

**Standards for the Growing, Harvesting, Packing and Holding of Produce for
Human Consumption: Draft Guidance for Industry 12/11/18**

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ND DRUG ADMINISTRATION (FDA) PUBLIC MEETING

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DRAFT GUIDANCE FOR INDUSTRY

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P R O C E E D I N G S

MS. McDERMOTT: Alright. Good morning, everyone. We're glad we're here in Albany. Welcome to today's FDA Food Safety Modernization Act public meeting focused on the draft guidance for standards for the growing, harvesting, packing and holding of produce for human consumption.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 busy time of year for everyone. We certainly appreciate you being here today.

My name is Cathy McDermott, and I'll be moderating today's meeting. I am in the communications division of FDA's Office of Foods and Veterinary Medicine. Also want to thank everyone joining us today via webcast. We certainly appreciate your attendance.

Before we jump into the program I just have a few housekeeping items to go over. All of you should have received a folder at the registration desk before you came in that includes a number of handouts including an agenda and biographies for all the speakers. So we'll be somewhat brief when introducing our speakers.

For the web audience you should also have access to the agenda, which is on FDA's FSMA website. Today's PowerPoints that will be used will be posted to the FDA website after the meetings. And for those of you who are members of the media I don't know if anybody is or anyone has signed up, if you are, please sign in at the registration desk, we'd certainly appreciate that.

For individuals who have signed up to make public comments, please check in with Juanita Yates at the back of the room. And certainly anyone else can make public comments, we certainly encourage that. It's not too late. So at the break or whenever you like please see Juanita at the registration desk and sign up to make a public comment if you still wish to do so.

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Parking, you can pick up discount tickets at the registration desk for parking whether you drove in or at a hotel desk. WiFi is available and you can pick up the instructions for that at the registration desk.

Just look around for the exit signs, so you know where to exit in case anything happens and as well the restrooms are on this level right around the corner. Cell phones, if you could please turn your ringer off or turn it to vibrate we'd appreciate that as well.

This meeting is being webcasted and transcribed. The transcription will be posted to the FDA website later on. So please note that for all public meetings, if you are publicly speaking or in the auditorium there is no expectation of privacy. So just be aware of that. Again, any questions or issues please Juanita Yates in the back or someone at the registration desk can help you.

So it is now my pleasure to kick off our speakers this morning. We're very pleased to have Richard Ball, the Commissioner of the New York State Department of Agriculture and Markets to welcome everyone to today's meeting. And, Samir Assar, the Director of the Division of Produce Safety and FDA's Center for Food Safety and Applied Nutrition. Commissioner?

MR. BALL: Thank you very much, Catherine. And welcome to the great state of New York for those of you that are here in the room and for those of you virtually out there. You have yet to enjoy a great treat.

Good morning and welcome, and thanks so much. Special thanks to FDA for putting this on in Albany. It's very good to be with you today, not only as a Commissioner of Agriculture in New York, but as a farmer. I'm a vegetable grower and a greenhouse grower and it's great to celebrate what I think is a bit of momentous achievement in this process. Special thank you to our legislators and to our farmers and

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all of you that are here today to learn some more about the Food Safety Modernization Act and how the Produce Safety Rule will affect how we handle things in the United States and how we go forward.

The Food Safety Modernization Act really probably the most sweeping reform of food safety legislation and at least 70 years created to prevent food-borne illness. And I think it's a rather significant move from a reactive type of food safety program to a more preventive integrated plan. It's pretty good.

Prevention is key here and the FSMA rule sets out to achieve that through its education before and why we regulate through its On-Farm Readiness Reviews and through science-based approaches that make sense.

We're joined by a lot of great people in this room here today including Bob Ehart from NASDA and -- the National Association of State Departments of Ag and the On-Farm Readiness Review, along with Betsy Bihn at Cornell. These have been really great efforts to help spread the word.

I think the word is collaboration. The Produce Safety Rule really is about collaboration with our partners at FDA and with all of you, and I see us achieving that as we stay collaborated. This collaboration began some time ago when New York and a lot of other states represented here today entered into a collaborative -- cooperative agreement with FDA to implement the Food Safety rule in our own states. We value the relationship that we have with our growers. We value the relationship we have with FDA as I say quite often, and when you value your relationship then you take care of it.

We're on the farms and we meet regularly with our commodity groups. If we're going to have success, it will ultimately dependent on making it achievable for our grower community. As I mentioned, I'm a vegetable grower myself, so I can appreciate both sides of this issue. Being involved with the industry I understood pretty quickly that food safety is not

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just big growers' business or not just scientist business or not just the researchers' business, food safety is everybody's business. And not just only the retailer or the wholesalers, but the whole food system needs to be on the same page with food safety.

So our state health department and our agriculture departments have been working on the quality of and the safety of food for some time. We've always had a strong relationship with FDA and we're encouraged to see the release of the guidance related to the Produce Safety Rule before the implementation next January.

So I'm glad you're in the room. I'm glad you're virtually out there. Keep your pencils up today. Continue to learn, remain a student here and provide commentary to FDA after you have absorbed this. You can use the Federal Register notice on this guidance document to do that. We have to get this right, we want to get this right. And we want it to be science-based and again we want it to be achievable. So again, it's a great opportunity for me to welcome you here and recognize this milestone. And again, keep your pencils up and learn a lot. Thank you, so much.

(Applause)

MR. ASSAR: Good morning. Good morning. Thank you. My name is Samir Assar. I'm the Director for the Division of Produce Safety and I thank you for joining us today to talk about the Produce Safety Rule compliance and implementation guidance.

As you know, the draft guidance is available and open for comment. And we're here today really to get your feedback face to face. And we found that when we were drafting the Produce Safety Rule that meetings like this were, and really the conversations that we'll have through this today are incredibly invaluable to us. And we really need to continue this dialogue as we move forward to implement the Produce Safety Rule.

The draft guidance has been a long time in the making and longer than perhaps we would have liked. But we wanted to make sure that it was -- it's

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helpful to farmers as is possible. It is a long document, we've heard that already. However, we built in examples throughout this process of ways to comply with the requirements in the rule and provided useful figures as well to make the document more user-friendly.

Is it the best that can be? That's what we want to hear from you. Implementing the Produce Safety Rule is a new territory for all of us here and we're looking forward to hearing back your thoughts about the Produce Safety Rule compliance implementation guidance and what changes may be needed to make it a resource that will be -- that will truly guide farmers in their work to comply with the Produce Safety Rule.

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 on -- based on science and risk. The Produce Safety Rule advances our thinking on Produce Safety Standards that began back in the '90s when we issued the Good Agricultural Practices guidance document. And it's been 30 years since then, unbelievable. And it's been a year since FSMA was signed into law.

But the importance of this mission has been driven home by the number of outbreaks that we've seen over this past year. And these include at least 77 illnesses of salmonellosis in nine states tied to pre-cut melons. At least 511 illnesses in 15 States of cyclospora infection tied to package salad sold in restaurants. At least 250 illnesses in four States of cyclosporiasis tied to vegetable trays. At least 210 illnesses, including 5 deaths in 36 States of E. Coli 157:H7 illness linked to romaine lettuce grown in -- in and around the Yuma region. And we continue to deal with the challenges of E. Coli and leafy greens as evidenced by the most recent outbreak of E. Coli 157:H7 linked to romaine.

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

The draft guidance covers each of these with some exceptions. I'm sure you know we're reconsidering the water standards in response to the feedback that the final standards were too complicated to understand and implement. The rulemaking to extend the complaint states for agricultural water requirements for covered produce other than sprouts will soon be final. And at this time we do not intend to enforce the agricultural water provisions in subpart E in the produce safety regulation for covered produce other than sprouts while we're going to through this reconsideration process for those requirements.

And in this process we're really considering how we might further reduce the regulatory burden or increase flexibility while continuing to protect public health.

Additionally, we're continuing to work on a framework for evaluating the safe use of untreated biological soil amendments of animal origin such raw manure. We are involved in multiple research projects that will inform a risk assessment that will be the foundation for future policy decisions. With both agriculture, agricultural water and soil amendments we've been and will continue to be involved with stakeholders and engage with stakeholders to develop the most practical and effective methods.

I would like to talk a little bit about how this guidance can be used. And there are some important points about the draft guidance that I'd like to point out. The draft guidance contains

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nonbinding recommendations that provides a means for us to update our thinking on implementation account for advancing science. It provides examples, clarification 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 the respective operation.

And there may be several different approaches that all results in compliance with the Produce Safety Rule not only the -- those recommendations or the -- or those that are included in the Produce Safety Rule compliance and implementation guidance.

Our target audience include those that are engaged with implementation on the farm, including the owner, operator and agent in charge of a covered farm or -- and farm management personnel, which, you know, this includes organizations that assist farms with implementation such as extension and trade associations and academia or otherwise.

Implementation is a long-term process and we will be learning from each other throughout this entire process. For both regulators and for those -- those that are regulated it's about awareness and changing behaviors and practices as needed and ensuring that implementation is consistent across the landscape of growers no matter where they are located around the world.

Just wanted to talk to you about how we're moving forward with implementation at this point. And larger farms, as most of you know, hopefully know, had to comply with the Produce Safety Rule provisions by January 2016, I'm sorry, January 26, 2018. Small farms face a January 28, 2019, compliance date for most provisions.

And Commissioner Gottlieb has conveyed that inspections for larger farms subject to the Produce Safety Rule will begin in spring 2019. And this was designed really to give FDA and the states additional time to prepare and also provide more opportunities

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for education and outreach. FDA also plans to begin its inspections of large produce farms in the foreign arena in spring 2019.

So in addition to this draft guidance there are other resources and tools available to prepare farmers for inspections. We continue to collaborate with our partners to advance our Produce Safety efforts in a coordinated way. FDA has been working closely with the National Association of State Departments of Agriculture and the development of the 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 on how prepared they are to meet the requirements on the Produce Safety Rule. More information about the OFRR and how to sign up could be found on the -- on the NASDA 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 a localized regulatory and technical assistance to support compliance with the rule. A network directory can be found on FDA's website and stakeholders are encouraged to reach out to their local PSN representative. And you will hear from a couple of them today during the panel discussion.

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 educational partners that are aimed at training different audiences including the tribal and sustainable agriculture and international communities.

The Produce Safety Alliance is an instrumental partner and have implemented over a thousand grower trainings -- training courses that have been conducted domestically and internationally.

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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 on important farming issues. And I think most of you might know that FDA formally recognize the USDA Harmonized Good Agricultural Practices Program as aligned with the Produce Safety Rule as growers have expressed concerns about facing both market access audits from buyers and inspections for compliance with the Produce Safety Rule.

And while this recognition does not exempt farms from the Produce Safety Rule from state or federal inspections, it's intended to help farmers meet the requirements as efficiently as possible. And I just like to close by saying we've come a long way since the GAP's guidance and there are still a lot to do and we've advanced produce safety and we'll need to continue to get ahead of emerging produce safety issues.

One thing I've learned in all these meetings that I have attended and all the conversations that I've had with stakeholders during and after these meetings is that we all want the same thing. And we want consumers to have the confidence in the fresh fruits and vegetables that they consume. And we want them to consume fresh fruits and vegetables. We encourage them to consume fresh fruits and vegetables, because it contributes to a healthy diet. The FDA cannot accomplish this mission on its own and we all need to be -- we all need to be in this together in order to follow through and make implementation happen at the scale that will be useful for the industry and for regulators to protect public health. And thank you for your time for joining us today and for your commitment to food safety. Thank you.

MS. McDERMOTT: Thank you, Commissioner Ball, for your remarks. And again, thank you for being with us today. And thank you, Samir, for your remarks as well. We'll now change seats here and have the first

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set of FDA speakers come to the stage please.

MS. McDERMOTT: So we'll now begin to hear from a number of our FDA Produce Safety experts. To begin, we have Mike Mahovic, the Fresh Produce Branch Chief, Division of Produce Safety in FDA's Center for Food Safety and Applied Nutrition. And we have Karen Killinger, a Consumer Safety Officer in the Division of Produce Safety, again in FDA Center for Food Safety and Applied Nutrition. They will both be providing an overview of the produce compliance and implementation guidance. After that we'll hear from Dave Ingram, a Consumer Safety Officer, the Division of Produce Safety and FDA's Center for Food Safety and Applied Nutrition. And he will be providing an overview of the general provisions, which is Chapter 1 of the draft guidance, as well as Chapter 8, the records of the draft guidance. So to begin I'll hand it, Mike.

MR. MAHOVIC: Thank you, Cathy. Good morning. I'm Mike Mahovic, the Chief of the Fresh Produce Branch within FDA's Division of Produce Safety. And it is my pleasure to provide an overview for the standards for growing, packing, harvesting and holding produce for fresh consumption of the draft industry for guidance.

So we know many of you have been looking forward to the release of this draft compliance implementation guidance and we look forward to discussions today and to your comments to this guidance.

First, I'd to thank our FDA staff who have contributed to his draft guidance for their hard work and for the consideration of numerous topics as they develop this. We had at least 16 of our Division of Produce Safety staff working on this contributing to the document and numerous other staff within the agency.

We made an effort to consider the diversity among farming communities both domestically and internationally as we worked on this draft guidance. Today's meeting is an important step to continue as to

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educate before and while we regulate. And we appreciate the input that we have received from stakeholders, from state partners, from educational partners and from other agencies and we continue with the implementation of the Produce Safety Rule.

So first let's review some of the steps towards implementation for the rule. The Food Safety Modernization Act or FSMA was passed into law in 2011 where FDA was directed to issue several rules including the Produce Rule which would establish science-based minimum standards for the safe production of harvesting of fruits and vegetables. We published the original proposed or draft version of the Standards for Growing, Harvesting, Packing and Holding of Produce for Human Consumption on January 16, 2013, for comment. Based on stakeholder input through submitted comments a supplemental notice of proposed rulemaking was published in September 29th of 2014 which involved a limited reopening of the docket to describe our thinking on some specific aspects of the rule and we received additional comments at that time.

Then November 27, 2015, we published the final rule for the standards for growing, harvesting, packing and holding the produce for fresh human consumption, of course now referred to as the Produce Rule.

Produce rule represents minimum standards for the safe production and harvesting and fruits and vegetables. And in many cases the rule requirements provide flexibility to comply in a way that accounts for specific conditions and specific risks on individual farms. As Samir already mentioned, the first compliance date for the larger farms unless they're producing sprouts was in January of this year. And the next compliance date for smaller farms is January 28, 2019. We have delayed routine inspection until spring of 2019 to give farms and state regulators more guidance and the technical assistance to help ensure that they have all the information that

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they need.

Now releasing this draft guidance is a step to help farms implement the rule and when it's finalized we'll describe our current thinking as an agency. Similar to rule-making process the draft guidance is open for comment. Comment on guidance may be submitted at any time, but we encourage submission of your comments for this by April 22 of 2019 so that we can take them into consideration as we work towards finalizing this version of the guidance. Again, April 22, 2019.

So I'd like to note that our efforts with this guidance document will continue even after it is finalized. We intend to continue to update the guidance to reflect our latest thinking and as additional scientific information becomes available. At every stage of this process we've made an effort to engage with stakeholder through public meetings, through listening sessions, through educational farm visits among other activities. And we intend to continue this engagement as we continue to advance our food safety efforts together.

And now I'd like to introduce, Dr. Karen Killinger, who serve as the project lead for the Produce Safety Rule compliance and implementation guidance.

MS. KILLINGER: Thank you, Mike. Good morning, everyone. Alright. Can those sitting in the back, can you hear me okay? Raise your hand if you can. Okay. Fantastic. Thanks.

Alright. I'm Karen Killinger with the Division of Produce Safety Fresh Produce Branch. And it's really a pleasure to be here today to talk to you more about the details and the draft Produce Safety guidance for industry. So let's start with reviewing the content of the draft guidance.

