean, it -- clear explanation that this should be evaluated under the wild and domestic animals framework would all -- you know, but that's -- it's easy to make that risk assessment. So you know, that would -- you know, that would be a place that it might fit.

And I'm sorry --

MS. KILLINGER: Yeah, no. I think you've raised a great point, Roland, and I appreciate you --

MR. McREYNOLDS: Sure.

MS. KILLINGER: -- bringing it up. And I don't know if -- how many of you in the room recall, but we did kind of reorganize our discussion a little bit in Subpart I from the proposed rule to the final. And if I'm remembering correctly, we did have designation of grazing, working animals, and animal intrusion in the proposed rule. And we broadened that out in the final rule to domesticated and wild animals.

And so in many places in the draft guidance -- and I'd ask you to take a look at page 75 -- we talked about the fact that wild animals include -- or wild animals -- and we provide some examples of wild animals. And we also provide some clarification with related -- with specific reference to domesticated animals like feral, grazing, and working animals --

MR. McREYNOLDS: Right.

MS. KILLINGER: -- to try to clarify that, under that umbrella of domesticated animals, grazing animals are included.

MR. McREYNOLDS: That's what I -- that's --

MS. KILLINGER: And so the terminology in the draft guidance when we say "domesticated animals," obviously, not every farm is going to use grazing animals, specifically. And if you'd like to see more examples related --

MR. McREYNOLDS: Yeah.

MS. KILLINGER: -- to grazing, we'd love --

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MR. McREYNOLDS: Okay.

MS. KILLINGER: -- to hear some comments in the docket.

MR. McREYNOLDS: Terrific. I appreciate that point.

MS. KILLINGER: Thank you.

MR. McREYNOLDS: Next item I wanted to address relates to untreated biological soil amendments of animal origin. On page 68 of the guidance, it specifically says that the application of these amendments to root crops does not meet the requirements of 21 CFR 112.56(a), implying that, regardless of an application interval, if there ever is an application interval established for materials under 56(a), that these materials still won't be able to be used for root crops. And that is contravention of the National Organic Program and your later statement, maybe even on the same page, or certainly in a later page, that following the NOP, it would be an acceptable practice. So clearly, NOP envisions the use of untreated soil amendments in growing root crops. You just have to apply them more than 120 days prior to the crop.

So I guess I'm interested in some clarification in that apparent kind of discrepancy.

MR. INGRAM: Okay. Again, a really good topic, and it's one which we're fully aware. And we're -- we are working through a regulatory approach.

Currently, yes, if you read the codified, it does differ a little from the language in the guidance, which might further change, pending our risk assessment activities, which we're currently ongoing. So the codified does say you cannot apply raw manure on any untreated BSAAO, including raw manure, in a manner that contacts produce directly.

MR. McREYNOLDS: Right.

MR. INGRAM: And in most people's minds, that means, okay, don't broadcast raw manure across leafy green crops. But it also means that root crops, when planted, are in direct contact with the soil amendment that you just put into the soil. So root crops are, by

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definition, in direct contact. And that is not allowed, according to the codified.

If you look at our guidance example where we do have an example of root crops, we do say -- we have an interesting word in there. And that -- it says "immediately." So you shouldn't plant root crops immediately --

MR. McREYNOLDS: Right.

MR. INGRAM: -- after you incorporate raw manure or any untreated BSAAO into the soil.

So that would suggest that we might be softening -- might be softening -- our regulatory approach with the use of untreated BSAAOs or root crops. And how we come out of that is going to be highly dependent on our risk assessment and research, which is very exciting. We are doing some great things right now. In fact, we have some targeted research directly that will answer that specific question.

MR. McREYNOLDS: Okay.

MR. INGRAM: So I appreciate your tolerance with us working through this topic. As fast -- we're working as fast as we can. But until then, I implore you to be careful about how you use raw manure, especially specifically for crops that come in direct contact, which is root crops, so your radishes and carrots and other vegetables that are grown directly in the soil.

MR. McREYNOLDS: Okay. I mean, you know, the National Organic Program standards actually provides it's a two-week integration period and at least 120 days. So it is kind of getting at that immediate issue. I mean, I would also point out that, in most soils, there will also be worm castings in the soil that a root crop is being planted into, right?

I mean, so the -- there -- you know, if -- I'm certainly hopeful that these risk assessments are recognizing kind of the attenuation that happens with time in -- with respect to these particular types of crops.

And so that just brings me to the issue of

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worm castings as well and their treatment. Their treat -- their identification as a soil amendment, you know, from -- in -- under the National Organic Program, I mean, vermicompost is actually a treatment process, essentially, of taking waste, and worms treat it, essentially. And there is ample scientific evidence to indicate that salmonella and E. coli and fecal coliforms are controlled by that process.

So you know, is that the approach of your risk assessment, is looking at that question or -- with respect to worm castings?

MR. INGRAM: So thank you, first of all.

Again, David Ingram, FDA.

Our -- the risk assessment and research activities that we're currently employing across the nation do not -- are not currently involving vermicompost or worm castings. We're -- we are looking at raw manure from beef, cattle, dairy, poultry, horse, so most of the mainstream raw manure products, not vermicompost.

However, you bring up a very important point. And I don't recall if you were -- had attended any of our soil summits. But -- and most of them we really had ad nauseum discussions about vermicomposting. And I am very pleased to hear that this is an activity that is increasing in favor. We fully support the use of compost, in general. Vermicomposting used to be a niche. Now it's becoming a mainstream commodity or product. So we fully support that.

I would be cautious about using USDA as a benchmark for treatment processes. The National Organic Program was not generally stood up to support science-based food safety. That's not their mission, is what I'm trying to say. And if you look on the NOP website, the first page you're -- you know, in the bottom of the first paragraph, it'll say none of our standards are associated with food safety. So I'd be careful about associating food safety with NOP, and that's why we're -- we decided it was important to do our own studies to support the provisions that we come

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up with.

But in the meantime, yes, we do support growers who intend to use the 90- to 120-day raw manure days to harvest standards. We think any days to harvest that you can wait longer than those would be prudent as well. The good news is human pathogens start to die off in soil as soon as you incorporate them. So the longer you can wait, the better. I don't think that's in dispute.

Vermicomposting, specifically, I have a vermicompost operation in my basement, right? All my food waste goes down there. This is a wonderful way of reducing the landfill burden, a good way to recycle your own waste. My two-year-old digs in there almost every day. So it's food waste --

MR. McREYNOLDS: Right.

MR. INGRAM: -- what I'm adding to my --

MR. McREYNOLDS: Sure.

MR. INGRAM: -- vermicompost bin.

So what came out of the soil summits? We discussed those red wigglers, the worms, right? They're cold-blooded. They are not necessarily at the same risk level as warm-blooded animals in terms of propagating and growing and harboring foodborne pathogens. What goes in comes out. So that would suggest that what you feed the worms might be more important in terms of determining the outcome for the worms.

And yes, this is an interesting example because the worms can be defined as a treatment process. I have seen some data to suggest that worms might be characterized as a treatment process. The digestive system is very interesting --

MR. McREYNOLDS: Right.

MR. INGRAM: -- in terms of the microbiome. What goes in does not necessarily mean what comes out. In fact, some foodborne pathogens might be reduced.

So I'm looking for studies to help me with a regulatory approach, soften our definition of BSAAO to maybe not include worm castings as part of that. But

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right now, yes, our definition of BSAAO includes animals, animal origin. Worms are animals. Therefore, by definition, it is a BSAAO. So right now, our regulatory approach is all worm castings are a BSAAO regardless of the feedstock of which you use to feed the worms.

So bear with us again.

MR. McREYNOLDS: Sure.

MR. INGRAM: We're looking at the science, and we have a lot of room, thanks to our risk assessment, to reopen Subpart F.

So I appreciate -- I would appreciate your comments on that specific topic because it'll help me move the ball forward. Submit more TAN questions because that helps me push our lawyers to soften our regulatory approach the best I can because, if we don't have feasible regulations, we're not going to have regulations.

MS. KILLINGER: I would just echo that, if you have additional data related to vermicomposting, we'd like to see that included in your comments as well.

MR. McREYNOLDS: Terrific. I appreciate that. Samir, anything from you?

MR. ASSAR: No.

MR. McREYNOLDS: Okay. Yeah.

(Laughter.)

MR. INGRAM: Just tell me to be more succinct in my responses.

(Laughter.)

MR. McREYNOLDS: But -- and I appreciate that. I -- you know, clearly, in terms of the risk assessment question, worms are in our soils already, and they are there leaving their castings. I mean, so I do think that there is reason, even in the absence of completing a risk assessment, to have a different approach with respect to worm castings as a BSAAO versus, you know, in terms of whether they're treated or untreated and in terms of the ability of the farmer to assess whether or not it's a risk.

MR. INGRAM: Very good.

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MR. McREYNOLDS: Thank you.

MR. INGRAM: Thank you.

MS. McDERMOTT: Other questions?

MR. STOECKEL: I wanted to jump up just because it's a segue. This is Don Stoeckel with Produce Safety Alliance talking about our favorite topics, F for feces and I for intrusions.

So I was a little surprised to see worm castings listed as a BSAAO. And just to summarize what I think I heard, although they may be considered a BSAAO, there may be some wiggle room, pardon the pun, on whether they're a treated BSAAO; is that fair to say?

MR. INGRAM: Yeah, that's fair to say, Don.

MR. STOECKEL: Okay.

MR. INGRAM: Yeah.

MR. STOECKEL: That opens a little bit of a Pandora box if we're going to be talking about all animals as animals, and we're talking about animal intrusions in Subpart I. Are we talking about worm intrusions and insect intrusions into the field alongside other wild animals?

MR. INGRAM: I -- so Dave Ingram, FDA.

We do not -- we decided that regulation of insects would be folly.

MR. STOECKEL: Yeah.

MR. INGRAM: We can't do it.

MR. STOECKEL: It -- I mean, acknowledging that's it's kind of a ridiculous question, but the more we can cut off that line of thinking by having some certainty, the less people are left to imagine the worst. So I guess I would encourage you to include that in the guidance as opposed to verbal.

MR. INGRAM: Thanks, Don. If you could come up with a list of animals that you think should be included on that list, we would entertain that.

(Laughter.)

MR. INGRAM: We already have flies.

MR. STOECKEL: Sadly, I did not write the rule, so I don't have that list for you.

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Third, my last bit on BSAAOs and treatment, I noted that Table 4b, Figure 4b, was a stoplight chart, which implies that one is riskier than the other, is riskier -- is -- so you had a red-yellow-green stoplight chart in 4b. Do we have data to show that no detectible E. coli 157 and no detectible listeria is safer than 1,000 fecal coliforms? Do we know that those are -- that there is actually a different risk when we compare the two standards?

MR. INGRAM: So you're referring to the difference between the two treatment, scientifically validated treatment processes --

MR. STOECKEL: And --

MR. INGRAM: -- not associated microbiological --

MR. STOECKEL: Specifically --

MR. INGRAM: -- criteria.

MR. STOECKEL: -- the endpoints. Specifically --

MR. INGRAM: So --

MR. STOECKEL: -- the endpoints.

MR. INGRAM: So the endpoints for our most stringent treatment process includes the zero detect 157, zero detect listeria monocytogenes, and zero detect salmonella.

MR. STOECKEL: Right.

MR. INGRAM: And yes, we do expect that the processes that have been scientifically validated to eliminate and verified to eliminate those pathogens specifically would attribute (ph) a more safer risk, if you will. And that's why we have a zero limitation on application methods for those products than we do, for example, compost, which we would expect to meet the lesser of the two stringent --

MR. STOECKEL: Okay.

MR. INGRAM: -- samples, so 1,000 MPN fecal coliforms and zero detect salmonella, yes.

MR. STOECKEL: Is that -- are those data things that could be included in the guidance? Because I had never seen a correlation between 1,000 fecal

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coliforms and detection of those pathogens.

MR. INGRAM: These microbiological standards are longstanding benchmarks. They have been around for decades. And they weren't originally used by -- proposed by us. We borrowed them from the Environmental Protection Agency when they were setting up their rules for biosolids, for example. And these were -- these standards have been adopted by United States Composting Council, among other agency groups that use these products. So we did borrow those standards as feasible standards that most people are already using, and we accept their level of public health protection.