On this slide you can see the chapters of the draft guidance. And as you can see, they closely follow along with the subparts of the Produce Safety Rule. I'd also like to mention a few things that are

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not covered in the draft guidance. At this time, we are choosing to not issue guidance related to Subpart Q on compliance and enforcement, Subpart R on withdrawal of a qualified exemption and subparts E and B with respect to agricultural water and alternatives.

As Samir mentioned, we do not intend to enforce the agricultural water provisions in Subpart E of the Produce Safety Regulation for covered produce other than sprouts. So farms should continue to use good agricultural practices to maintain and protect the quality of their water sources and to ensure that their food is not adulterated under the Food, Drug, and Cosmetic Act.

Moving on, with respect to Subpart M, we released a Draft Guidance last year to primarily assist sprout operations to comply with the sprout specific requirements of Subpart M of the Produce Safety Rule. The recommendations in this draft guidance are applicable and may be helpful to sprout operations to take into consideration with regard to compliance with several other subparts of the Produce Safety Rule.

Finally, I'd like to note that this draft guidance does not address the farm definition. The guidance for industry titled Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practices and Preventive Controls Produce Safety and/or 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. So please look to that guidance for more information about those topics.

Moving on, before we talk in more detail about the draft produce safety guidance for industry, I'd like to spend a little bit of time talking about the purpose and content in general of an FDA rule in comparison to a guidance document. And we have a table on this slide to summarize that information. So first, an FDA rule includes both the codified and the preamble. Let's start with the codified which is

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in the first column on the table. In the codified we state the legally binding requirement. And in many cases the legal requirements are specified using the word must. The codified is a numbered portion of the rule and it's located near the end of the document.

More specifically, the final produce safety rule specifies the science-based minimum requirements to reduce risk associated with biological hazards. It's also important to note that the codified often provides definitions of terms that are important to understand.

Moving on to the next column in the middle of the table on the preamble. The preamble of the rule often represents the bulk of the document. And the preamble has several purposes. To outline our thinking related to our development of the rule, to describe the rationale of the provisions in the rule. And in a final rule provides responses to comments that we received on the proposed rule.

Now let's review some information related to a guidance document which is summarized in the third column on the table. Guidance documents contain non-binding recommendations to assist in understanding how to comply with the rule requirements. Guidance documents when finalized describe our current thinking and in some cases we update them from time to time. Our recommendations in the guidance document often use the word should or recommend. In a guidance document use of the word must or the citation of a specific provision number specifies a rule requirement.

We typically issue a draft guidance document first and see comments from stakeholders. And that's a very important stage that we're in at this time. Comments provided within a certain timeframe are taken into consideration as we work on the final guidance document. And as mentioned earlier, the -- we encourage comments to be submitted for the draft produce safety guidance for industry by April 22, 2019, so that we can take them into consideration as we work on the final guidance document.

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Now I'd like to provide an overview of our approach as we worked on the draft guidance and review some concepts from the background and introduction of the document. Regarding our overall approach, we made an effort to take into consideration the diversity of the farming community as we prepared the draft guidance. We understand that there are operational differences that need to be taken into consideration as well as differences in awareness of food safety topics.

As a starting point, we reviewed the comments that we received in the final rule and looked at our responses in the preamble. We also reviewed scientific literature as appropriate and considered materials that were already available from industry and academic groups.

As a starting point we also made an effort to communicate with other entities within FDA as well as other agencies to develop consistent approaches across the board. We also worked with a group of commissioned state representatives who were appointed by NASDA (ph), AFTO (ph) and ASTHO to receive feedback on the draft guidance document.

We continue to value our engagement with stakeholders. And our participation and listening sessions, meetings, educational farm tours and other activities have been very helpful to us. I'd like to note that another important way to communicate with us after the rule published has been through the technical assistance network or TAN. I understand that some of you may be frustrated about our response time to TAN inquiries and we've been working to streamline our process and our response time continues to improve.

Please keep in mind that TAN inquiries are a way for us to review your questions and understand farm-specific scenarios. The TAN inquiries were an important source of information for us as we worked on the draft guidance.

Moving on, I'd like to talk a little bit about some key concepts that are introduced in the

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background and introduction sections of the draft guidance. First, I want to emphasize that the draft guidance when finalized is intended to provide our recommendations to comply with the requirements of the Produce Safety Rule. These are nonbinding recommendation.

In many cases the rule requirements are flexible, so there may be many ways to -- for a farm to comply with a given requirement. You can use an alternate approach as long as it satisfies the requirements that are applicable.

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

The introduction of the guidance also notes that the draft guidance is intended to help the owner, operator or agent in charge of a covered farm. In other words, you as defined in the rule to comply. So many of the recommendations are framed as you should to note that something is recommended but not required.

I'd also like to mention that not all of the definitions in the rule are provided in the Draft Guidance document, so it may be helpful for you to review the definitions in the rule as you go over the guidance, the draft guidance language. The Produce Safety Rule definitions are in the numbered section or codified portion of the rule. And in your packet today you have a copy of the definitions from the Code of Federal Regulations for your reference.

Now I'd like to discuss some concepts that are common over many of the chapters in the draft guidance. As I mentioned, in many cases 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

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and practices, keeping in mind the framework of the rule requirements to assist you in identifying 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 the rule requirements.

In several chapters we provide a summary of key recommendations often using bulleted lists at the beginning of the chapter. We're at the beginning of a section to help highlight recommended steps towards implementation and we hope you find these helpful. Again, we made an effort to include numerous examples to illustrate certain concepts in the chapters. So there are over 51 examples noted in the draft guidance using a numbering system within each chapter. And there is even more examples embedded in the narrative text.

With respect to our examples, we generally identify a specific type of covered produced for illustrative purposes. And in several places we know that even if you use similar practices and the specific cover produced mentioned in some of the examples, you should perform your own evaluation of your farm's specific conditions and practices.

In a few places we also provided visual aids to summarize certain information, and these will be introduced during the presentations today. We'd appreciate your comments on these overall approaches and whether you find them helpful to emphasize some of the key points in specific examples within the chapters.

This slide summarizes some of our resources that are available, and we'd encourage you to visit our webpage for the draft guidance. And that webpage is listed here in the upper right-hand corner of the slide. At our draft guidance webpage the draft guidance itself is available for download. And in addition to the draft

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guidance document, we prepared overviews of each of the chapters or at-a-glance summaries. And these overviews provide important aspects of each chapter. The at-a-glance overviews are also available on our website and can be downloaded as a group.

Moving on, we also have two fact sheets that are available at our final Produce Safety Rule website, also provided here on the slide. And those fact sheets relate to rarely consumed raw produce and biological soil amendments of animal origin.

Next, an important way to communicate with us continues to be the technical assistance network. If you have questions about the interpretation or applicability of the Produce Safety Rule to your farm, your practices, the TAN is a helpful way for us to receive those questions and provide a response to your enquiry. More information about the TAN is also available on the slide.

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

And I'd like to acknowledge some of our PSN staff who are with us today and will be joining us for a panel later this morning. We have Dr. Socrates Trujillo from the Division of Produce Safety and with the PSN staff. And we also have Dr. Wendy Johnecheck from the Produce Safety Network staff as well.

And we look forward to your comments later this morning. With respect to other resources, we also have other guidance documents available. So we've issued several guidance documents related to produce safety. Three of them are shown here on the slide.

And first we have the Small Entity Compliance

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Guidance which is intended to assist small entities in complying with the Produce Safety Rule and provides a summary of the definitions and requirements associated with the rule. Next, as I mentioned earlier, we issued a draft guidance document to assist sprout operations to comply with the sprout-specific requirements in Subpart M.

We also recently issued a draft guidance guide to minimize food safety hazards of fresh cut produce that discusses how fresh cut produce processors may comply with requirements for the good, current good manufacturing practices in requirements for hazard analysis and preventive tools. We also intend to issue draft guidance documents for produce, including an updated version of the guide to minimize microbial food safety hazards for fresh fruits and vegetables and a draft guidance on alternate curricula. We also intend to post updates and new questions to the TAN, frequently asked questions on the Produce Safety Rule.

So you may be wondering what are the next steps for the draft guidance. This is our third public meeting to discuss the draft guidance, and we are very excited to be here today and hear from you about your initial response to the draft guidance.

Most importantly, you have the opportunity to share your thoughts with us through public comment so that we can take them into consideration as we work on the final guidance. As I mentioned, these comments need to be submitted to the docket for our consideration. And you may submit comments at any time, but we encourage your comments to be submitted by April 22, 2019, so we can take them into consideration as we work on the final guidance.

There are several ways to access the docket to submit comments. So on the slide we've listed several of those options. First is through the Federal Register notice of availability. That website is there on this slide. I'd also like to note that in the Federal Register notice you can learn more about

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how to submit both electronic and written or paper comments as well as information about confidential submissions. Additionally, the Federal Register notice, which is also provided in your packet today, provides some questions where we seek specific comments, information or data. And we'll mention these questions in our presentations today when we talk about chapter 5 on domesticated animal -- domesticated and wild animals, and Chapter 7 on equipment, tools, buildings and sanitation.

I'd like to take a couple of minutes to talk about information that's particularly helpful when you submit a comment. We welcome your comments both on what you find positive in the draft guidance as well as changes that you'd like to see, so that the final guidance is balanced and applicable to a variety of circumstances.

Commenting on positive aspects of the guidance is helpful so that we are aware of information that should be retained. We also encourage substantive comments that thoughtfully describe your position on changes that you'd like to see. Please submit your comments with enough specificity or examples to describe how it relates to specific farm conditions and practices.

The slide also provides information about how to access the docket directly. And so another option for comment submission is to go directly to www.regulations.gov for comment submission and to learn more information. You can either enter the docket number or access a link directly for comment submission.

Moving on, as a reminder, our efforts with this guidance are likely to continue after we issue the first final version. We intend to update the guidance similar to our updating of the seafood HACCP guidance, which is in its fourth edition. It's important to us that this document continue to reflect our current thinking as we learn from each other, and that it continues to account for advancing science. We may also choose to issue other more targeted

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guidance documents.

We look forward to continuing to engage with you as we move forward in our process of implementation together. If you have questions related to this presentation, please hold on to them until the Q&A session later this morning. And we'll now move into our presentations on the draft guidance chapters.

Please keep in mind that these presentations are overviews. We can include all of the information in the presentations, but we look forward to engaging with you today in hearing more from you about your thoughts on the draft guidance. And thank you so much for this opportunity to share information with you today.

(Applause)

MR. INGRAM: Good morning, everyone. Thank you for joining us today. I'm David Ingram from the Division of Produce Safety, Fresh Produce Branch. And we will begin by discussing Chapter 1, General Provisions and Chapter 8, Records. Great.

Chapter 1 provides draft guidance to help determine the applicability of the Produce Safety Rule to your farm and to your produce. And now many of you will have questions about this topic, and we would very much like to hear those at the end of the session today. Records is another topic that impacts several farm activities, so we'll cover the general requirements for records early in our discussions today. Let's start with an overview of the content in Chapter 1.

We recommend you consider these topics as discussed in this chapter in the order with which they are presented. Starting with Section 1, Produce, then Section 2, Raw Agricultural Commodity, and the 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 in the guidance.

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

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

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

I'm using the computer to move the slide. I see the slides moving, but I don't see it on the screen. I should be on this slide.

SPEAKER: Go back to -- I apologize.

MR. INGRAM: That's okay. Cold morning this morning here at Albany, New York. I was prepared for it. That's perfect, thank you. So thank you for your patience.

We have heard from stakeholders that having a tool to assist us in determining whether your farm and your produce is covered would be helpful and important. And this figure here is on Page 8 of your draft guidance as well as a link to the PDF version on our webpage. I don't have time today to walk through each step, but this is an updated figure you see here summarizing the steps in the order recommended in the draft guidance. We hope you find this useful and we look forward to your comment on it.

The first topic we recommend that you

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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 examples, additional examples of produce in the draft guidance. We received several comments on the rule about the term produce, and food that is covered by the rule. And we received numerous TAN enquires on these topics.

Thanks to those of you who submitted TAN enquiries on this topic so we can understand your farm situation and your questions. While we cannot address every scenario, we include a discussion of some types of produce that are not subject to the 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 into 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 would welcome your comments on this topic.

Moving onto Section 2. You should consider next 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 process food including hydro cooling, refrigeration and removal of stems and leaves. We also list activities that changes a RAC into a processed food like chopping, cutting, cooking and irradiation.

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

Next, you should consider whether your food

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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 a 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 do intend to consider updating the list of rarely consumed raw commodities in the future as appropriate. And any changes to the RCR list would require rule making and cannot be adjusted through comments to the draft guidance.

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

Moving on, we discuss three conditions that you must meet in order to be eligible for the commercial processing exemption. First, produce must receive commercial processing that adequately reduces microorganisms of public health significance such as processing that meets the requirements of the low acid foods regulation, can foods regulation, the juice hazard regulation or validated process to eliminate spore forming microorganisms.

We recognize through stakeholder comments that there was a need to clarify the types of commercial processing steps that adequately reduces 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.

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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 sold to the fresh market.

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

You must 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 this slide, we announced that we intend to exercise enforcement discretion regarding the written assurance requirements, which means we do not intend to enforce the written assurance requirements while we consider options for these requirements.

Let's move on to the last two sections of this chapter. First, we covered -- the covered farms include farms and mixed type facilities. Some farms may not be eligible -- 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 with sales to include in your calculation. So we assist you in determining whether the farm is above or below the \$25,000 threshold.

The draft guidance describes the types of produce sales that should be included in your calculations, such as all produce sold, not just covered produce. And in the applicable three years, produce sales at farmers markets, direct to consumers,

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or online sales would also be included. Keep in mind that your -- the calculation also includes the previous three years. If 2018 is the applicable year for example, the total produce sales for 2015, '16 and '17 would be included in your calculation.

Next, farms that exceeded -- 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 enquiries on what to include in these calculations as well. The draft guidance mentions that livestock sales are included in food sales, as well as sales of hay, grains, wine and other foods.

In the draft guidance, we provide several example calculations related to both the \$25,000 threshold and the qualified exemptions to demonstrate how these calculations would be performed in specific scenarios. We look forward to your comments on these examples to illustrate how to perform the calculations. Note that farms that are eligible for a qualified exemption do remain subject to modified requirements under the Produce Safety rule.

Finally, covered farms must comply with all applicable requirements when conducting covered activities. The draft guidance provides some examples such as for a farm that composts, a Biological Soil Amendment of Animal Origin or BSAAO, the farm needs to implement the relevant rule provisions applicable to this activity.

And this concludes our overview of Chapter 1. So 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 the 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

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generally self-explanatory. As we worked on the draft guidance, we targeted providing clarification about the rule requirements and providing our current thinking on topics based on comments on the Produce Safety Rule, stakeholder questions and input through the 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's important to develop a strategy for keeping the required documents.

The required records for your farm will depend on the requirements of the Produce Safety Rule that are applicable to your farm. So let's start with the recommendations associated with general requirements.

The topics listed on this slide are all discussed in the draft guidance. We will not have time to discuss all of them, but a selected few -- we selected a few to highlight which are emboldened on the slide. We expanded on these topics based on stakeholder comments from the Produce Safety Rule requesting information on content of the required records. Your records must list the farm name and location. The location should include a postal address or 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 apps that have unique names for fields and buildings. Required records must include actual values and observations. These records should be accurate without rounding or generalization. For example, records stating pass, okay, or greater than six do not accurately reflect the actual value or observation. These types of

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records do not ensure that required measures were taken to minimize hazards and do not allow you to determine trends in the recorded information.

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 errors such as forgetting the value of the record to be -- the value to be recorded. Confusing multiple values or not creating the record at all.