MR. STOECKEL: Thanks for that explanation.

MR. INGRAM: Sure.

MS. MENDEZ: Hi. Good afternoon. My name is Angela. I am from Guatemala from Banana Farms Association.

We have a question about page 125. And you talk about sewage systems. We have a question about you mentioned individual septic systems, self-contained units, that which could be portable, and any associated plumbing. But what about facilities that doesn't have any plumbing or consisting deep well that is only in the ground?

We suggest that you clarify that definition of what is an adequate sanitary system for these waters. And our concern about this is that it could be misunderstand and concept. So we suggest that facilities will be defined more precisely.

The other topic is about arithmetical (ph) death rates. And it could be a future guide about the use of this criteria, time that we need to pass from harvest to final consumption of the produce. We need some orientation about how to use these rates of death in bacterias, how to use it.

And finally, we want to comment or suggest if it could be possible to create a division of crops based on risk, considering edible peel or not edible peel or these particular characteristics of each

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freight of -- or vegetable.

So -- and that's our comments, and I don't know if you want to add something. It's okay. So that's our -- the points we want to share with you.

Thank you.

MR. ASSAR: Thank you.

Just real quickly with respect to -- this is Samir Assar -- with respect to the question, the point about the high-risk -- you know, including a list that specifies or delineates or distinguishes high-risk from low-risk commodities based on edible peel or edible outer, you know -- yeah, that's basically -- or rind, I guess you could say. And that is an approach that we did consider as we developed our regulatory approach for the rule.

And one of the major considerations and the reason for how we landed was because we'd seen studies that suggest that, you know, even a cantaloupe rind, which is not edible, or isn't eaten typically, you know, if there's contamination on that rind, it can get -- it can become internalized. So it's not as simple as just saying that, because it's inedible, you know, it's -- and there's an outer, you know, rind or a peel that's inedible, that it's -- it doesn't mean that the produce inside can be -- can't be contaminated.

So -- but, certainly, with respect to, I would say, some of the other thoughts -- I guess do you have any -

MS. KILLINGER: Yeah, I can follow up.

MR. ASSAR: Yeah, sure.

MS. KILLINGER: Yeah. Thank you for being here today. And I definitely appreciate your comments related to sewage systems in Chapter 7. And I think, in particular, you providing more detail and, perhaps, examples in a comment to the docket would be really helpful to us to help expand covering that topic. And we really look forward to that comment. So thank you for raising that.

MS. McDERMOTT: Thank you.

Better get up there.

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MS. ESCH: I've been trying to get up here for a while.

Good afternoon. Hi. My name is --

MR. INGRAM: Good afternoon.

MS. KILLINGER: Good afternoon.

MS. ESCH: -- Kristin Esch. I'm with the Michigan Department of Agriculture and Rural Development. I appreciate your time today and everybody's work on the guidance document.

I did want to start off, though, by saying that there's approximately 74 "adequates" or "adequately's." And for guidance, that doesn't really help because my adequate may be different from FDA's adequate. And how would an inspector determine what is adequate if it's not more defined?

So I'm wondering if that's something in some of these adequate or adequately examples that could be further defined or some examples for those. I know that we do need to use some level of common sense sometimes, but I think in some of these instances it might help.

The other thing I wanted to discuss is plumbing. So I was wondering -- reading through this how a layperson, a farmer, or an inspector who is otherwise not a plumber can determine good maintenance on a plumbing system. Specifically, it talks about -- let's start with septic. It says, "Tanks must be properly sealed, in good working order, free from damage. Inlet and outlet plumbing should be good, in working order, and the drain fields should be working properly."

As an inspector, if I were to do an inspection, I would have no capacity to be able to figure that out except for if there was sewage bubbling on top of the ground. So I'm just wondering how a layperson would do that and if that can be further defined.

MS. KILLINGER: Thanks for that question.

With respect to the question on plumbing, we understand that some of these areas are going to be

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somewhat gray or challenging. But I think we talk about starting with a visual assessment of the plumbing system for obvious defects. And there is an expectation for these systems to be maintained over time. And so a farm may have to seek help or guidance on how to maintain those systems.

And so if you have specific examples that you'd like to share with us that you think would help to support determining adequate maintenance for these systems, that would be really helpful to provide in a comment.

MR. ASSAR: Yeah. And just generally speaking, with respect to the word "adequate" and we say "generally," and people are -- they don't understand what we mean by that. They want a little bit more clarification about what we mean regarding adequate. We totally get that. And at the same time, when we do define "adequate," you know, what do we hear back? Well, you know, that doesn't work for me, you know.

So there is a need to strike that balance. And the way that we've generally taken -- the approach that we've generally taken with this guidance is we've provided examples and, you know, clear examples that where it's inadequate or where it's adequate. And that's, again, part of this process to help us include more examples that will be useful to the community as a whole. And that's really the best we can do.

I mean, again, we will try to draw lines when we can, but it's so tough when you consider that the line that you draw for one commodity or one region or even in the U.S. may not be workable or relevant in countries outside the U.S. or with other commodities. That's the challenge of produce.

MS. ESCH: And farming, in general.

MR. ASSAR: And farming, in general.

MS. ESCH: So finally, the only other thing -- well, not the only, but the last thing I had is the -- there seems to be an extreme discrepancy between buildings. So if you have a closed building, fully

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enclosed building, there's a lot of guidance as to what you should do and how you should maintain it and the size of your building and the distance between equipment and the side of your building and roof. And actually, it even talks about putting screens around doors and windows and different things.

So it seems to me that you're -- the guidance is almost pushing people to drift -- to, like, rip off a wall so that it's an open building so that they don't have to follow a lot of these recommendations that are listed for fully enclosed buildings.

MR. ASSAR: That's -- thank you for that point. Certainly, that's not our intention to have, you know, people rip out their walls, as you suggest. So that's just something we'll have to look at and with your help. So thank you.

MS. ESCH: Thank you.

MR. ASSAR: Yep.

MS. McDERMOTT: One last question.

UNIDENTIFIED MALE SPEAKER: Only one?