So moving on, our next topic is review by a supervisor or responsible party. Supervisor review of records is important to ensure completeness of the records, accuracy of the records and that any necessary corrective actions and measures are performed. The draft guidance recommends that supervisors should look to any -- for any unexpected results and follow up as needed. Generally, we believe record review should occur within 1 week after the record is created. In some cases a shorter or longer timeframe may be appropriate.

Next, the draft guidance describes some examples of ways to comply with the requirements for record 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 farms office.

Moving onto record format, there are several options. And some are listed on the slide. Keep in mind that the record should be sufficient to determine the original record whether or not 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

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information, you can keep additional information required for compliance separately or in combination 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.

I think we're -- Okay. Section 7 reviews -- the wrong slide here. Sorry, folks.

Section 7 reviews specific records requirements, and there are four chapters of the draft guidance that provide more specific recommendations on required records. And we encourage you to review this information on chapters 1, 2, 4 and 7.

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

So this was a brief summary of the topics covered in the draft guidance for chapters 1 and 8. And we do look forward to your comments. If you have questions or comments, please hold on to them. We welcome the questions in our question session before lunch. And after lunch we will have a comment session which will look forward to your comments.

Thank you for bearing with our technical difficulties, and we'll be here all day. Thank you.

(Applause)

MS. McDERMOTT: Thank you for your presentations Dave, Karen and Mike. At this time, we're going to take a little break. I know we're running a little early. So let's meet back in the room at 10:00 a.m. That's a 20-minute break. 10:00 a.m., and we'll start again then. Thank you.

(Recess)

MS. McDERMOTT: Hi everyone. If we could have everyone come back into the room and take their seats please. If everyone could just take their seats

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please, we'll start again.

Welcome back from the break, everyone. We'll now hear again from Karen Killinger, consumer safety officer, Division of Produce Safety with FDA's Center for Food Safety and Applied Nutrition. Karen will be speaking on Chapter 2, Personnel Qualifications and Training; and Health and Hygiene which is Chapter 3. Thank you. Karen?

MS. KILLINGER: Thank you Cathy. Hello again everyone. Can you guys still hear me okay in the back? Wonderful. Alright, it's my pleasure today to speak with you more about the recommendations in the Draft Guidance related to both Chapter 2, Personnel Qualifications and Training; and Chapter 3, Health and Hygiene.

Before we get started, I'm just interested, as we talked about, the Draft Guidance was released a little over a month ago and I'm curious how many of you have had a chance to look through some of the guidance so far? Okay, so about half the room. And how many of you specifically have looked at the content in Chapters 2 and 3? Alright, awesome. Well, we're looking forward to discussing some more of the content in these two chapters.

And let's start with Chapter 2 on Personnel Qualifications and Training. This slide lists the sections in the Draft Guidance chapter related to personnel qualifications and training and the sections in this chapter include evaluating personnel's assigned duties; qualifications necessary to perform assigned duties; training frequency; and easily understandable training; minimum training requirements; additional training for personnel who conduct harvest activities; food safety training for a supervisor or responsible party; supervision to ensure compliance and training records.

We don't have time to discuss all of these sections today, so we've selected a few to highlight in more detail. Please note that the section numbers are provided on this slide and are listed on later

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slides to provide a sense of where the information is located in the Draft Guidance. As we worked on this chapter, we were targeting providing recommendations and examples to describe options for implementation on farms. We considered stakeholder comments from the rural as well as TAN inquiries and our engagement with educational partners as we worked on the Draft Guidance.

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

On this slide we cover two sections of Chapter 2. Section 1, evaluating personnel's assigned duties; and Section 8, supervision to ensure compliance with the rule. For these topics we took into consideration some of the TAN inquiries that we 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 of your personnel and observe them to help you identify the personnel subject to the qualifications and training requirements. As a reminder, all personnel who handle covered produce or food contact surfaces or who are engaged in the supervision thereof must have a combination of education, training and experience necessary to perform their assigned duties in compliance with the Produce Safety Rule.

You should consider the breadth of covered activities on your farm and how they are performed to determine whether personnel performing these activities contact covered produce or food contact surfaces. In some cases, infrequent contact with covered produce or food contact surfaces could occur and the Draft Guidance provides some examples of these situations. Moving on to Section 8 of Chapter 2,

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supervision to ensure compliance, for this topic we also recommend evaluating your operations and ensuring that you identified personnel to supervise each aspect of your operation for compliance.

As a reminder, you must assign personnel to supervise your operations to ensure compliance with the requirements of the Produce Safety Rule. You could find that you need multiple individuals to fill this role, but in some cases one person could be able to perform all of the necessary duties. Such personnel can include full-time, permanent, temporary, part-time, seasonal, contracted or other personnel. The assigned personnel play an integral role in ensuring compliance with the produce safety requirements.

The owner, operator or agent in charge of a covered farm should also ensure that the 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 which are covered in Section 2 of Chapter 2 of the Draft Guidance. For personnel that handle covered produce or food contact surfaces or those engaged in the supervision thereof, the owner, operator or agent in charge of a covered farm should evaluate whether these personnel have a combination of education, training and experience to perform their assigned duties.

Appropriate qualifications prepare them to perform their assigned duties in a way that meets the requirements of the Produce Safety Rule. They should be able to apply their knowledge when performing their job duties. The Draft Guidance provides several examples about evaluating the education, training and experience of farm workers and supervisors. Your

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evaluation can help you decide if additional steps need to be taken in order to ensure that they have appropriate qualifications to perform their assigned duties.

Now let's discuss some of the recommendations for personnel qualifications. Let's move into some of the general recommendations for training. This slide discusses content related to Sections 3 and 4 on Training Frequency and Easily Understandable Training in Chapter 2. In these sections, we were aware of stakeholder comments from the rural and expanded our discussion of these topics.

First, let's discuss Section 3 on Training Frequency. As a reminder, you're required to provide training upon hiring, periodically thereafter at least once annually; and as necessary and appropriate 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 food-borne illness. There's a great deal of flexibility in how you arrange the timing and frequency of your training, as long as periodic training occurs at least once annually.

Factors to consider when determining the timing of training includes the type, number and timing of your crops and the timing of hiring and initial training of your 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 harvest.

Moving on to Section 4, Easily Understandable Training, the slide reviews some of the recommendations around making sure that training is

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easily understood. The Draft Guidance discusses several considerations of these topics, including structuring shorter or longer training sessions depending on the type and depth of information being presented. In some cases, training delivered at or near workstations can be useful to connect with specific job duties, to add demonstrations or to 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.

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

Additionally, training topics should help personnel understand how their actions can affect the safety of covered produce and food contact surfaces. Further, the training should help personnel understand the roots of contamination so they can recognize how on-farm practices could result in contamination. Training should also include your farm's procedures so personnel are aware of them as well.

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 the following training topics should be included; relevant sources of food-borne pathogens such as humans, animals and their waste; roots of contamination such as animals or pests contaminating

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covered produce or food contact surfaces or handling an untreated BSAAO in a way that it contacts covered produce during an application. Other recommended topics include preventive and corrective measures.

Training on health and hygiene should help ensure that personnel understand that 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. The Draft Guidance also contains recommendations and examples related to training that covers the standards of sub-part C through O of the Produce Safety Rule that are applicable to an employee's job responsibilities. The Draft Guidance also provides recommendations for training those who conduct harvest activities.

Another training requirement specifies that at a minimum at least one supervisor or responsible party from your farm must complete food safety training at least equivalent to that received under the standardized curriculum recognized as adequate by FDA. The standardized curriculum was developed by the Produce Safety Alliance and is offered as one way to meet this requirement. We will hear more from some of our educational partners as part of our panel later this morning.

This wraps up our overview of Chapter 2 and we'll now move on to covering Chapter 3. These recommendations in the Draft Guidance are related to health and hygiene and in this chapter we were aware of stakeholder comments from the rural, expanded on some of these concepts and provided examples to illustrate options for compliance. This chapter is divided into three sections which are listed on the slide; measures to prevent ill or infected persons from contaminating covered produce; hygienic practices; and measures to prevent visitors from

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contaminating covered produce and food contact surfaces.

Again, the section numbers are provided on this slide and on later slides to provide a sense of where the information is located in the Draft Guidance. I'd like to point out that at the beginning of Sections 1 and 2 we provide a summary of some of the key recommendations for each section and we hope you find these helpful to become familiar with the content in these sections.

In this chapter, communication on the farm is emphasized and it's important for owners, operators or agents in charge of a covered farm to communicate the responsibility of personnel as well as supervisors or responsible parties to prevent contamination through hygienic practices. In Sections 1 and 2, Chapter 3 discusses recommendations that are 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 the content in Section 1 of Chapter 3. The main bullets on this slide and the next two slides list the sub-section topics. In the first sub-section, 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 and visitors. In the sub-section 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

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food contact surfaces can identify applicable health conditions. There is also discussion of training requirements and recommendations related to health and hygiene topics.

Moving on, as a reminder, the owner, operator or agent in charge of a covered farm must instruct personnel to notify their supervisors or a responsible party if they have or if there's a reasonable possibility that they have an applicable health condition. The Draft Guidance also provides recommendations to promote self-identification of applicable health conditions by personnel, including training all personnel who may contaminate covered produce or food contact surfaces on applicable health conditions and how to identify them; encouraging personnel to be aware of exposure to individuals with symptoms of an applicable health condition; and informing personnel who 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 food contact surfaces, recommendations and examples for appropriate measures to prevent contamination when a worker reports an applicable health condition and recommendations to assist in making decisions about excluding or reassigning workers with applicable

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health conditions. In the next subsection, the Draft Guidance discusses requirements, recommendations and examples on responding to potential contamination of covered produce or food contact services.

Moving on to Section 2 on 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 this section to help identify steps towards implementation and these are listed on the slide. There is a recommendation that you should ensure that all applicable personnel are aware of hygienic practice requirements and can identify and correct a 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 also be aware of and follow hygienic practices to protect against contamination.

There is also a recommendation that you should ensure that personnel are aware of farm procedures associated with the minimum hygienic requirements of the Produce Safety Rule, including avoiding contact with animals other than working animals and wearing jewelry. Continuing on, the main bullets on this slide represent the subsections in Section 2 of Chapter 3. The Draft Guidance recommends that you should evaluate those covered activities where covered produce or food contact surfaces are at risk of contamination and ensure that your personnel are following hygienic practices. As mentioned

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previously, you should ensure that all personnel use hygienic practices as necessary to protect against 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 other personnel consistently follow hygienic practices on the farm. As mentioned on the previous slide, these supervisors or responsible parties should also 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 the requirements described in 112.32(b) (ph) and if you've looked at the Draft Guidance, you know that that's a long section in this chapter which includes recommendations and examples related to topics such as maintaining adequate personal cleanliness, thorough hand-washing and using gloves among other topics.

Now let's move on to 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 one of those terms that's defined in the rule. In the Draft Guidance, there is a recommendation that the owner, operator or agent in-charge of a covered farm evaluate the different types of visitors and their interactions with covered produce or food contact surfaces to determine appropriate approaches. There is flexibility in how to meet these requirements and the Draft Guidance describes options and examples on possible implementation strategies.

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As a reminder, you must make toilet and hand-washing facilities accessible to visitors and you should inform visitors of the location of the accessible toilet and hand-washing facilities. This concludes our presentation on Chapters 2 and 3 and we look forward to any questions or comments that you have in the questions and comment session later this morning and we definitely look forward to your comments on these chapters for the Draft Guidance. Thanks for your attention.

MS. McDERMOTT: Thank you for that presentation, Karen. I'd now like to invite our stakeholder panel to come and have a seat on the stage and I'll be handing over the mic to Karen Killinger who will be now moderating our panel discussion with our external stakeholders.

MS. KILLINGER: Give everyone a couple of seconds to get situated here. I'd like to start off by thanking all of our panelists for joining us today. We're very excited to hear from them about their initial thoughts on the Draft Guidance and rather than introducing them, I'm going to -- myself I'm going to ask them to go through and introduce themselves, but it's really exciting to have the opportunity to hear from our academic partners, as well as industry groups and the state regulatory folks as well as some of our PSN staff.

So I'd just like to start off by asking each of you to introduce yourselves and tell us a little bit about your role and your organization's role in implementation of the Produce Safety Rule, such as activities like outreach, education and training and specifically for our PSN staff, I'd like you to speak a little bit to the differences in the roles of our PSNRA staff and our PSN CFSAN staff. Chris, would you be willing to lead us off?

MR. CALLAHAN: Is this okay? Yes, it is. Wow. Good morning everybody. I'm Chris Callahan with the University of Vermont Extension. I really have two roles relative today's discussion. One is as an

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extension educator I work directly with growers -- produce growers who are impacted by the Produce Safety Rule and provide educational programs and direct technical assistance to those seeking to improve produce safety practices, particularly relevant to the rule.

The other role I have is as director of the Northeast Center to Advance Food Safety. We are one of the four regional centers funded jointly by the USDA and FDA. That support is very much appreciated. Our work is intended to support training education and outreach, particularly focused on small and medium-sized producers and small processors who are impacted by the Food Safety Modernization Act, in particular the Produce Safety Rule and the Preventive Controls for Human Foods rule. Thanks.

MS. KILLINGER: Thank you.

MR. NOONAN: Good morning. I'm Roger Noonan. I'm a certified organic diversified farmer from New Boston, New Hampshire and I serve as president of the New England Farmers Union and I'm on the steering committee of the local food safety collaborative which is a FDA cooperative agreement with National Farmers Union; the National Young Farmers Coalition represented by Cara Fraver over there; Maryland Department of Agriculture; Washington State Department of Agriculture and Cornell University, Betsy Bihn.

And our task there is to work with -- directly with local foods producers, beginning farmers, socially disadvantaged, so sort of the -- I don't want to say the folks that aren't going to have industry folks in Washington all the time working with the team. And then of course as a farmer and advocate, I got involved with FSMA a long time ago. First meeting was in Connecticut at a NEASDA, Northeastern Association of State Departments of Agriculture meeting, and you know, realized for the small farm community as stated in -- and this is a long introduction, I apologize, but that we really needed a voice at the table for this rule for that

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smaller community and I really appreciate the opportunity to be here and to have been involved in this process. Thank you.

MR. FINLEY: Hi, good morning. I'm Aaron Finley, New York State Produce Safety Program office administrator. Together with Steve Schirmer, our field administrator, we are responsible for developing and implementing the Produce Safety Rule in New York State. We report to John Luker, the assistant and acting director of Food Safety & Inspection and we work with the Commissioner's Office on a variety of activities, including outreach, education, development of a compliance and enforcement system.

We have five inspectors located throughout the state and they are at this time assisting us with outreach and education activities. My job, specifically I'm responsible for grant deliverables; building farm inventory; attending the annual consortium for Produce Safety Program development; annual and mid-year reporting; I liaison with FDA state and local partners; NASDA; we develop partnerships with many industries in New York, the Food Safety -- Food Industry Alliance; New York Farm Bureau; New York State Apple Association; Vegetable Growers Association and others.

And right now before we reach this compliance and enforcement in 2019, our main goal is to reach farmers -- conduct outreach and education to prepare them for the Produce Safety Rule implementation while at the same time building our farm inventory.

MS. KILLINGER: Thank you.

MS. JOHNECHECK: Hello, can you hear me in the back? So I'm Wendy Johnecheck and I am one of the four regionally based produce safety network staff in the northeast. There are three of us who sit within the Office of Regulatory Affairs, as Karen was alluding to earlier, ORA and there is one of us who resides in the Center for Food Safety and Applied Nutrition, Soc here and I'll let him speak to his Role.