MS. McDERMOTT: Well, we can do two if you -- we (inaudible) schedule.

MR. MOSHER: Okay. Well, since we're already on the topic of definitions, Chapter 6 mentions the word "distribution." I recommend it needs to be defined. On page 82, Part 1, states, "Keep covered produce separate from excluded produce, except when placed in the same container for distribution." It's not defined in the PSR. It's not defined in the draft guidance.

So what is the definition of "distribution," and when does it start? Does it start during harvesting, does it start during packing, or does it start during holding? You know, some growers would see that as a potential loophole to combine -- you know, comingle the covered and excluded produce to say, well, I'm distributing it.

So I'm just wondering if there's an idea for the definition.

MS. KILLINGER: Yeah. Thanks for your point

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on that. And that is language from the rule itself, and you're correct. There is not a definition for "distribution." And so again, I think the best route to go here would be to comment for clarification related to our description of distribution in the guidance.

MR. MOSHER: Okay. Is that it or ...

MS. McDERMOTT: Well, there's a gentleman behind you. But if you had another one, that's fine.

MR. MOSHER: Oh, I've got one, two, three, four, five -- six more.

MS. McDERMOTT: How about the gentleman behind you.

MR. MOSHER: Okay.

MS. McDERMOTT: And then we'll see how the time is.

MR. MITCHELL: Hey, y'all. This is Billy Mitchell from the National Farmers Union.

Kind of keeping on the topic of definitions, then also outhouses and plumbing. I'm just wondering if there is a definition. On page 120, you mention an outhouse as acceptable. And is there a definition of what an outhouse is? To me, this kind of speaks to the area. The gentleman from North Carolina earlier spoke about the daylight in between what inspectors are going to think something is and what a farmer might think something is.

MS. KILLINGER: Okay. That's a great question. And typically, as I talked about this morning in the overview, the definitions that we provide are linked to the rule. And so the definitions that we utilize in the guidance tend to be the definitions from the rule. So we can add clarification about what we mean by certain terms.

And what I'm hearing you say is that the term "outhouse" is not a term that -- or it could be interpreted differently among farmers.

MR. MITCHELL: Well, to me, not to put my business in the street -- but to me, an outhouse would be digging a hole in the ground and putting a structure

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around it and then doing my business in that hole in the ground. And I'm not totally sure that an inspector would come out and feel like that's okay that I'm doing something like that. And so I feel like a better understanding of what an outdoor structure we would use to go to the bathroom --

MS. KILLINGER: Okay.

MR. MITCHELL: -- could lead --

MS. KILLINGER: We --

MR. MITCHELL: -- (inaudible).

MS. KILLINGER: -- appreciate a comment to clarify that further.

MR. MITCHELL: Okay. I'll find a way to put it a little more formally online.

(Laughter.)

MR. MITCHELL: All right. Thank you for your time.

MS. KILLINGER: Thank you.

MS. McDERMOTT: Sir, if you'd like ...

MR. MOSHER: Sure. Okay. Mike Mosher again with the Wisconsin Agriculture, Trade and Consumer Protection.

In Chapter 6, Part 4, it begins, "You must not distribute dropped covered produce," 112.114. Will that cover the sale of windfall apples? We get this question a lot, so sale of windfall apples for animal or -- you know, for animal feed. It's a very common practice among orchards to sell their windfall apples for either deer feed or hog feed. But the rule states must not be distributed, period. There's no other explanation on that.

MS. KILLINGER: Okay. Great question. Thank you for that.

So I think there's really two parts to your question, if I'm hearing it correctly. And let me repeat back. You're asking about windfall apple sales for both human consumption and as animal feed? Is that --

MR. MOSHER: No, just --

MS. KILLINGER: -- correct?

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MR. MOSHER: -- strictly for animal feed for either deer or hog.

MS. KILLINGER: Okay. So our rule is related to human consumption. And so that's -- this guidance document is relevant for covered produce for human consumption. And there's another part of FDA that deals with animal food and feed. And so if you have a question about animal food and feed, which it sounds like these windfall apples that are sold for animal feed is relevant to that, we encourage you to submit that question to the Center for Veterinary Medicine Technical Assistance Network because that really falls more in their area of focus.

MR. MOSHER: Okay. But as I said, it just says must not be distributed and period. It doesn't say with the exception for anywhere in there.

MR. ASSAR: Okay --

MR. MOSHER: That would be very useful. And that would reassure a lot of the --

MR. ASSAR: I see what you're saying.

MR. MOSHER: -- apple orchards because --

MR. ASSAR: Yes.

MR. MOSHER: -- right now, their interpretation of the rule is they can't do anything to their windfall apples. They must --

MR. ASSAR: I understand.

MR. MOSHER: -- let them lie on the ground and let them rot in place.

MR. ASSAR: Yeah, no. That's a very good point. And yeah, that -- we appreciate that. We didn't realize that that was a concern. Thank you.

MR. MOSHER: Okay. Now, with respect to when we're talking about dropped produce, so I think it would be useful if we added a line produce that is intentionally dropped to the ground as part of growing or harvesting could address the issue when you have certain types of tomatoes because tomatoes are a vine plant. Certain varieties naturally come in contact with the ground as part of their growth.

MR. ASSAR: Right.

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MR. MOSHER: I think that would, you know, easily address that, you know.

MR. ASSAR: Okay.

MR. MOSHER: It would avoid the issue of a dropped produce as opposed to one that comes in contact with the ground as a natural part of its life cycle.

MR. ASSAR: Thank you.

MR. MOSHER: Chapter 7, I'm wondering if there's any consideration or if there's been any studies on latex foam for use on food contact surfaces, you know, for the type of rollers. We had a very interesting conversation with a gentleman from the industry talking about latex foam's natural microbial characteristics and its use as, you know -- as rollers or, you know, contact surfaces to prevent bruising.

As it stands right now, you know, any type of foam or, you know, rubber type, you know, any kind of sponge material should not be used, or it should be avoided. But again, you know, latex foam does have a natural antimicrobial property. And you know, I think it would be worth doing some more study on.

Chapter 7, Part 1c, again, this -- we're getting into definitions, and I know we already talked about it. But you know, if we can get a clear definition of what "reasonable" is, you know, what it can mean because, again, one person's standard of reasonable can be different from another person's standards, you know, especially when you're talking about inspection frequency. It says, you know, you should reasonable inspect your -- or you should inspect your equipment on a reasonable basis. It would be useful to put in, like, at least -- or at least annually, same thing we do for water distribution systems. You know, that would give -- you know, that would be something that's enforceable. Someone -- you know, a farm could argue, like, well, I only have to reasonable inspect my equipment every five years.

MR. ASSAR: Right.

MR. MOSHER: You know, that's his standard. And again, you know, "reasonable,"

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"foreseeable," and "necessary," you know, I think those are terms that could -- would be useful to have definitions for, clear-cut definitions for.

And oh, bottom of page 105, I believe -- or is it 103? I can't remember. It would be useful to provide some examples of dry-cleaning techniques. Up in the -- you know, the upper Midwest and so forth, we're not too familiar with dry-cleaning just because of the humidity and so forth. So we -- you know, just for their clarity, it would be useful to include some -- you know, some examples so they'd know, like, well, that circumstance doesn't apply to us, so, you know, that's not a technique that we would use.

That's it.

MR. ASSAR: Thank you.

MR. MOSHER: Thank you.

MS. McDERMOTT: Anybody else?

MR. McREYNOLDS: Thank you. And I do apologize, but I did understand the comment period went through 3:15. So I apologize for prolonging this.

I did want -- but had a question related to Chapter 7 -- or a comment and a question. First of all, I wanted to commend the statement in the guidance regarding that, to the effect that porous material may be allowable in equipment if those pieces of equipment, those surfaces can be adequately cleaned and properly maintained. It was really important because there are many farmers who are sitting on existing infrastructure of things that they don't need or want to have to replace if they can keep it clean and maintained.

But then there's the -- there's an example in Chapter 7, Example 7j, that says a farmer looked at his nonporous surface and decided it couldn't be cleaned and maintained, so he got rid of it. It doesn't provide any sort of explanation or rubric of how he came to that -- how he or she came to that decision that that material couldn't be cleaned. And so therefore, it kind of has the effect of undermining the broad statement to say, yes, you can do this. But then when you actually look at an example, it says, well,

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this guy looked at it and he said it can't be done, so I had to replace it.

So I would just, you know, encourage that some more criteria or explanation of an analytical process be incorporated into these examples.

MR. ASSAR: Yeah, no. There -- it is intended to be flexible, but I understand your point with an example that doesn't provide more criteria or provide more of a description as to how that determination was made.

MR. McREYNOLDS: Exactly.

MR. ASSAR: It could undermine the general approach that we were looking to accomplish.

Thank you.

MR. McREYNOLDS: Terrific. Thank you.

MR. STOECKEL: Do you got a minute?

MS. McDERMOTT: Sure.

MR. STOECKEL: I will also try to be very brief. But it feels like there are two definitions that would make a difference to people, and so I just wanted to clarify two things, if I may.

This is Don Stoeckel with the Produce Safety Alliance.

The difference between an enclosed building and a partially enclosed building, a lot of farms have a packhouse, say, 20-by-20 in a concrete pad that has a couple of garage doors that they will leave open for four, six, eight hours during a day. Would those -- could you describe the line between a partially enclosed building and a fully enclosed building? Because I think that makes a big difference, as Kristin from Michigan said earlier.

MS. KILLINGER: Yeah. I would, I think, have to go back and look at what we currently have in the draft guidance. But we did make an effort to do some clarification around fully and partially enclosed buildings. So again, if you find that that language is not sufficient to clarify the difference between the two, a specific example, such as the one you provided here, would be really helpful in a comment to the

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docket to help us take that next step with the language. So ...

MR. STOECKEL: Yeah. I think there was discussion of open doors and open windows and having a person posted to make sure animals didn't come in. But there are matters of scale where --

MS. KILLINGER: Okay.

MR. STOECKEL: -- a front -- or Dutch door is different from a garage door. So ...

And the other one is food contact surfaces. There was some discussion of food contact surfaces in the growing environment. And I was looking for some clarification, probably not the only one, about black plastic mulch in the outdoor environment or floats in hydroponic environment during growing, whether those are considered food contact surfaces.

MR. ASSAR: We did not specifically address black plastic mulch. Very good point. So yeah, we'll look at that.

MR. STOECKEL: Okay. I just want to make sure we didn't miss anything. Thank you.

MR. ASSAR: Yep.

All right. This is Samir Assar. And I am -- I have to, unfortunately, head out and miss the rest of the public meeting. My colleagues will be here to hear your -- the rest of your comments today and also provide some reflections around what we've heard today.

And I'd just like to say this -- it's incredible. This group is very well prepared for this discussion. There were a lot of great questions, a lot of interesting points that, you know, some of which we have thought about and discussed internally. And your comments will help us kind of lean one way or the other to make the decision that we need to make to make the -- to finalize the guidance.

In other cases, you raised some things that we just, you know, just weren't aware of. And they had to do with situations or, yeah, scenarios that are -- that you're familiar with in the work that you're doing and in an area that we need to address. We either didn't

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get those scenarios through the comment periods, or, you know -- and that's really the purpose of why we're here today, to really hear about it. And we encourage you to continue to provide those scenarios to us as we develop the draft guidance to finalize it.

So I really appreciate everyone's time, and I appreciate, greatly appreciate, how everyone came prepared. And we look forward to hearing your comments, and we will continue to stay engaged with the produce community, stakeholder community, as a whole -- whole. And yeah, please stay tuned with respect to further developments on this guidance and other FDA produce safety efforts.

Thank you.

I turn it over --

MS. McDERMOTT: Thank you.

MR. ASSAR: -- to my colleagues.

MS. McDERMOTT: Thank you, Samir.

We're going to move into the Public Comment session right now. We have a number of people that have signed up to make public comment.

So I will be calling the organization that has signed up, and the representative for that should just step up to the podium. Again, state your full name and your organization. And I think we've indicated you have four minutes to make public comment.

So I'll start with Chemstar Corporation.

MS. HOLLINGSWORTH: Thank you.