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I'd like to speak to just the role of the PSN who reside in the Office of Regulatory Affairs. As I mentioned there are four -- well, for those of you who don't know the Office of Regulatory Affairs is the field -- is the part of the FDA that actually carries out field activities, both all across the U.S. and internationally. So as being part -- being a Produce Safety Network individual in that part of the agency, we are tasked with doing -- carrying out field activities. We're specialized in carrying out Produce Safety Rule-specialized activities. And so what that means in real terms, we will be conducting inspections in states and the very few number of states that do not have cooperative -- produce safety cooperative agreement programs with FDA and will also be conducting inspections internationally.

So in addition to that, in instance of an adverse event or a food illness outbreak, we will be conducting -- working with state partners to conduct investigations. So in addition to field activities, we're also involved in collaborating with state partners. I see some folks in the room as well on work planning activities. We are liaising with our other entities in the region, so other FDA entities in the region who are carrying out activities say under the Preventive Controls for Human Foods and also the state agency so that with an eye to minimizing our time on the farm and coordinating to the extent that we can, so.

MS. KILLINGER: Thanks Wendy.

MR. TRUJILLO: Thank you Wendy. I hope my voice carries. Socrates Trujillo, Produce Safety Network, Center for Food Safety and Applied Nutrition. As Wendy indicated, I am the person who works with the northeast region here at the -- on the Produce Safety Network from the Center for Food Safety and Applied Nutrition, CFSAN. I cover the states all the way from Maine down to West Virginia, Maryland, Delaware, including the District of Columbia.

And my role here is to interact with our

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state partners and our academia regarding the technical questions that they may have regarding the Produce Safety Rule. So as Karen had indicated, there are -- TAN is one of the sources that you can get information regarding the interpretation of the Produce Safety Rule, but when the answers are already being provided or information has already been described in other means, we have access to that and we are able to provide hopefully a quicker response once the answers have been clear.

I also work directly with the Department of Agriculture in the states and visit farms to understand the reality of the farming communities on these regions where we are located and develop tools that will help the states to interact with the farmers to provide more information as appropriate to the farmers and what required. I also had the opportunity to interact with our colleagues working on the guidance document and provide them information who were appropriate to include them on the guidance based on what we had seen out on the field.

I also support our partners when they have questions regarding the proper interpretation of the Product Safety Rule and participated in outbreaks as an expert on the area of product safety.

MS. KILLINGER: Thanks to all of you for those introductions. And it sounds like a commonality among all of you is that you have some direct engagement with farmers and then there's also collaboration that occurs between groups like educational groups, state partners, FDA and industry groups, so that's helpful to know. And I'd like to move into hearing how you see using the Draft Guidance document as you're working on these efforts related to education, outreach and training and that question is for all of you, so feel free to go down the line and tell us more about how you think you'll use the guidance document.

MR. CALLAHAN: Okay. This is Chris Callahan speaking. I was told to reintroduce myself. I think

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first and foremost is first of all thank you for the work that went into the guidance. I recognize the challenge of the task and what's most helpful about it is it's another opportunity to inform and educate myself and then take it further and try to help others gain clarity and reduce confusion around practice. I think there is -- there are great opportunities to develop add-on and supplemental material for example to supplement PSA grower training and other educational activities and the examples provided in the guidance specifically to me suggest great reflective activities and breakout session-type opportunities in those sorts of trainings.

The other place where it's very helpful for me is when providing direct technical assistance, so during a farm visit or e-mail or phone discussion with a grower who's really trying to navigate the rule, you know, having a bit more detail to dig into from the guidance certainly would be helpful. I think I'll leave it at that and let others chime in.

MR. NOONAN: Well, I'm just keeping going down the line here. This is Roger Noonan. So as a grower and that I work with a lot of growers, I read the guidance, I read it from my own farmer's perspective which is a very small farm by the way. I'm not a very good industry representative in that I'm not going to be one of the first farms inspected, but as a grower of fresh produce and other products, I want to assure that I'm doing things in the safest way possible. I mean I'm a organic farmer. We're going to -- you know, we're trying to be environmentally sound and I certainly want to be as sustainable in how I treat my customers as I do the water and environment around me.

And there's a lot of good stuff in there, I'm not going to say there's anything new I learned because I've been hanging around with these folks for a while, so I've learned a lot especially taking the PSA training and all the other reading. But again find yourself if you're a farmer and I'm not sure how

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many farmers who are in this room are online, but find yourself in there. If you don't see yourself in there, the best advice I got was write yourself into it and submit it as a comment.

And if you need to work with a group like the Farmers Union or Farm Bureau or Young Farmers Coalition or other groups that are out there, work with those groups, collect your comments, find yourself in there and submit them. I think that's the -- you know, we are two phases here, how do we use the guidance and how do we get better comments back to the FDA to make sure that this is covering everybody.

MR. FINLEY: Aaron Finley, New York State Agriculture & Markets. So how we see this guidance is as a tool. As I mentioned, we're in the outreach and education mode right now and we welcome any and all tools to engage, connect and help the farmers with the Produce Safety Rule. And this will definitely be added to our toolbox and we will use this as we attend PSA grower trainings; the on-farm readiness reviews; on-farm readiness review mentoring which we're doing in New York State; industry meetings and events such as the Farm Bureau meetings; Empire Farm Days and on-farm educational visits where we have an informal visit to help the farm with whatever concerns they may happen to have. This guidance will be one of the tools that we use to engage farmers in that process.

MS. JOHNECHECK: Wendy Johnecheck, ORA Produce Safety Network. So I'd like to address how I'm likely to use the guidance during the course of an inspection. So I've had the pleasure of working with other FDA guidances in other regulatory areas, so I have a sense of what it brings to the table to have that guidance document along with you when you're actually conducting an inspection. So I envision that I'll actually bring two hardcopies to every inspection, one for my own as a resource and one in the instance that we are in the process of talking about a part of the operation and it seems that the examples or something in that guidance document is

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relevant, I will typically open that guidance document if it seems appropriate at that time.

We will have a discussion relating to the examples and at that, you know, based on the scenario often end up leaving a section of that guidance document with the farmer or at the actual facility as I have in the past. So it really depends on the scenario, but I really do see that this is going to be a fantastic help during the course of an inspection to draw on the examples.

MR. TRUJILLO: Thank you Wendy. Socrates Trujillo, PSN CFSAN. So the way I have been using the guidances to actually identify the current thinking of the agency because I wish I could tell you I know everything about what the agency is doing at this moment, but they usually don't, so I rely on all the tools that the agency produces and I read those documents and discuss it with my stakeholders, with my state partners and also with the industry when appropriate and they ask questions.

So I have a copy already written on all my comments and what I talk to the people who ask questions, first we tell them to submit the docket and then we go into the discussions and we provide more information about what the agency is thinking. It is something that I bring with me since the Draft Guidance was released to the farm visit that I've done. I talk to the farmers and say have you read it and make sure that the states are providing that information to the farmers when we're going to farm visits and direct with the states as well. So it's something that I've seen very useful.

As I mentioned, I like to read and understand where we are on the current thinking of the agency and that was a really good piece of information for me to further the providing the tools to the states and the farmers.

MS. KILLINGER: Okay, thanks to all of you for that insight and I think it's interesting to hear that, you know, both Socrates and Aaron mentioned that

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they would use the guidance kind of as a global tool to understand our current thinking and policy, but also to reach out to the industry and to other state partners to communicate about certain concepts, but that also Roger mentioned finding yourself in the guidance and that farmers need to look at the guidance and kind of see where they're at and where they need to go.

And several of you mentioned that you would use the tool -- or use the guidance as a tool in a more specific or targeted way and Chris, you mentioned that you might look at developing some activities to help farms to find themselves in that guidance and to look at the examples or the language in the guidance and how they specifically connect to a specific farm's practices and really take that next step, if you will, towards implementation on farms.

And so I really appreciate the comments on how you might use the guidance in a more targeted way given where a farm is currently at and Wendy mentioned that that also plays into the approach to inspections and identifying where a farm is at in order to again look at what practices they have and if there's things that need to be changed or improved upon with respect to inspections and using that guidance as a tool. So thanks for that.

The next series of questions are really more for Chris, Roger and Aaron, as they're targeted more at responding to their initial reactions to the Draft Guidance. We'd definitely like to hear more from our partners and from all of you later today about your initial thoughts with respect to the Draft Guidance. So the next question for the three of you is can you tell us more specifically about some points in the guidance that you found particularly useful, meaning that you thought, wow, that's really helpful information to clarify a specific concept or topic.

MR. NOONAN: Well, I mean all of it, it really -- it puts some meat on the bones where we have not had any meat on the bones in a lot of these places

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and I guess I'm going to go back to sort of the perspective of the smaller operation that, you know, maybe has very few employees, you read a lot of language in there, you know, designated person, the supervisor. Well, that person may all be one person. It may just be dad, you know, and that's so you have to -- you have to -- you know, we can't write guidance, you know, for every -- well, FDA can't necessarily write guidance for everybody, but I think like in our local food safety collaborative perhaps we should tailor this guidance, streamline it down to that smaller may be qualified exempt operation or the -- or parse it out, parse this information.

It's a fairly daunting document for a non-professional in, you know, food safety or agriculture and even as a farmer which -- technically I'm a professional in food, but it's still -- this is -- you know, this is a little bit above my pay grade to get into the details of some of the science-based stuff. As a grower I always like to know what do I have to do, is it simple, is it effective, can I do it without putting myself out of business. And I think there's a lot of stuff in here that is going to assist me personally and the groups that I work with in helping people comply. That's not very specific, but --

MS. KILLINGER: I think it helps give us an idea of, yeah, how you see it moving forward with implementation, so thanks for those comments.

MR. FINLEY: Aaron Finley, New York State Department of Agriculture & Markets. So I like a lot of this guidance, specifically the expanded definitions produce versus rack and rack versus process product, I think -- that discussion I think is useful to further clarify what may or may not be produce, you know, produce that's intended for human consumption versus intended for commercial or, you know, material manufacturing uses or seed or crop propagation.

I was hoping that seed and bulbs would be addressed as food in there, but it wasn't. Discussion

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of covered farm, I think that was good. Covered farm was not really defined in the rule, it's used as a sentence, but not included in the definitions and this discussion comes a little closer to creating a definition for the covered farm. Clarifying microgreens as covered produce was helpful.

That's a question that we've seen before here in New York State. Defining seed crops, use of hand sanitizer, it was good to see that's clarified again that it's not allowed in place of proper hand-washing, but it can be used in addition to a proper hand-washing procedure. I was glad to see that because I would hate to see a regulator, you know, just ding somebody automatically for the hand sanitizer even though it's used in the conjunction with proper hand-washing.

Examples on how to make visitors aware of food safety policies, I thought that was helpful. Examples of qualified exemptions and the associated calculations, that was also very helpful. The discussion of produce for personal consumption, that was a little bit confusing to us because we didn't understand without a produce -- without a sale of produce, why would that discussion or situation even be looked at, but the guidance explains that that particular produce grown for the on-farm consumption could be separated from the produce that's grown for distribution and for sale, so that was good.

And we would assume -- it didn't say that, but we would assume that there be required separation just like there is with non-covered commodities such as potatoes or other crops that aren't grown accordance to -- with -- in accordance to the requirements of the rule.

MR. CALLAHAN: This is Chris Callahan, UVM Extension. The -- like what both Roger and Aaron mentioned, the examples provided really help provide a more specific and detailed communication of current thinking and that is really appreciated, the -- in particular personally with our team in Vermont,

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including regulatory folks at the Agency of Agriculture Food and Markets, we've had some phone calls on using the guidance as a basis for conversation and reflection and sort of trying to get a sense for how we all read it differently at times and where it provides clarity and where it may not.

And so it's helpful as a team exercise to provide a framework for those discussions. The -- specifically the provision of examples for exemption calculations are thorough and helpful, I -- in particular I spend a lot of my time on the post-harvest side of things and so the expansion on cleaning, whoever put the effort into that, thank you. We'll come back to that in the next question as well though.

MS. KILLINGER: Okay.

MR. CALLAHAN: And -- yeah, I think that covers what I wanted to.

MS. KILLINGER: Alright. Well, thanks for all of those comments and I think couple of you have already alluded to some things that you might like to see expanded or changed in the Draft Guidance, so please feel free to go ahead and tell us more about the topics that you'd like to see that may need to be expanded or clarified or if you found something -- a topic missing that you'd like to see added.

MR. FINLEY: Water.

MS. KILLINGER: Go ahead and -- yeah.

MR. FINLEY: Okay. Aaron Finley, New York State Department of Agriculture & Markets. So missing from the guidance possibly could be a discussion on sections P, Q -- subparts P, Q and R where specifically regarding states that adopt by reference if those authorities and procedures that are mentioned for withdrawal of a qualified exemption; reinstatement of a qualified exemption; application for variances et cetera where specific offices and specific procedures are mentioned having to do with, you know, those applications; specific offices within the FDA need to be applied to and communicated with, how does that

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affect a state that adopts by reference?

You know, you can't just substitute the state for the FDA in that case or can you? But that could be addressed anyway and spelled out. Maybe that's a conversation that has to be had state by state, but it could -- if it could be addressed in guidance, then that might be a good topic to cover. And then not really having to do with the guidance, but subpart E of course, you know, the farmers are always looking for little simpler standard to follow with the water regulation. That's a big concern that we hear here in New York is the -- is subpart E. Thank you.

MR. NOONAN: And this is Roger. I'll just mention, so, you know, obviously water missing and I know it's in -- you know, there's a process ongoing. And Karen, you've said in your opening remarks something about, you know, using good agricultural practices and I thought, well, boy, if they had a statement in there like relative to animal (ph) amendments where they said we recommend -- we find it prudent I think is the exact term to use the NOP 190 day.

You know, good agricultural practices also has sort of a standard, I think it's 3, at least for basic gap is 3, you know, before, during and at the end of the season, even some guidance like that because water testing for -- a lot of farms in the northeast use surface water, multiple sources, even small farms can have four or five different sources. Whatever we end up with for a water program, the more we can ensure that the investments made now in water testing and monitoring are at least compatible with what may be required later I think would be really helpful.

And you know, the sooner people can get onboard and get on a program of testing and monitoring of water, the sooner they can have a sense of what their water quality is like.

MR. CALLAHAN: This is Chris Callahan, UVM Extension. I think to continue a bit of what Roger

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said earlier, I think the guidance document is unlikely to be completely read by small and medium-sized producers, I think that's just a reality. And what it points to for me is the need to integrate the guidance intentionally with other educational and outreach initiatives, the PSA curriculum and other educational curricula; the OFRR (ph) activities; and just more broadly technical assistance.

And so thinking about how to take what's in the guidance and in future revisions perhaps and how to really integrate that with other educational activities I think would be time well spent while the guidance is being drafted. I won't repeat the need for more information on water. That continues to be a source of challenge for folks even though it's pushed out on enforcement. There -- I do -- I did get a sense when reading through the guidance that I had a hard time picturing a number of the small farms that I work with who are likely to be covered, even though they are relatively small, I had a hard time seeing them in some of the examples.

And so I think there could be additional examples developed that really are informed by practices, let's say in rural New England more, a good example -- maybe a good example is when I look at the section on condensate page 116, every single high tunnel used to grow winter greens could be considered a problem there or at least the inside plastic could be considered a food contact surface area as written. I'm not sure that's the intent, I hope it's not, but that's an example of where I think that the actual practices are different regionally and hopefully we can work to include more specific examples.

The other thing that I worry a little bit about is consider unintended consequences, there are a number of instances in the guidance where the -- a potential mitigation that's offered is use a plastic liner, use a plastic covering or -- and I think there are some cases where that's appropriate if applied appropriately. I think there are cases where that

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could actually lead to an increase of harborage if done incorrectly. And so I worry a little bit about how some of this would actually be put into practice at times.

Some of the examples are a bit odd in terms of the produce referenced, so gooseberries as an example. I'm sure it applies to somebody and I do think there's a need for more clarity on cleaning. Again, I appreciate the expanded coverage of the topic, but you know, just in our conversations among some of us, that section can be interpreted wildly different according to different people, you know, is one example.