My name is Jill Hollingsworth. I'm with Chemstar Corporation. We provide food safety and sanitation solutions to retail food stores and primarily supermarkets.

We also provide an antimicrobial water treatment that's used -- the product is called Produce Maxx. It's a hypochlorous acid. It's used for washing and crisping produce in retail stores. And currently, we are in over 5,000 stores using that product.

I want to, first of all, thank FDA for getting this guidance out and also for hosting these public meetings. The guidance has been a long time coming,

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and it's very comprehensive. Yet we must acknowledge that we continue to see food safety outbreaks at an unacceptable level. Outbreaks of especially of E. coli 0157 linked to leafy greens continue at a rate of more than three incidents per year, and that has been going on since 2006.

In a November letter from FDA to Arizona and California Ag Departments, the FDA specifically said that our approach to preventing leafy green contamination must change in order to protect the public health and that new, bold action is needed. So as much as we are applauding FDA in the produce industry for all that they've done, we also want to question the continued delay of the agriculture water standards.

FDA has said themselves that the status quo was unacceptable, and yet the agriculture water standards, as far as we can see, will be delayed for another six -- three to six years. At the current rate, if outbreaks continue the way they are now, by the time everyone implements a water standard, we will have seen another nine or more STEC outbreaks linked to leafy greens, and it's just not sustainable.

So we ask that FDA consider expediting the water standards. We understand they are complex. We understand they're costly. But public health must prevail. Outbreaks are more difficult and more expensive than a water standard would be. Perhaps FDA and the produce industry will consider some sort of interim steps for the water standards rather than just leave them out of the guidance document.

The FDA environmental assessment following the Yuma leafy green outbreak demonstrated that there is a need for additional ag water interventions. For the current outbreak that is linked to leafy greens from parts of California, the FDA and produce industry have responded by agreeing to a voluntary label program. But still, nothing has been done to address the concerns about prevention steps and water standards.

We cannot put harvesting, marketing, and sales

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over produce safety. We must look at water standards and do it quickly.

And lastly, although this isn't directly related to the produce standards, it should be noted that, in looking back over the most recent STEC outbreaks, there has not been any recall of the products involved. If FDA has sufficient evidence to stop the sale of a product, like romaine lettuce, from a region of the country, then we feel there is sufficient evidence for all of the suppliers in those regions to recall the product and remove it from the marketplace in the best interest of public health.

In closing, we are asking FDA to please move forward more expeditiously with the agriculture water standards and consider enhanced commodity-specific standards, such as a product like leafy greens, in order to prevent and reduce outbreaks. Thank you.

MS. McDERMOTT: Thank you for your comment.
Tennessee Department of Agriculture.

MS. McDONALD: Good afternoon. I am Carol Coley McDonald, Assistant Commissioner with the Tennessee Department of Agriculture.

We appreciate FDA hosting this meeting and providing a forum to address concerns with FDA's draft industry guidance for the Produce Safety Rule. Our department is responsible for implementing and enforcing the produce safety program in Tennessee. We understand that state agency interpretation will play a significant role in this endeavor. However, we are commenting on the federal guidance document to foster consistency and administrative ability among all states.

Our first concern is FDA's interpretation of produce sales, includes produce purchased or otherwise obtained from another entity and then resold. This interpretation artificially inflates the quantity of produce in the marketplace and the contribution of some farms. One strawberry will be counted multiple times as it travels in the stream of commerce. This distorts the measurement of produce attributable to each farm.

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Produce enters the marketplace upon its initial sale, and the quantity of produce attributable to each farm is the produce that was actually grown on that farm. Thus, produce sales should only include produce grown and sold by the same farm.

Similarly, Tennessee is concerned with FDA's interpretation of food sales for qualified exemption calculations. FDA interprets food to include livestock and meat. It interprets food sales to include food purchased or otherwise obtained by another entity and then resold.

Tennessee producers operate diversified farms that heavily feature cattle and other forms of livestock. Live animals are rarely sold directly to consumers, restaurants, or retail food establishments. So many farms will be fully covered under the rule merely because they sell livestock. This will significantly harm smaller, diversified operations because many will consolidate production efforts to exclude or decrease produce sales. This will result in less produce entering local markets, which, in turn, will result in larger food deserts.

We urge FDA to limit their interpretation of "food" as it applies to the Produce Safety Rule.

Next, Tennessee is concerned with FDA's interpretation of a qualified end-user. A sale to a qualified end-user would be -- would -- must be readily determinable at the point of sale. The current interpretation incorrectly supposes that farmers can somehow anticipate where their food will eventually land. The resulting analytical requirement is cumbersome, time-consuming, and confusing. It is also virtually impossible for religious-based farming communities that forego the use of technological resources.

Again, thank you for this opportunity. We look forward to further collaboration with our sister states and federal partners to establish an efficient and practical regulatory program.

Thank you.

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MR. INGRAM: Thank you.

MS. McDERMOTT: Thank you for your comment.

Public Health Innovations.

(No response.)

MS. McDERMOTT: Texas Department of
Agriculture.

MR. DE LOS SANTOS: Thank you very much.
Richard De Los Santos, Texas Department of Agriculture.

We learned a lot today, and I appreciate everybody's input and hope that these final -- the guidance come out can really be used to help the industry. As we -- as inspector, regulator, we can't begin to hold these farms accountable for something they don't understand. So hopefully this will go a long way into helping -- help them understand what's -- what the produce rule really is and what it's meant to do.

That's all the comments I have.

MS. McDERMOTT: Thank you. Thank you for your comment.

Quality Certification Services.

MR. BALASUBRAMANIAN: Hi. My name is Ramkrishnan, Executive Director, Florida Organic Growers/Quality Certification Services.

Florida Organic Growers is a grassroots organization (inaudible) organic and sustainable food production for more than 30 years. We are very unique because we also operate a third-party CAP (ph) certification as well as the USDA organic certification programs.

We want to thank FDA, specifically, the Produce Safety Network staff and, more specifically, Mr. Trevor Gilbert, who, in my personal opinion and our opinion, has made a positive impact about FDA by strongly interacting with stakeholders, build trusting relationships. So we want to say a big thank you.

There are quite a bit of comments, but I'm going to restrict. We will be submitting written comments. But four important areas that is very important to us, to all stakeholders -- number one,

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worm castings. You hear it a lot, and I know Dave talked about it a lot about today. I understood their process.

But the issue here for us is organic growers use worm casting. It's a valuable source. My question is not to debate the 90-120-day rule. And currently, (inaudible) guidance states if the worm castings comes from a vegetative matter, then the 90-120-day rule does not apply. So we definitely need a better clarity because that will help us to see how we want to deal with that part.

The second one is examples given in the draft guidance are very good. However, we would like to see more examples from the organic sector that's applicable to the organic sector, more importantly, from the international situations. In our written comments, we plan to and intend to give better examples that is applicable to the international situation as well. The situation is very different than what we see in the U.S. farms.

Third, grazing and harvest. We need a better clarification on this. There are many integrated (ph) farming systems outside the U.S. that we -- that also produces produce. Example, the banana industry, they talked -- today we had here. Sometimes they have farms adjacent, and they may have up to 50 chickens running (ph). It's not technically grazing, but it's foraging as well. So there will be clarity needed, please.

The last one is records. Because we are also a regulatory certification/auditing body, we'd like to have -- this may not be a popular thing. When we do audits on the farm, the number one noncompliance is fees, failure to pay fees.

The second noncompliance is records. We prefer the records -- I know the rule allows 24 hours access. I know there's a lot of flexibility to build in it. But we prefer that these record are readily available to be understood and available in one location at the time when an audit or some kind of visit happens. Again and again, the farm, a lot of

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problems with records -- that's one area that the guidance document will address.

So those are the four important things. And thanks for your time.

MS. KILLINGER: Thank you.

MS. McDERMOTT: Thank you for your comment.
CFSA.

MR. McREYNOLDS: Good afternoon. Pardon me. My name is Roland McReynolds. I'm Executive Director with the Carolina Farm Stewardship Association.

First of all, I want to thank FDA for hosting this and the series of meetings for this public discussion. It is definitely a strong indicator of willingness to hear from affected stakeholders in the -- in informing the final guidance. And it helps us as stakeholders to sharpen our guidance to have this dialogue and discussion. So thank you very much.

Comments that I wanted to make were to, first of all, underscore the importance of providing guidance on Subpart R related to the withdrawal of qualified exempt status. And this is especially critical as to helping farmers to understand what are the situations and conditions that would lead to that withdrawal and what are the actions that they would be allowed -- that they could take to regain their status.

This -- providing this guidance is consistent with your goal of protecting public health by helping these farms to ensure that they are not putting adulterated products into the marketplace. So this kind of -- so it -- although it is less about what happens on a farm and more about process with the regulator, this would still be critical information for the huge number of exempt -- qualified exempt farms in order for them to be able to make sure they are doing the best possible job of applying a food safety culture on their operations.

I do want to support the fact that this guidance does not include information on the water rule. It is entirely appropriate to wait until there is a final standards on water that are practical and

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cost-effective in terms of allowing farms to effectively manage water and, in particular, because we must always keep in mind that farms do not have control over so much of the water that they use. If there is contamination, it is likely somebody else's fault that the water that they're using has some contamination, whether it's an upstream surface. Whether it's surface water where upstream polluters are causing problems or underground aquifers, this is not a burden that should be placed solely on farmers. This is a burden -- this is a societal burden. And so certainly, the -- your rule-making process must come to a reasonable approach and balance about how to manage -- how farmers can work on managing that risk, and then guidance should follow from that.

I would finally ask or remind that farms and farmers are not like facility operators that you're typically -- that FDA's guidance process has typically been addressed, right? If you issue guidance on manufacturing of pharmaceuticals or even fresh-cut produce, yes, somebody at Merck and somebody at Earthbound Farms will take that document, and they will read it through. And they'll have their compliance folks make sure they understand it completely.

But a farmer is not going to sit down with a 150- or 200-page document and decide -- and read it through and implement their food safety plan accordingly. Extension offices, farm support organizations like ours, you know, we -- in our experience and the things that we do is to provide resources, tools, fact sheets, tip sheets, a whole range of information, to provide it bite-size chunks so that it can be incorporated.

So I guess what I want to say is that, when you've published final guidance here, please understand that that's not the end of the process of providing guidance. It's the beginning. And partnership with industry and extension offices and state government offices to provide extensive outreach and a variety of tools for taking this guidance information and actually

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getting it into farmers' hands in digestible way will be critical to the success of your goals with respect to this rule -- to the implementation of the rule as well as the goals of farmers to remain in business and take care of their customers.

Thank you very much.

MS. McDERMOTT: Thank you for your comment.

Did I miss anyone? Or would anyone else like to offer a public comment?

(No audible response.)

MS. McDERMOTT: All right. In that case, I know Samir had to leave early, but I wanted to just offer Karen or David if they had any closing remarks.

MS. KILLINGER: We do.

MR. INGRAM: Okay. Hi. David Ingram, FDA.

So I guess what I'd like to do is just peel back the curtain a little bit for you all to give you an idea of what it's like to work in our offices. And this guidance was quite a heavy lift for all of us.

We, as subject matter experts, were handed specific chapters within our domains, and we were asked to harmonize our approach. And going through each individual one, you can imagine the battles that each individual had to fight to get certain things through. Not everything that we wanted in the guidance got through legal counsel.

So with your help and your comment and your continued presence during our discussions, we can make this a much better document. We understand there's gaps, and I heard a lot of gaps today. I really appreciate everyone's input.

But I'd particularly like to thank Dr. Killinger sitting next to me. Dr. Killinger was our ring leader. She corralled everyone together under one roof. And I can't imagine the monumental task she had dealing with each of our individual personalities on a daily basis to get this document through.

So what you're looking at was largely responsible from Dr. Killinger's diligence and tenacity and expert guidance. So thank you.

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(Applause.)

MS. KILLINGER: Thank you.

MR. INGRAM: And she's having her first baby in February, so we're all excited for her.

And thank you for being here. I want to -- I appreciate all your comments. And please, let's continue our dialogue. Our offices are open.

And I also want to suggest and make sure that you understand when you call me, you might get a direct answer. But that answer may not be beneficial to everyone.