So generally what cleaning is the most effective method to remove organic material? It involves the use of water and cleaning solutions. So is it that wet cleaning is generally the most effective method to remove organic material or is it generally what cleaning involves the use of water and cleaning solutions, you know? So I think there's some clarification of the wording that could be helpful.

And also in the following page 107 where it notes that some steps can be -- could not be applicable to your operation, one of the steps noted is Number 3, washing with a cleaning agent mechanical action, I'm pretty sure we need to do that for an appropriate cleaning step. So some people might interpret that that could be removed as a step when I'm not sure that was actually intent. Thanks.

MS. KILLINGER: Well, thank you for some very specific references to topics that you think could be clarified or adjusted. And I definitely appreciate the input from all of you and I think that some of these comments on topics that may be need additional clarification or need to be added really speaks to the helpful comments that we're looking to all of you to submit. It would be, as I said earlier this morning, particularly helpful in your comments to describe those farm-specific scenarios where you're looking for additional clarification such as Chris' example

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related to high tunnels or specific regional considerations that need to be accounted for.

It'd be particularly helpful if your comments could describe that level of details so that we understand the types of scenarios where you'd like to see the information in the Draft Guidance expanded. So thank you very much for providing those comments and hopefully that provides some helpful illustrations for all of you who we definitely are looking to, to provide those comments to us and I hope it will generate some additional thoughts that we'll hear from you in the question-and-answer session a little bit later this morning.

I just want to note that several of you mentioned agricultural water and we appreciate that that continues to be a challenging area and it's a difficult position given that we've the enforcement discretion and extension of the compliance dates to be able to add that type of content to the Draft Guidance. So we appreciate the comments and we'll take that under consideration as we move forward.

Another question for the three of you related to the content of the Draft Guidance, and I imagine you have given this some thought, with respect to were there topics that were in the guidance or perhaps were not in the guidance that you see as real areas of need with respect to research as we move forward?

MR. CALLAHAN: This is Chris Callahan with UVM Extension. I'll kick us off. I think in my own review and also in talking with colleagues and growers, not only about the guidance, but about the Produce Safety Rule and our educational activities, the common theme is research to help inform what the relative risks of different situations are. So, you know, from a grower's perspective, I sometimes get the sense that this is a lot of required practice and you know, folks want to -- want to work toward being complaint, but sometimes it's an awful lot to try to achieve and being able to prioritize investment of time and money and resources with some sort of real

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risk-based assessment would be helpful again to prioritize mitigations.

The section on Biological Soil Amendments of Animal Origin I think has some contradictory information and some gaps obviously lower case g-a-p-s, and so that points to an obvious need and Samir alluded to the research -- the ongoing research in that area, but you know, avoiding contact with edible portion of the crop, but at the same time pointing to NOP harvest waiting periods, so better understanding the interaction of Soil Amendments of Animal Origin and produce safety risk clearly is a need.

Water, again I think the point has been made. The other thing that I'd point out is I think there probably are -- there probably are opportunities for research that focuses on the impact of scale and diversity of produce operations and the relative risks of those operations when compared to other models of operation.

MR. NOONAN: This is Roger Noonan. So I guess from the perspective -- well, start with some of the capital expenses that the farm has to take on and so if you're going to move away from wooden workbenches to stainless steel, well, you don't have to. You know, there's -- the guidance is pretty clear, you know, you don't have to cut back the tree line around your field.

I think some of the stuff on the wildlife, domestic and animals really clarified a lot of things for me, you know, it's like, oh, I saw deer tracks in the field, I don't have to plow it all under, you know, if there's -- you know, so it's -- there's some commonsense, you know, which we -- we don't often read commonsense and statutory if we required things, but I didn't say a lot of things is alien, but more research, you know, so that wooden bin I use, so those wooden bushel baskets, what is the best way to maintain those in a sanitary way?

You know, maybe I just use them for certain crops and not others. I think those are things we all

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on our farms are constantly doing anyway because nobody likes cleaning out a funky basket, so -- but anyway.

MR. FINLEY: Aaron Finley, New York State Department of Agriculture & Markets. Going back to the water standards, a lot of comments that we hear in New York are comparing the FDA to the EPA and the amount of knowledge and research and resources that the EPA has to identify science-based standards that are targeted towards drinking water or recreational water. And while we realize that the EPA or the FDA is not the EPA, but that would be nice to have science-based standards targeted towards ag water and create an ag water standard. Thank you.

MS. KILLINGER: Okay. Well, thanks for those comments. Definitely hear that ag water continues to be a research area of interest, but also it helps to hear that some topics related to cleaning would be helpful as well. And it was very good hear that you found some of the approaches in the guidance to be commonsense and useful with respect to domesticated and wild animals.

So thanks to all of you for your thoughts on the research and specific aspects of the Draft Guidance. I've got another more targeted question specifically for Aaron and Wendy and just want to clarify, when we move into performing inspections, what standards will be used to evaluate a farm for compliance and would a farmer ever be cited for not following the guidance document?

MR. FINLEY: Aaron Finley, New York State Department of Agriculture & Markets. We assume that the department our inspectors will regulate according the musts in the rule. You know, the guidance is just that it's non-binding recommendations, so we're not looking to go above and beyond what's in the rule. However, the question kind of assumes that the rule -- the guidance rather would be more restrictive, but in a lot of cases the guidance is not, you know, attempting to be restrictive, it's explaining, you

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know, how a farm can more easily meet the requirements. So we'd be looking at that. Also for example easier ways to satisfy record requirements by adding a farm name and location to an existing document. There's a lot of cases where this guidance makes it easier for the farmer. It doesn't necessarily make it more restrictive, so -- but the short answer is, no, we'd not be regulating according to the guidance, just according to the rule.

MS. JOHNECHECK: Wendy Johnecheck, Produce Safety Network. So ditto in many ways, FDA will not be regulating according to the guidance document. We will be regulating according to the rule and what that usually means is when you're out on an inspection, you are using the guidance document as one of your many tools in your toolkit for conducting the inspection. There's always a -- it's always important to step back and to actually reassess whatever you're looking at in light of the actual language in the rule. So I think that's standard procedure for FDA investigators and I envision that come spring 2019 that's exactly what we'd do as well.

MS. KILLINGER: Okay. Thanks. It definitely helps to emphasize that the rule will be the standard to which farms are held and that the guidance is merely a tool with some examples to help illustrate options for compliance, but there's definitely other alternatives available. Alright, well, that concludes the questions for the panel and again I'd like to thank our panelists for their willingness to share some initial thoughts on the Draft Guidance.

And I think some common themes that we heard from our panelists include the need to integrate the Draft Guidance as a tool for both education and outreach efforts, as well as considering what topics we need to move forward with research on to advance science. And then many of us will be using the Draft Guidance as a tool or resource as we all move forward with implementation together and I appreciate how many of you emphasized the importance of collaboration and

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communication as we move forward with implementation together. So let's thank our panelists for their thoughts today.

(Applause)

MS. KILLINGER: And I'll invite Cathy up to let us know our plans for the lunch-break. Cathy?

MS. McDERMOTT: -- all again to our panel members and for participating in our meeting today, we really appreciate it. Thank you to Karen. Just to note I need to add here for our webcast audience we've had a complaint. Please everyone who is watching via webcast, please mute your phone, mute your computer or however you're listening to it. I guess not everyone has and it is hard for the webcast audience to listen to the presentation, so please again everyone listening via webcast or watching it, please mute your phone, thank you.

MS. McDERMOTT: Alright, this time we're going to take questions from the floor for FDA produce safety experts. If you could have a question, if you could come to the podium in the middle of the floor, there's a mic right there, we'd be glad to answer your questions. So please when you do if you could state your name and your organization because again the meeting is being transcribed, we'll need that information. So please feel free to step up to the mic and ask a question. Anyone at all? Someone -- oh, there we go.

MR. ZIMMERMAN: I'll get things started and my question is a little bit -- target a little bit broader audience, but you could start the conversation. My name is Rick Zimmerman. I'm with the New York State Vegetable Growers Association. And the question that's come to my mind over the course of the morning is really with regard to effective implementation of this new program onto the -- into the industry and the previous panel was all about that and I appreciate and respect the focus that they've given. Two questions in that regard, one is clarification with regard to the role of FDA with

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regard to implementation of the program versus other elements of the public sector and also leaders with -- and elements within the private sector, who is on first with regard to the implementation aspect?

And obviously we're all about that in order to make sure that the new rule is properly adhered to and all for the good of the cause, so to speak, it remains unclear and you were talking about interfacing with a community that has not had this sort of regulatory experience or at least to this degree ever before and there's a wide variety, wide spectrum of engagement from sitting in a corporate boardroom that represents a nationally-based food production company to an individual farmer, one who was sitting on the dais a few minutes ago.

So you can just visualize the different types of interface and skill sets required in that regard, all for the common cause. And then the second question I would ask in this regard is what additional tools should be considered with regard to successful implementation? And I would suggest that may be other folks that are in the implementation business or have focused a little bit more on that might also want to volunteer some suggestions on that regard in that issue, but again it's all designed -- all -- we want this to go out smoothly and effectively delivered and at the same time in a manner that demonstrates the industry is in shall we say cooperative partnership with the regulators in order to get this thing done instead of just being a regulatory mechanism and forced upon an industry. That's a tough challenge. Obviously you've probably given it some thought, so perhaps you want to chew on it a little bit. Thanks.

MS. McDERMOTT: Thank you for your question. Samir?

MR. ASSAR: There's a lot to chew on, on that question and I appreciate the question. This is Samir Assar by the way. So -- and I'll assume for purposes of today's discussion, when you say implementation, you're thinking of primarily the kind of the

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inspection aspect of it, but I also -- and I also see education training being a big part of implementation as well and I'd say the philosophical approach, the approach that we're taking with implementation is around supporting or fostering compliance with the Produce Safety Rule primarily around -- and you probably heard us say educate before and while we regulate and so that is a community-based effort.

It does involve -- you know, certainly FDA is accountable for the Produce Safety Rule and the enforcement of the Produce Safety Rule, but it's a community effort to bring the growers up to speed as to what the standards are and how they should be implemented. It's -- we talk about that FSMA is about prevention oriented standards and protecting public health. That is certainly the case. That's the primary purpose of FSMA. It's also important to note that FSMA is about establishing a level playing field and when I say level playing field, that's not only with respect to the standards, but also the implementation of those standards ensuring that there is uniformity and consistency in how we approach inspection and compliance around those standards, as well as education.

If -- and so there has to be as much attention on the development of the standards to develop the rule and now we're at the guidance stage and looking for feedback on the guidance. There needs to be as much attention on that as there is also on the implementation side or in the enforcement side. Otherwise this won't work. And we are working with the National Association for the State Departments Of Agriculture (ph) as well as AFTO and other organizations to ensure uniformity and consistency with our implementation approach.

The -- I'll say that it will be a challenge for us all and there will be -- there will be some bumps in the road as we move forward with the implementation, but our goal is to minimize those bumps and you know, head off what we can as early as

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we can in this process and yeah, just recognize that this is a -- the implementation of the rule is a succession just like other programs had started with a lot of -- there isn't a major program out there that didn't start with a lot of discussion and a lot of I would say some issues in the early start of it and eventually as stakeholders became more familiar with the approach and more connected and collaborative in working together on implementing the approach, you almost see that those stakeholders are defending, you know, their respective programs.

And that's where we want to be. We want to be at a point where we're building this together and we can defend the work that we've done together as a community to foster produce safety compliance and preventive measures to avoid -- to basically -- yeah, to -- our goal is to prevent these outbreaks from occurring and ensure confidence in the produce safety supply.

MR. MAHOVIC: Thanks Samir. And this is Mike Mahovic and I want to address one piece that you had mentioned talking about the interfacing with a previously unregulated community and there are many different aspects on how we're doing that, listening sessions for one; interacting with a lot of different stakeholders who are major players in those communities, but the one I really wanted to touch on is at the staff level, you know, those of us sitting up here at the table right now happen to all -- our headquarters, we are all based out of the D.C. area, but yet everyone of us have also been on multiple farm tours, we've been all across the country visiting stakeholders at different levels, large organizations, large conferences, individual farmers walking out on their fields being invited to go and see what they're doing and taking that back in.

And of course 2 years ago, the end of 2016 of course, you had the two staff (ph) at the end of the table here, the Produce Safety Network was stood up and that involves about two dozen people between ORA

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and CFSAN who are all out there regionally located, none of them are actually based in D.C., they're in Florida, in Arizona, in Oregon and they are out there spending a vast majority of their time interacting with the community, going out to those farms, going out and talking with our state counterparts, other partners and setting up opportunities to again bring us out there to see what's going on.

And when we can't get out there, the PSN during those interactions, they're not just trying to educate stakeholders, they're trying to educate us, they are out there gaining all kinds of intel and bringing that back and telling us what are those kinds of things that we need to be thinking about, what are those kinds of examples that we need to be adding into these guidance documents to make it more real world so that we are actually knowing what's going on out there, and that's what we're working towards, that's what we're writing when we put pen to paper, all of those lessons learned from all of those staff, from all of those trips, from all of those interactions are coming out in the ink that we're putting down.

MS. McDERMOTT: Thank you. Are there any other questions? There you go. And if you could just state your name and your affiliation, thank you.

MS. BIHN: Betsy Bihn, Cornell University. I realize this guidance does not have water in it, but a lot of questions were asked on water. So have any decisions been made regarding addressing the water issue? When we had the Water Summit in February, there was a discussion of opening the rule up to address the water; there was a discussion of addressing it solely in guidance. Has any decision been made about what avenue is going to be taken at this point?

MR. ASSAR: So you're right in that. The ag water standard is obviously not part of the guidance. We don't address it in the guidance and it is more of a rule issue. And at this point we have not -- we've not made a decision. This is one of our top

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priorities. We understand the importance of addressing water, particularly in view of the outbreaks that are happening and we've done extensive stakeholder engagement through the ag water summit as well as with technical experts and we've done farm visits around the country as well and you know, we have good information to kind of, you know, kind of distill and make decisions on we are -- we are -- there is a lot of robust dialogue going on internally about water.

And as soon as we make -- the decision isn't really the decision until it's really out there I would have to say. You never know what the decision is going to be until we indicate formally and publicly that this is the approach and it may come across as a tentative approach or a proposed approach and again open for feedback. We -- you know, we definitely are always open for feedback, but certainly if we propose a new set of requirements or modified requirements, those requirements -- proposed requirements would be open for comment.

MS. BIHN: Okay. And currently we have this extension of the water requirements proposed. Will there be a time when those are confirmed as extended?

MR. ASSAR: There will be a time when those are confirmed and we're hoping that will happen very soon, yes.

MS. BEN: Okay. Super. Thank you.

MS. McDERMOTT: Thank you for your question. Do we have other questions? Okay.

MS. BIHN: Betsy Bihn, Cornell University. One of the things you did address that was talked about -- not talked about this morning, but that I thought was good in the first section was there's a comment about ripeness or maturity level not being part of addressing it, so it doesn't matter about ripeness or maturity level, which was good to see. My question is was there any discussion about when you actually see fruit set occurring, right, so we get a lot of questions about are you -- do they include it

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at flowering, is it just at fruit set, so have you guys had any internal discussions about that beyond just the maturity level?

MS. KILLINGER: Thanks for that comment Betsy, or question. That is a topic that we discussed and we definitely like to hear comments on if folks would like to see more information to help clarify the issues around ripeness and maturity. If that's the type of language that you'd be interested in hearing more about, we would love to receive comments to help us understand what topics specifically need to be clarified around the harvestable or harvested part of a crop, so thanks for that question.

MS. BIHN: Thank you.

MS. McDERMOTT: Is there any other questions?

MR. TOCCO: Phil Tocco, Michigan State University Extension. So in the first part where you're talking about -- where you're talking about where -- who -- so one of the issues that we've had is looking at how third-party harvest crews were recognized potentially as farms and it was clarified very well in this guidance as to who bears responsibility for third party harvest crews. I would respectfully -- in the guidance specifically it talks about the grower having responsibility over third party harvest crews. One of the concerns that we're having in the field is that in some cases growers don't necessarily have access or oversight of third party harvest crews, so I'm wondering if it's possible to maybe explore that a little bit and to see if there's a possibility to expand responsibility beyond just the grower for third party harvest crew's conduct and health and hygiene, if that's possible.

MS. KILLINGER: Let me may be ask for a clarifying question here.

MR. TOCCO: Sure.

MS. KILLINGER: So you're saying that the grower doesn't have access to the harvest crew. Can you expand more on that?

MR. TOCCO: Sure, sure. In some cases

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growers are actually actively told not to interact with the harvest crew, so it's very difficult for that grower, for instance if the grower sees the harvest crew doing activities that would be considered unsanitary to even reprimand that third party harvest crew or the harvest worker. So if the grower is -- and I totally understand from the standpoint of enforcement having the grower responsible for a third party harvest crew makes a lot of sense, but from the standpoint of practical -- actually making the food safer, it may not be possible to remedy any situations that are seen in the field and that's really the largest concern.

MS. KILLINGER: That's helpful information to know and it would be great if that type of information could be submitted in a comment --

MR. TOCCO: Sure.

MS. KILLINGER: -- so that we can understand some of the challenges around implementation specifically related to contract harvest crews and other topics like that, so we would look forward to seeing that type of comment in the docket.

MR. TOCCO: Thank you.

MR. ASSAR: Perhaps with some specific examples too.

MR. TOCCO: Absolutely.

MS. JOHNECHECK: Definitely. Thank you.

MS. McDERMOTT: Thank you for your question. Are there other questions?

MR. FINLEY: Aaron Finley, New York State Department of Agriculture & Markets. So I've realized that it's not guidance, it's a rulemaking issue, but one of the comments that we hear in New York quite often is about food versus produce in calculating a qualified exemption, so farms want to know why they're being asked to calculate bottled water, pumpkin pies and maple syrup along with their produce when calculating the qualified exemption. Thank you.

MR. ASSAR: Alright. I'll just touch on a high level and Karen can provide more -- a more

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specific response maybe. This is Samir Assar by the way. So the qualified exemption is actually we were directed by the statute to include the qualified exemption and it provides parameters around how that qualified exemption should apply and be calculated. And food is the kind of the determining factor and so we have a definition of food, there is a definition of food, in the Food, Drug, and Cosmetic Act and so that's kind of our starting point in making those calculations as to whether or not an operation would be qualified exempt. And Karen, I don't know if you have anything else to add or others.

MS. KILLINGER: Yeah, I think that it would - - I would just like to point out that we were directed to include that content and so in the Draft Guidance we did try to provide some specific examples and language to describe the difference between the calculations for total produce sales and total food sales. And through some of the TAN inquiries, we were aware of specific questions about specific products, like you brought up, Aaron.

And so again if there's more information, that would be helpful to help clarify what to include in those calculations for total food sales. We'd appreciate specific comments to help us understand what topics or what information might be helpful to include to describe how those calculations could be -- should be performed.

MR. ASSAR: And just to elaborate -- or the original proposal we had in that \$25,000 exclusion from the rule based on foods, that was what we included in our original proposal and that we were able to change to produce because that was our own exclusion or own scoping of the Produce Safety Rule. We weren't directed to include that, it was based on our own decision-making as to who should be covered in and -- or not, and with this qualified exemption that you're referring to, we just don't have as much flexibility to do -- to kind of further provide parameters around the meaning of food and how those calculations should be made, it's in the law.

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MS. BIHN: This is the last. Betsy Bihn, Cornell University. First of all, one of the real benefits of -- as has been mentioned by several people are the examples that were provided. Some of those really did help clarify. Some of the examples I think perhaps added confusion or made us wonder what your expectation was for how a grower might go about doing what was suggested in the guidance. One of the examples I would like to give is on page 19, Criterion 1 at the bottom of the page where it talks about produce sold at an auction and that if it's sold directly to a retailer or a consumer that it meets that qualification as long as it meets the distance requirement.

And so one question would be how is a -- you know, a grower brings his products to an auction, gets his number, it sells to somebody, is he supposed to then ask that person how far they intend to drive that produce once they leave the auction? So it's just one of those questions like how would a grower know how far that buyer intends to drive that product. So some of those things make us wonder how would that be managed.

MR. ASSAR: Right.

MS. BIHN: So I just -- I don't know if you have a feedback or if you just want to take that as a comment, but some of the examples are good except it makes us wonder how does that actually get done from a grower perspective. Do you want to comment or just take it as a comment?

MR. ASSAR: Yeah, I mean just -- again that -- we appreciate that question/comment and it's absolutely something that we need to think further about. It's not just we need to kind of think beyond what the examples are, but really how they would play out for the farmer in various contexts. And we are again open for comment on your thoughts with respect to how that should and could be implemented.

MS. BIHN: Okay. The other thing that I would just -- I think would be welcomed both in

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presentation and in written form is when you mention dollar amounts that are adjusted for inflation, if you could consistently say this adjusted for inflation and in the written make that consistent if they are adjusted for inflation because there is a lot of confusion about which numbers are adjusted for inflation.

MR. ASSAR: Okay.

MS. BIHN: And if you would consistently say it, I think that would help people understand, oh, that's one of the numbers I need to realize it's adjusted for inflation. So that's more just a comment in noticing the reading and in the presentation.

MS. McDERMOTT: Thank you for your question. Any other questions? Well, there'll be another opportunity for questions later today as well at the end of the day there is a public comments session, so please if anyone wants to make a public comment, there's still time to do so. You can still sign up, no deadline. We welcome your comments and we encourage them, so please feel free to see 188 (ph) to check at the registration desk, so please there are opportunities to make public comments at the end of the day and we encourage you to do so.

I want to thank our FDA panelists here and thank everyone who's asked a question here this morning. At this point we'll break for lunch and we're running a little early, so I think we'll be back at 1:00 p.m. And have a good lunch. Thank you everyone.

(Recess)

MS. McDERMOTT: We'd like to begin again. Welcome back everyone. Thanks for coming back. And I hope everyone had an enjoyable lunch. We'll now hear from our Produce Safety Experts again, as they walk you through the guidance in Chapters 4 through 7. Our first speaker is Dave Ingram, who will discuss Biological Soil Amendments of Animal Origin and Human Waste, Chapter 4, as well as Domesticated and Wild Animals, Chapter 5. Dave will be followed by Karen

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Killinger, who will speak on Growing, Harvesting, Packing and Holding Activities, Chapter 6 and Equipment, Tools, Buildings, and Sanitation, Chapter 7. So I'll give it to Dave now.

MR. INGRAM: Thank you, Cathy. That's a good way to make an entrance. So again, I'm David Ingram with the Division of Produce Safety, fresh produce branch. And I'm pleased to provide an overview of two more chapters today. First will be an overview of Chapter 4, Biological Soil Amendments of Animal Origin or BSAAOs and Human Waste. The requirements of subpart F are the minimum standards for BSAAOs including agricultural teas that are BSAAOs and Human Waste. Chapter 4 provides Draft Guidance to help determine the applicability of subpart F to you and your farm as well as recommendations and examples related to BSAAOs. Then 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.

This slide provides an overview of the sections covered in Chapter 4 of the Draft Guidance. The section numbers and titles listed on the slide are provided on later slides as well 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 experiences on farm tours, and participation in several soil 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

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examples. And we hope you find these useful.

The first step is to determine whether your soil amendment including an agriculture tea is a BSAAO. There are several definitions provided in the Produce Safety Rule that are important to understanding the terms in this chapter. You should refer to these definitions in the Produce Safety Rule. Some of the defined terms are listed on this slide and in the Draft Guidance. Section 1 of the chapter provides several examples of BSAAOs including treated, stabilized compost, compost ingredients, or intermediary compost materials that contain materials of animal origin, worm castings, and animal bedding materials 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 us 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 determining whether your BSAAO is treated or untreated. The Draft Guidance reviews the requirements for BSAAO including an agricultural tea to be considered 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 applicable requirements. Treated BSAAO compost contaminated by untreated manure runoff after treatment and agricultural teas 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 grow covered produce in accordance with the applicable requirements and treating or retreating it in order to use it as a treated BSAAO to grow covered produce in accordance with the applicable requirements among other options.

Now let's discuss chapter -- Section 3.

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Determining the Appropriate Treatment Processes and Associated Microbial Standards for your treated BSAAOs. There is flexibility for you to determine a treatment process for your BSAAO. You can use any physical, chemical, or biological process or in any combination. 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 microbiological standards as described in the Produce Safety Rule. The Draft Guidance notes that FDA does not expect farms to perform validated studies for BSAAO treatment processes. However, farms should ensure that the treatments 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 enquiries, and soil summit discussions as we worked on this section.

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

Moving on to Section 4, Determine How to Apply your BSAAO. In this section, we were aware of stakeholders comments from the rule, TAN inquiries, and discussion with growers at soil summits and

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educational farm visits. The section begins by providing a list of factors to consider. Many of which are listed on the slide. I'd like to review a few of these in more detail. First, the application restrictions are based on whether or not your BSAAO is untreated or treated. There are two different levels -- treatment levels that is microbial standards specified in the Produce Safety Rule and the level of treatment also impacts the application restrictions. The Draft Guidance recommends that you consider the application method 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 also provides a figure to summarize the requirements related to microbial standards and application requirements for BSAAO.

While we don't have time to walk through this figure in great detail, we wanted to create a visual. A visual aid to assist with conducting the relevant microbial standards with the application requirements. This figure can be found on page 70 of the Draft Guidance and it reviews the relevant requirements for treated BSAAOs including the microbial standards for different treatment levels, the application restrictions, and the minimum application intervals. We hope you find this useful to understand the relevant requirements for treated BSAAOs and we welcome any comment.

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. This entire -- the entire figure is located on page 59

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of the Draft Guidance. In Section 4, we discussed that FDA reserve the provision represented in the first, red highlighted row 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 differing action on an application interval until we pursue certain steps including a risk assessment and further research. As a result, the requirements of the minimum application interval for untreated BSAAOs highlighted in red in this figure do not differ as of the date of publication of the Draft Guidance. We do not object to the use of the national organic program standard of a 90 or 120 days application interval for untreated BSAAOs applied in the manner described in the first row red highlighted on this figure. We believe adherence to a 90 to a 120-day application interval to be a prudent step towards 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 in this 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 produce.

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 storage practices for both treated and untreated BSAAOs for the potential to contaminate your growing areas, water resources, 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 include incomplete or

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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, transporting, and storage of BSAAOs. Briefly, I'd like to highlight that Section 6 covers recommendations related to Determining What Records to Keep for your Treated BSAAOs. And we look forward your comments on that section.

And I'll move forward 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 the review of background information and some of the rule requirements. Domesticated and wild animals are sources of pathogens and 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 domesticated animals, by domesticated animals from a nearby area, or by wild animals. Your requirements for -- of subpart I, apply only when covered activities occur in outdoor areas or partially enclosed buildings and when under the circumstances there is a reasonable probability that animals will contaminate covered produce. We support co-location 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 provided here and on later slides to provide a sense of where the information is located. We described several factors to consider for each of these steps. And we included several examples to illustrate how a farm could evaluate information related to these topics. Please keep in mind that even if you have similar circumstances mentioned in these examples, you should perform your own

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evaluations based on your farm's specific conditions and your farm's specific practices. In the first section of this -- 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 maybe subject to the requirements of subpart I.

The next recommendation is that you should determine whether 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 farms covered produce conditions and practices. This should also include an evaluation of the types of animals that could contaminate your covered produce based on 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 this section of the Draft Guidance. It is recommended that you should periodically reevaluate your farms conditions and practices. Changes on or near your farm could impact the probability that animals will contaminate your covered produce. This section also provides examples related to the farm

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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 with question 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 wild life such as the removable -- removal of habitat or wild animals from land adjacent 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 covered activity for evidence of potential contamination of covered produce as needed during the growing season. This would be a second step -- 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 the assessment, which could vary depending on the types of animals and the other factors you identify in determining whether there is reasonable probability that animals will contaminate your produce in each relevant area on your farm. It is recommended that the owner, operator, or agent in-charge of the covered farm should periodically evaluate your approach to assessment and modify it as needed. This section of the Draft Guidance expands on factors to consider in developing and modifying your assessment approach. Some of which are listed on this slide including personnel

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responsible for monitoring, timing and frequency of monitoring, and details on reporting observations of evidence and 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 a farm, 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. The Draft Guidance recommends 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 that monitoring including visual examinations for evidence of potential contamination by animals in the relevant areas.

Now let's move 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 growing to assist you later during harvest when you must identify and not harvest covered produce that is reasonably likely to be contaminated with a known or reasonably 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 the concepts -- these concepts. Further several examples are provided to illustrate approaches for determining whether significant evidence of potential contamination by animals exists including scenarios involving monitoring observations

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that are likely -- that likely are significant evidence of potential contamination and scenarios that likely are not significant evidence of potential contamination. We hope you find these examples useful and we look forward to your comments.

So this concludes our overview of Chapter 5, Domesticated and Wild Animals. And we thank you for your attention. There will be time for your questions at the end, question session after the next round. And we look forward to your comments. So thank you for your attention.

(Applause)

MS. KILLINGER: Thanks Dr. Ingram for that presentation. Good afternoon everyone. Alright. I'm just checking in the back. Can you guys hear me, okay? Awesome. Alright. I'm excited to be back up here. I'm Karen Killinger from the Division of Produce Safety and I'm looking forward to sharing more information about Chapter 6, Growing, Harvesting, Packing, and Holding Activities. And Chapter 7, Equipment, Tools, Buildings, and Sanitation today. Just out of curiosity, how many of you had a chance to review these chapters? Okay, that is a heavy lift. So I'm glad to see some of you had a chance to get through these two chapters. And these will be brief overviews of the content of these chapters, highlighting only selected recommendations. We don't have time to cover all of the content of both of these chapters this afternoon.

But first Chapter 6 provides our current thinking and recommendations related to the requirements of subpart K. This subpart is applicable to growing, harvesting, packing, and holding activities including the transition points between those spaces. Then Chapter 7 provides Draft Guidance related to equipment, tools, buildings, and sanitation associated with the requirements of subpart L. In both of these chapters, we recommend evaluating your relevant procedures, processes, and practices periodically to consider the breadth of your practices

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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 recommendations and principles discussed in both chapters. And we hope you find these helpful and look forward to your comments.

Please be aware that even if you have similar circumstances or produce crops mentioned in these examples, you should perform your own evaluation based on your farm specific conditions and practices. This slide provides an overview of the sections in Chapter 6 and we will only discuss a few of these today, so those sections are highlighted in bold. The section numbers and titles are listed on this slide and provided on later slides to provide a sense of where the information is located. So again, the sections in this chapter include separation of covered and excluded produce, identifying and not harvesting contaminated covered produce, handling harvested covered produce, dropped covered produce, packaging covered produce, and finally food-packing material. Each of these sections directly relates to a specific requirement in the Produce Safety Rule. As we worked on these sections, we were aware of stakeholder comments on the rule as well as TAN enquiries. This chapter really covers a diverse set of topics related to growing, harvesting, packing, and in holding activities. And in several sections, we provided summaries of key recommendations of requirements or other information to highlight the content and certain points within each section. So we hope you'll find these useful to become familiar with the content of this chapter.