So if you don't mind -- I know it's tedious -- but submitting your questions to the Technical Assistance Network gives me a chance to push our legal counsel's comfort zone in a way that might be -- provide groundwork. What is written by FDA is a little more -- it's a little more challenging to get written material through the door. And what we need is written material through legal counsel.

So when I have a response to the questions that you asked me today in writing, it will be beneficial to further crafting the guidance in a way that's more feasible to your constituents and your farms and yourselves.

So thank you again. Thank you all for being here.

MS. KILLINGER: Thank you, Dr. Ingram, for your kind remarks and for providing a sense of our experience and getting to this point with the draft guidance. And it is unfortunate that not everyone on our project team has the opportunity to be here today and hear from you firsthand. And we are very fortunate to be here and appreciate all of you being here to share your thoughts with us. This is an incredibly important time for the guidance document to hear your thoughts and to encourage your comments to the docket so that we can continue to strengthen this document.

So thanks to all of you for your time commitment today and for traveling, some of you, very, very long distances to be here.

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As Dave said, we all worked very hard to try to provide a draft guidance that does provide useful and effective information. And we know that this is a draft and that we can continue to strengthen it. And we need your help to continue to do that.

And just to clarify, the TAN inquiries, those inquiries help us and help you submit inquiries related to rule interpretation questions, whereas, for the guidance document, those comments need to be submitted to the docket, not the TAN. Those comments to the document are very important.

And again, we've provided links and, in your packet, information related to the Federal Register so that you can access more information on how to submit your comments to the docket. And we absolutely look forward to your comments and encourage you to submit those by April 22nd of 2019 so we can take them into consideration.

Again, we want this to be a practical document and a useful document for farms as well as our other stakeholders like our state partners and academic groups that are working towards incorporating information into their training programs.

And I'd like to reflect back on some of the topics. And I'm just so appreciative of everyone looking through the guidance document. Many of you are clearly extremely familiar with a very long document already. And we've had a great discussion here today.

And so some of what I've heard on where we've at least close to the mark so far, in Chapter 1, some of the information related to clarifying the definition of produce and raw agricultural commodities and the differences between processed foods as well as in Chapter 2, worker training and examples. And I appreciated the comment about including some information about the why behind our thinking to help people understand why certain concepts are important.

In Chapter 5 on Domesticated and Wild Animals, I heard that some of those examples specifically related to monitoring frequency and examples related to

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identifying significant evidence of potential contamination was helpful. Chapters 4, some of the information on BSAAO records was helpful. And on Chapter 7, cleaning and sanitizing examples to clarify "as necessary" and "appropriate." It sounds like some people found that information useful.

As I move into areas to improve, I'd like to acknowledge that we have a difficult task ahead of us. And part of that difficult task is to incorporate many of the topics that you have asked us to clarify further in what is already a long document. And so we want this document to be helpful. And please keep in mind we are trying to include helpful information, yet balance that with trying to keep the document user-friendly. And I think that's an area where we can look to our partners as we move forward to help really target and work with farms, those of you who work with farms more directly, to find those useful pieces of information for individual farms and point them to those specific areas in the guidance document that's going to be most useful to them because we understand sitting down and reading the whole thing is a bit of a challenge. But we want to include these pieces of information that is going to be helpful.

And some of the areas we've heard that we need to improve upon are the discussion of covered produce, covered activity, and covered farms in Chapter 1 as well as items related to produce sales and the \$25,000 threshold and qualified exemption as well as our approach to new farms. Again, there's lots of unique farm scenarios that are complex, and we want to try to help provide useful information where we can.

It was interesting to hear that some of you found our interpretation related to harvestable and harvested part of the crop helpful, where as some of you would like to hear additional information. So again, submit your comments, both positive and negative, to help us understand what we need to clarify around that.

And then let's see. In Chapter 8, some more

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examples might be helpful. Chapter 4, there was a lot of discussion today on soil amendments, and we really appreciate your thoughts on clarifying some things around agricultural teas, and particularly around worm castings. Chapter 6 and 7, examples related to buildings and separating covered and excluded produce as well as service animals, dropped covered produce, and handwashing facilities.

Again, I'd like to acknowledge that, as we move forward, there are going to be complex issues and gray areas in the area of produce safety. And so we're all going to have to work together to advance in some of these areas that are more gray. And we also will need to account for advancing science.

And so again, we anticipate that this will be version 1 of a final guidance, and we'll have to continue to update it. I thought the panel did a great job of talking about some of the areas that maybe need potential research and some of those areas connected to topics where people are asking for more clarification, such as topics around animal intrusion and buffer zones as well as cross-contamination during specific practices during growing, harvesting, packing, and holding, particularly around harvest containers and post-harvest surfaces like those porous materials that we know farms are interested in continuing to use but they must continue to use them in a safe way. And that's going to be a process. It's not going to happen overnight. And so we're all going to have to continue to work together as we move forward.

And I think Commissioner Black started us off really well this morning by talking about the importance of partnerships and continuing to improve. And I think we -- everybody in this room wants to get this right. And I hope that, by our presence here today, we've indicated we want to get it right, and we want to work with you to make sure that we all advance this food safety mission for produce safety together.

So our work isn't going to stop here. And this type of engagement -- maybe -- it may not be

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public meetings, but we absolutely intend to continue to work with stakeholders and to communicate with you as we move forward with implementation. And we recognize this is a process and that everyone comes to the table with valuable information that needs to be considered.

So please submit your comments by April 22nd of 2019 so we can take into account all of the information that you have to help us strengthen this draft guidance document.

And we really appreciate you being here today.

MS. McDERMOTT: All right. Thank you, Karen and David.

And again, thank you all for being here. I know everybody's very busy and taking a whole day out of your schedule. We truly appreciate it and hearing your comments.

Thank you to everyone at the FDA who helped in planning and preparing for this meeting.

We have a gift from the hotel. We have three free parking tickets. So anyone who can reach Juanita Yates in the green jacket first gets those three free parking tickets.

And again, we look forward to working with everyone on implementing the Produce Safety Rule. Thank you again. Have a wonderful evening and safe travels.

Thank you.

(Whereupon, the meeting was concluded.)