I'd like to take a minute to point out that in several of these sections, the Draft Guidance provides recommendations for personnel, supervisors, or responsible parties related to each of these topics. The owner, operator, or agent in-charge of a covered farm should instruct supervisors or

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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 your farm's procedures and practices to protect covered produce from contamination. Finally, as applicable, certain personnel must receive training related to some of these topics and those are pointed out in the Draft Guidance.

So let's start with 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 excluded produce. It is recommended that you visually assess farm activities during this evaluation. If the requirements of 21 CFR 112.111 apply, then the owner, operator, or agent in-charge of a covered farm should evaluate the farms practices related to separating covered and excluded produce. During the growing, harvesting, packing, or holding of covered and excluded produce, separation could involve location, time, or both. You should identify the locations where activities for covered and excluded produce occur. Further, you should identify shared equipment and tools and personnel that are involved with both covered and excluded produce. The Draft Guidance expands on these recommendations and provides additional examples.

Now let's move on to Section 2. In this section we were aware stakeholder comments on the rule and expanded on several concepts. As a reminder, immediately prior to and during harvest activities, you must take all measures reasonably necessary to identify and not harvest covered produce that is

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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 are flexible requirements to allow appropriate steps based on your farm's conditions and practices. The Draft Guidance recommends that in addition to animal excreta, you 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 that visually examine the entire designated harvest area including areas that will be mechanically harvested. These visual assessments are most effective when performed as closed in time before beginning harvest as practicable or during harvest. The Draft Guidance also expands on signs that cover produce as reasonably likely to be contaminated, requirements and recommendations for harvest personnel and their training, and procedures when evidence of contamination is observed including your expectations for supervisors and responsible parties.

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

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establish procedures to ensure that harvesting, packing, and holding practices 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's additional information in the Draft Guidance on all of these topics. 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 in handling harvested covered produce.

Now let's review some of the Draft Guidance content in Section 6 on Food-Packing Material. First, I'd like to point out that we addressed some overlap in content between Chapter 6 and 7 of the Draft Guidance related to this topic. Food-packing materials including food packaging are subject to requirements provided in both subpart K and subpart L. To minimize redundancy on the topics, we provided 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, which can increase the potential for materials to introduce contamination. Both porous and non-porous materials can facilitate contamination if they are damaged or if their surfaces are not intact. At the beginning of this section, the Draft Guidance list recommended steps to help the owner, operator, or agent in-charge of the covered farm determine whether a food-packing material is adequate for its intended use. And these steps are listed on this slide.

First, you should identify the types of food-packing materials that you use and determine whether each type is reusable or single use. Then, determine whether

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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 also 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 the content of Section 6 on food-packing materials, the Draft Guidance expands on evaluating your practices and the food-packing materials. The Draft Guidance recommends that the owner, operator, or agent in-charge of a covered farm should periodically evaluate your practices including handling, maintenance, and storage of food-packing materials. This evaluation is important to account for changes that may occur over time including the use of certain food-packing materials or your practices. The Draft Guidance lists several factors to consider. Many of which are included on this slide, such as the type of material, such as if the material is plastic, wood, foam, or cardboard. The nature of the material for example, whether it is smooth, course, absorbent, porous, or non-porous. The durability of the material, how the material is constructed. The existing condition of the material, whether it is intact, scored, cracked, or damaged. As well as maintenance practices for example, practices to repair or replace, worn or damaged components; as well as handling and storage practices, such as how the material is received and prepared for use among other practices.

The Draft Guidance also provides examples to illustrate how a farm could evaluate food-packing materials and their use, taking into consideration these factors described in the Draft Guidance. And we hope you find these examples helpful. We look forward to the comment -- to your comments on this section and this concludes our overview of Chapter 6.

Now we'll start talking about Chapter 7,

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

As we worked on this chapter, we considered stakeholder comments from the rule, TAN enquiries, experiences from our educational farm tours, or outbreak investigations, and engagement with educational partners. The topics in this chapter are important concepts for consideration. Based on our inspections for sprout operations today, the most frequent area of citations relates to the requirements of subpart L, particularly requirements for equipment, tools, and buildings. So the content of this chapter maybe useful to farms including sprout operations to assist with the 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 the slide. So let's review what those steps are. 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. Step two, evaluate the design, construction, workmanship, installation, and maintenance. Then evaluate storage and maintenance practices and storage locations. Establish procedures and schedules for cleaning and when necessary and appropriate, sanitizing, food contact surfaces of these equipment and tools. Establish procedures and schedules to conduct inspections. Evaluate your use of transport equipment with covered produce; and evaluate the accuracy, precision, maintenance and numbers of instruments and controls used to measure, regulate, or

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record conditions to control or prevent the growth of microorganisms of public health significance.

I recognize that's a long list of recommendations and we hope that you find it helpful to identify the key steps towards implementing the requirements related to equipment and tools. And I'd like to point out something that was mentioned by Roger Noonan, one of our panelists this morning. He suggested that one of the ways to use the guidance was to find yourself in the guidance document and so I think this might be an opportunity to illustrate Roger's point that as a farm you could look at "Okay, where am I now with respect to implementation of these recommendations" and you could look at what you already have in place, and then focus on the specific recommendations, where you need to maybe take some additional steps to implement the requirements. And so, that's one way that you might choose to use the guidance and are non-binding recommendations in the guidance. Thanks, Roger.

So these steps do follow closely with the sub-sections related to equipment and tools in Section 1 of Chapter 7. And this is a long section, so we don't have time to talk about all of these steps today. But I would like to highlight some of these steps in more detail and those steps 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 we do provide recommendations related to some aspects of food-packing materials in this section of the Draft Guidance. So I'd like to take a minute to talk a little bit more in detail about step 1. It's important to identify the equipment and tools that are subject to the requirements of subpart L. And that's really what the first step in this list is intended to do. You should visually assess your covered activities and your growing, harvesting, packing, and

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holding areas to identify the equipment and tools that are intended to or likely to contact 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 also like to note that in the Federal Register Notice of Availability, we believe that additional input would assist us, and we seek specific comments, information, or data on the following. 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 equipment and tools? And we will look forward to your comments on that question.

Now let's move on to step 2 and discuss some of the recommendations related to design, construction, workmanship, installation, and maintenance for equipment and tools. The Draft Guidance recommends evaluating the materials used to make your equipment and tools and the impact of the materials and their construction on adequately cleaning and properly maintaining them. You should evaluate the design, construction, and workmanship of your equipment and tools. And the Draft Guidance recommends considering several factors including those listed on the slide.

We also recommend that you use equipment and tools made of non-porous materials to the extent practical. We understand that some covered farms may use equipment or tools with porous materials. And if you choose to use equipment and tools made of wood, fabric, foam, or other porous materials, the equipment and tools must be of adequate design, construction, and workmanship to enable them to be properly cleaned -- adequately cleaned and properly maintained. Equipment or food contact surfaces that can no longer be adequately cleaned and 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

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help you identify signs of potential contamination and determine whether maintenance, replacement, or cleaning, or sanitizing is necessary. The outcomes of your inspection should guide your decisions about continued use of equipment and tools. The Draft Guidance recommends that the owner, operator, or agent in-charge of a covered farm should establish and communicate the following: Procedures for inspecting equipment and tools including food-packing materials, the frequency of these inspections, the personnel involved, the 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 material. The Draft Guidance also provides a list of factors to consider when determining inspection frequencies. You could determine that different inspection frequencies should be specified for different types of equipment and tools. The Draft Guidance in this section provides other recommendations and examples as well.

I'd like to emphasize that in this section in particular, there are several examples throughout the narrative of the Draft Guidance in Section 1. And we were mindful of stakeholder comments from the rule, questions we received through Tan enquiries, and our experiences on educational farm tours as we worked on this chapter and other interactions with stake holders.

There is a sub-section in section 1 focused on providing examples that use the principles and recommendations discussed earlier in the chapter. To illustrate how a farm could visually assess and evaluate your 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 do not lead to a change in equipment and tools, practices or procedures on the

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farm. These examples are intended to help 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. We hope you find these examples helpful and look forward to your comments on them.

The Draft Guidance includes a great deal of information related to our current thinking on cleaning and sanitizing and we appreciate Chris Callahan (ph) one of our panelists pointing that out today. And we can only provide a brief overview of this topic in this presentation. So let's start with the key recommended steps summarized at the beginning of this subsection. The Draft Guidance recommends that the owner, operator or agent in charge of a covered farm evaluate equipment and tools by identifying food contact surfaces and non -food contact services of equipment and tools. And determine cleaning practices and as necessary and appropriate sanitizing practices for each type of equipment and tools and the frequency at which you will perform these practices.

The Draft Guidance recommends visually accessing your covered activities to identify food contact services during production activities. Several more specific recommendations are provided as well as examples to illustrate how to evaluate equipment and tools, practices and conditions to identify food contact and non-food contact services. This is an important step to understand the applicable requirements for your equipment and tools. Moving on, there's a sub-section that provides more detail on recommendations and examples as well as factors to consider related to cleaning and sanitizing procedures. There's also a sub-section that expands on the frequency of cleaning, and when necessary and appropriate, sanitizing. This section includes recommendations, examples, as well as factors to consider. This is another topic where we seek specific comment, information, and data as noted in the

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Federal Register Notice of Availability, with the question what information and 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 material, and we look forward to your comments on this question. And again for your reference, the Federal Register Notice of Availability is available in your packet of material.

So now let's transition to talking about a few topics under Section 2, Buildings. The sub-sections are listed on this slide and will cover some of the content related to size, construction, and design, as well as pest control in this presentation. First, I'd like to highlight an overall recommendation related to buildings. The first recommended step is to identify all fully and partially enclosed buildings that you use for covered activities. Many of the requirements related to buildings are designed to be flexible to accommodate a wide range of buildings where covered activities are performed on farms. Now let's discuss a few recommendations on building size, construction and design, some of which are provided on this slide. The Draft Guidance recommends that the owner, operator, or the agent in charge of a covered farm should evaluate whether your identified building size, construction, and design are appropriate considering the covered activities performed and the operating conditions in the building. This includes an evaluation of the building's materials.

The Draft Guidance discusses several factors to consider and many of these are listed on this slide. Such as drainage and ventilation, sufficient space around equipment, activities that occur in the building, separation of operation to reduce contamination, volume and frequency of activities, number and size and placement of equipment and tools including use and storage, and the number of people at any given time.

In the section on preventing contamination

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including floors, walls, and ceilings, the Draft Guidance also provides recommendations for evaluating your building and their components including a visual assessment.

Moving on to some recommendations for pest control, this section provides several examples some of which are highlighted on this slide. The Draft Guidance recommends that the owner, operator, or the 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 frequency.

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.

Moving on to Section 3, Other Sanitation Measures, this slide provides the topics covered in Section 3. Including animal excreta and litter from domesticated animals, toilet facilities, hand washing facilities, sewage systems, trash, litter and waste and plumbing. However we will only talk about hand washing facilities in more detail in this presentation.

The Draft Guidance recommends that the owner, operator, or the agent in charge of a covered farm should consider personnel and visitor activities in growing, harvesting, packing, and holding areas to help determine the number and locations of hand washing facilities to accommodate typical numbers of people accessing these facilities.

The Draft Guidance discusses recommendations

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for accessibility for use such as near entrances to packing or other work area as well as access for servicing, maintenance, and disposal activities. The location of hand washing facilities and associated waste disposal is also important to prevent contamination. The owner, operator, or agent in charge of a covered farm should ensure that they establish monitoring, servicing, and cleaning, and sanitizing procedures as well as schedules for hand washing 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 hand washing facilities. Your personnel responsible for maintaining hand washing facilities should understand your procedures and your supervisors and responsible parties should be directed to ensure that these activities are conducted and make corrections as needed. As a reminder, hand washing facilities must be furnished with soap, running water, and adequate drying devices. And I think earlier this morning Erin Finley (ph) pointed out that this is a topic covered in the Draft Guidance. It's a reminder that you may not use antiseptic hand rubs as a substitute for soap and the Draft Guidance discusses that hand sanitizers could be used as an additional measure after hand washing with soap.

So this concludes our overview of Chapter 6 and 7. And we are very glad to have the opportunity to review some of the content of the Draft Guidance with you today. So we look forward to your comments on these chapters and we'd be happy to answer any question in the Q and A session this afternoon. Thank you.

(Applause)

MS. McDERMOTT: Thank you Karen and Dave. And I'd like to invite Samir and Mike up to the stage so we can conduct the question and answer session. So we welcome anyone to approach the microphone there in

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the middle of the room and ask a question on what we've just covered or really anything that's been covered during today, please feel free. Just a reminder state your name and affiliation, thank you.

MR. CALLAHAN: Hi, Chris Callahan, UVM Extension, can you help me understand an example of a material -- a porous material that can be cleaned adequately? Thanks.

MR. ASSAR: I'll address that at a high level. And so one thing to keep in mind as we -- and my name is Samir Assar I'm with the Food and Drug Administration. You know, as we develop the guidance in view of our regulation, we are looking at the big picture, we're looking at the landscape, we're looking at the current base line, who is using what? And where ultimately growers or packers in this case may need to -- or assuming that you're thinking about packing houses, where they need to be. And so, I guess there are certainly materials that are being utilized out there that are -- that have been sold with a suggestion or a recommendation that it would improve the quality. It would basically spare the fresh fruits or vegetables from being subject to bruising or something like that. And so investments were made in that regard, I found. At the same time, we've definitely seen some public health issues associated with those materials. And so we've tried to strike that balance looking at what we found through again at our root cause analysis of outbreaks and trying to kind of parameterize where we see the biggest food safety risk. But leaving open to -- leaving the door open to perhaps there is -- there are materials out there that could be cleanable and at the same time there would be, you know, there would be some porosity.

So I guess bottom line, we're trying to strike a balance given food safety risk but at the same time what growers are currently utilizing in their packing houses and other aspects of their operation.

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MS. KILLINGER: Thanks for the question Chris. And I think I need to echo Samir's comments that this is an area that is challenging yet we need to continue to allow flexibility for options for purchase. And I think we are certainly asking for additional, specific comments, information, or data as we pointed out in that question in the Federal Register Notice we're asking for more information about how to clean, sanitize and have maintenance practices specifically for porous materials. So we're looking for comments from all of you on that particular topic. However we know that many farms are already using those types of material, so we did try to provide some information in the Draft Guidance to illustrate that flexible approach, because we want to accommodate to the extent we can given the requirements, the ability to use certain materials. And so in that Section 1 that has a series of examples, we provide an example related to the use of foam pads, and that on that particular piece of equipment actually let me give you an example number just so everybody's on the same page literally. It's example 7 K on foam pads and the farm recognizes that there are some challenges with those foam pads. And so rather than providing a prescriptive approach, we say, "Okay, there's some options in how the farm could choose to address that challenge." They could replace the pads as necessary so that they are cleaned -- or clean. They could also remove the foam pads but as Samir noted that might present some challenges with respect to damage to the produce. Clean liners is another option that we mentioned and I think you mentioned in your comments today on the panel that that may present its own set of challenges. And again the farm would have to kind of assess that and whether or not that's a workable scenario or not. And there's also the option of ultimately developing a long-term approach to replace that equipment if needed.

So again we're trying to establish here that there may be several options available, and really

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that's something that the farm will have to look at given their specific practices and the particular piece of equipment, as well as the type of material being used.

MR. ASSAR: Yeah, just to add that this is an area that we wrestle with internally as well. So then again we'd like to hear your feedback on this area and you know whether -- how we should address those types of materials in the guidance moving forward.

UNIDENTIFIED SPEAKER: That was Karen Killinger that responded first and Samir Assar. Just to state our names. You have another question?

MR. LARTEY: Yeah. I am Nat Lartey from Cornell Cooperative Extension, Orange County. Yeah my -- I have two questions. The first question is kind of actually the VA is trying to encourage farming, veterans into farming. And most veterans use service animal. So I want to find out if the draft is looking into that too because like most these veterans will be using their service animal on the farm and how safe it will be for them to use that? Then my second question is on the single use packaging material. Most farms don't use the single use packaging material. They raise -- they go for the one that has been used already. So in this case would the new draft be flexible on that aspect since most farms don't use that? Thank you?.

MS. KILLINGER: We're going to address your second question first, this is Karen Killinger, and we did have the -- just the -- your voice level, I had a little bit of a hard time following your question. So let us know if we got this right. I'd like to address your comment and question related to single use packing materials. You were saying that those aren't frequently used. There's definitely opportunities to use reusable packing materials, and we have quite a bit of information in Section 6 of -- or in Chapter 6 on food packing materials related to reusable materials. And we definitely understand that many farms utilize packing materials that are reusable. So

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there's opportunities to do that. However there certainly other farms that do use single use materials like liners in harvest containers. So we needed to address that as its part of the rule. But we definitely support the use of either single use or re-usable materials.

MS. McDERMOTT: Are there other questions?

MR. ASSAR: Yeah I had a -- we had a -- we are trying to figure out because again the voice level was low. Were you asking about -- yeah, I'm sorry we might have to ask you to come up --

MS. KILLINGER: Was it a grant opportunities for veteran farmers that you're asking about? Oh service animals. Sorry, yeah, we did mishear that.

MR. ASSAR: Okay.

MS. KILLINGER: My apologies.

MR. ASSAR: And what specifically about service animals? Sorry.

MS. KILLINGER: Thank you.

MR. LARTEY: My question is, currently the VA is trying to push a lot of veterans into farming. And most of these veterans use service animals. So in this case where are we going to put them? Are we -- do we have any aspect of the draft that's going to look at it like where to put those service animals, the limit that it could go? Yeah because it's a matter of consent that needs to also be addressed. That's what I'm trying to say. Thank you.

MR. ASSAR: Alright we got it. Thank you.

MR. INGRAM: Okay, thank you for that clarification. We currently -- we have no restrictions on in the use of service animals or any such domesticated animals that are trained well enough so that they are not going to contaminate produce on the farms. And it's up to the growers -- it is the grower's responsibility to recognize the potential for contamination of the produce on their farms and not harvest those produce items that maybe contaminated by domesticated animals. In fact we recently received some enquiry regarding the use of sniffing dogs, dogs

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that are highly trained to smell feces of wildlife. And how these animals might be useful as a surveillance tool for growers and harvesters -- harvesting crews during harvest to actually locate areas that are contaminated with wildlife excreta. So we have no objections to the employment of such service animals. We don't intent to restrict the use of service animals. Clearly FDAs in support of the veteran community, we recognize the widespread use of service animals everywhere and the need for them. So we respect -- certainly respect the use of those animals throughout the growing practices that we intend to regulate.

MS. KILLINGER: And I'd like to follow up that there are some requirements related to excluding domesticated animals from fully enclosed buildings in sub part L. So you should take a look at those requirements. However, guard dogs and guide dogs are allowed in the guidance -- the Draft Guidance talks a little bit more about that topic, but that's in sub part L. So you asked a question that kind of crosses over into two different chapters. So thank you for your question.

MS. McDERMOTT: Other questions. Don't forget to state your names.

MR. OBER: Chris Ober (ph) from New York State Department of Agriculture & Markets. I was just wondering has there been any updates on the farm definition?

MR. INGRAM: So right up there with water and soil amendments the farm definition is also a high priority for us to resolve. And I think, you know, most of you know that we have an enforcement discretion at play around the farm definition, which would essentially allow for packing houses that maybe subject to the preventive controls regulations to either implement GMPs that are in that regulation or the requirements in the Produce Safety Rule. So it's an area that we understand that we need to address as quickly as possible. There's confusion about where

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certain operations fit. The enforcement discretion is intended to kind of help address those concerns but we recognize also at the same time that, you know, the industry is expecting an answer around how we're going to come out with respect to farm definition. So I can't give you any specific time line right now but I will say it's a priority for us, it's -- we understand the importance of getting it resolved this -- as quickly as possible.

MS. BIHN: Betsy Bihn, Cornell University. I'm curious if there's been any internal discussion related to growers ability to do some of the tasks that you are asking them to do. In this panel you've mentioned that growers need to make an assessment of risks related to materials. You also say that you're looking for input to define risk to help define what can be done. So it's clear that there's lack of clarity about where's the risks really exist and how to manage them. Yet we're expecting growers to be able to make these risk assessments with implementation dates already in and coming in. So I'm wondering if there's been any discussion at FDA about these expectations that are being put on growers and whether or not they are prepared to adequately be able to address these risks when there's so many questions regarding materials?

MR. MAHOVIC: Sure, this is Mike Mahovic. One thing to consider in there, is as you said, is where are these risks and how could FDA help to address them. But the simple fact is every farm is going to have different risks, and FDA cannot address every risk on every farm in these situations. So we are trying to take a more baseline approach to help farmers understand what they should be looking for, what kind of risks do they need to be assessing, and how do they present themselves in that farm's unique situation. And that is what we're trying to do, is trying to put more into the farmer's hands so that they can assess what they're doing, they know best what their practices are based on what we're trying to

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provide at the higher level, they can get more granular into what their specific needs would be. I am not trying to do an across the board thing to tell everybody that your risk is this because as we've been saying since day one with this, one size does not fit all.

MS. McDERMOTT: Okay. Then I would like to leverage this comment. It would be very helpful if you could provide expressed examples of materials that are not acceptable and materials that are acceptable. And I think we all have opinions on what those might be. But if you gave growers a list of materials or even attributes of materials. And I would like to say that adequately cleanable is not an attribute of a material that would help them determine if that material can be used. Because I think we're putting a lot of pressure on them with not a lot of guidance in terms of what is and is not acceptable. And I appreciate that every farm is different, but I think we're putting expectations on them without enough details to help them make that assessment. I would also like to say that in some of the examples that were given, I'm going to point out 7H in particular, where the guidance is about using a liner on the floor of a wooden trailer that the issue there is actually damage of the product not safety of the product. And I think, you know, taking into mind when safety is an issue and when damage is an issue should be reviewed. Thank you.

MR. ASSAR: This is Samir Assar, I just want to follow up on that -- on the last comment. Well not -- I guess one of the last comments with respect to clearly defining, you know, what is and what isn't adequate in terms of materials. And again, I think Mike alluded to it. Yeah, I mean, part of this process again, is to hear form the stakeholder community as to the thoughts about what that is. And to the extent that you can provide your rational basis for your, you know, thoughts, for your comment, and not including science, you know, that supports that you know one

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material is clearly not safe to use. That's something that we can use -- that is information that we can utilize and build into the guidance. We want as much justification including scientific information to support those lines. And where we can draw lines we will draw those lines but we certainly need the science that's reflective of a wide range of use, not just a single application in a very unique setting. But one that is more reflective of production. Certainly domestically, but to the extent possible abroad as well. I mean that's the challenge that we're facing in this, in this rule and with this guidance is that we have to think not only about how production happens here in the U.S. but also outside of the U.S. So I'm just saying bottom line, help us help you. And that's all part of the process.

MR. TOCCO: This is Phil Tocco from Michigan State University Extension. So two quick questions. On page 78 in Chapter 5, you mentioned that the farm should -- you're talking about monitoring for wild life, and you talk about the farm should monitor, under sub 5C, the farm should monitor the outdoor base of growing areas at least twice during the growing season and then in 5D you mentioned that the farm should monitor the outer (inaudible) growing areas at least monthly during the growing season. Could you shed some light on how you came up with those numbers, sort of the thought processes behind those?

MR. INGRAM: Thank you, Phil. So those two examples might seem at odds with each other. This is Dave Ingram. Sub part -- I'm sorry, I have to look up the sub part remind myself exactly where those refer to.

MR. TOCCO: No worries. Yeah, it's 11283 B -- sub B sub 1.

MS. KILLINGER: Yeah.

MR. TOCCO: And then 112 -- yeah they're both sub -

MS. KILLINGER: Yeah. That's a good question Phil, thanks for that. So in the examples that

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you're referring to page 78. If you look a little bit earlier in the example it talks about -- I'm just going to go ahead and read the example if that's okay to be clear. So in example 5C, the farms outdoor areas used for growing BSAAOs near a pond and a wooded area that a farm determines is a habitat for several types of wild life. The farm observes deer herds and ground squirrels on the farm around the growing area throughout the season. More of than several occasions. So the farm determines that the growing areas are within animal movement pathways. So those sentences are establishing an overall frequency of observations. So they observed them on several occasions and clearly they feel that the fields are within animal movement pathways. So in that particular instance, we determine the frequency by describing what the farm was seeing and the general frequency with which animals were occurring, so that they at least twice during the growing season, in that example perform assessment and monitoring activities. In the next example, the observations are more frequent. So an example 5D. There are observations in (inaudible) growing areas located near a pond that serves as a water source for ducks and deer and ducks and deer and their excreta are observed in those outdoor growing areas one to two times a month. And so then that description of what the farm was observing led to us establishing that frequency of at least monthly. And if you'll see in the next example, I think the determination is at least weekly based on the observations that the farm is occurring. So we tried to line up the examples to illustrate what the farm was observing. And again, we certainly have to have a flexible approach here, because we can't predict how frequently farms are going to observe animals on their farms. But we try to provide some information to help guide how you might establish an appropriate monitoring frequency.

MR. TOCCO: Okay.

MS. KILLINGER: Does that help?

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MR. TOCCO: It does help, thank you.

MS. KILLINGER: Great.

MR. TOCCO: My next question is on page 88, in regards to dropped covered produce and the change of, sort of -- the somewhat reinterpretation of dropped covered produce under -- within the -- from the preamble to this document where you talk about -- so this will be the first full paragraph at the end, produce that grows of the ground such as peaches or tomatoes and that drops to the ground before harvest is considered drop covered produce that's same as it was in the preamble. Even if the -- this is where changes. Even if the produce is still attached to the plant when it contacts the ground. Could you maybe explain your thought processes as to why that change was made?

MS. KILLINGER: I think that I'm not only certain that we would see that as a change. I believe that we would see that -- the preamble and the Draft Guidance align in that concept that even if the produce is still attached the plant that it does represent dropped covered produce, and we talk in a preamble, we do go into more detail in the preamble about some of the thinking and research that's currently available related to dropped covered produce.

MR. TOCCO: Thank you.

MS. KILLINGER: Uh-huh.

MR. LUKER: Good afternoon. John Luker, New York State Department of Agriculture and Markets. I am just wondering if you could clarify what is meant - what you mean by enforcement discretion with regard to - and talking about FDA as a whole -- with regard to firms that are waiting the final definition on the term farm.

MR. ASSAR: So enforcement discretion can apply in different ways and it really has a lot to do with how that enforcement discretion is provided, the context that you know each one might be a little bit different. Enforcement discretion could mean that we are deciding to regulate one area, let's say, for the farm definition.

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We are basically saying that you can -- if you are subject to PC (ph) by virtue of the current, the existing farm definition, you can again -- you don't have to do the preventive controls piece develop a food safety plan and so forth and you can do the JMP requirements, implement the JMP requirements as well as the Produce Safety Rule. So it's basically saying not this but this. You know this is what you will be held accountable for.

And there are enforcement discretion guidances and positions out there where we've indicated that, you know, we know that a practice exists. However, it's not the focus of our, you know, inspectional oversight. And therefore -- and there is low risk associated with it and therefore we decided to practice enforcement discretion and not enforce, you know, any regulations around those activities.

So, it really depends. I can't give a broad, you know, kind of overarching definition that applies in every case. It really is specific to the subject to the issue that we are addressing to an enforcement discretion.

MS. BIHN: Liza Bihn Cornell University. As a follow-up to Phil Tocco's comment about dropped covered produce, it's clear from conversations we've had as well as in the guidance that a lot of the concern is related to damage. The impact of damage increasing risk. But in terms of tomatoes there is also bush tomatoes that grow on the ground that are not staked. I'm assuming that's okay, because they grow on the ground. Is that correct? Because that's their natural growing habitat, correct? If the crops naturally grows on the ground.

MS. KILLINGER: Yeah, I think we're going to have to take another look and more in-depth discussion on tomatoes.

MS. BIHN: Okay.

MS. KILLINGER: So we'd appreciate comments related to maybe difference in certain types of produce.

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MS. BIHN: Okay. So the other thing I would ask for clarification on is, in a crop, well let's go with staked tomatoes, since we are a little more comfortable there. If you have a staked tomato and the tomato develop slowly over time, and as they get larger, eventually the wines give way and they eventually touch the ground not in a dropped form, in a slow form where there is no damage. What is the science behind ground contact? If we're allowed to have crops that naturally growing on the ground be okay but crops that develop slowly over time, not resulting in a drop or a damage situation, where -- what's the science related to the risk which just ground contact?

MS. KILLINGER: Yeah. So I'd suggest you look at the preamble discussion on this topic, because it provides the scientific rationale for that thinking. And if you have additional comments, we'd appreciate it, if you submit them to the docket.

MS. BIHN: Okay. So use the preamble language as the basis for a comment.

MS. KILLINGER: Correct.

MS. BIHN: Okay. Thank you.

MS. KILLINGER: I would say that's an area if folks are aware of additional research or information that we should take into consideration. We'd appreciate it if you would include that in your comments as well.

MS. McDERMOTT: Any other questions? Any issues or anything else the panel members would like to discuss or bring out?

MS. KILLINGER: One thing we did want to do especially given some of the topics of this afternoon's conversations is we would like to point out in your packet or available on the website, on the slide that gives you access to the Federal Register Notice. If you look in your packet, there's a document, Federal Register Volume 83, Number 204, issued on October 22, 2018, that's the Federal Register Notice that we keep referencing. And this

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provides information about submitting comments on the Draft Guidance.

And in particular, with respect to the content of the Draft Guidance and technical information if you flip to supplementary information on page 53197 in the background section. The second column contains those questions that Dave and I referenced this afternoon for Chapters 5 and 7 with respect to questions, where we seek specific comment information or data related to equipment and tools as well as domesticated and wild animals.

And we definitely appreciate, you taking a look at those questions and providing comments around that. And again, the more specificity and data and specific examples that you provide, the more helpful it is to us to help clarify some of these points that have been made this afternoon.

MS. McDERMOTT: Any other questions? Well thank you to those that did have questions. We're going to move into the Open Public Comment Session. If anyone would like to make a public comment, please feel free to walk up to the mike. We had a few listed in the folder but they have decided to submit their comments in written format.

So if there is anyone now that would like to submit or have an open public comment, feel free to come to the mike. State your name and your affiliation. Thank you.

MS. FRAVER: I am too short for this. I am Cara Faver, I am with the National Young Farmers Coalition. I would just say that there are a couple of places in this Draft Guidance where you kind of lay out the why, the dropped cover produce is a good area for that. And I think in the worker training -- at least in the worker training segment of the Produce Safety Alliance training, we spend a lot of time talking about why you might want to tell your workers, why produce safety matters. And so I would like to -- I'm happy to see you implementing the same rule when training us -- to train people. So, I would just say

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-- it -- that's very helpful.

And I would love to see more of it in this Draft Guidance. That's helpful as a reader and as an educator. And I think that sometimes it does open you up to a lot more of that conversation. I think dropped covered produce is one of those areas where there can be push back when you've said why, but I think that that's very helpful for all of us.

MS. McDERMOTT: Thank you for your comment. So anyone else that would like to make a comment? Again we really want your comments. Please, submit them in a written format to the docket. The information is in the packet on how to do so. We really want to hear from you and we really need to. So, thank you.

So, I think I'll hand it to Samir now to make closing comments. Samir.

MR. ASSAR: Yeah, and now -- and thank you so much. And thank you for being here. And thank you for sticking it out for the day. We know everyone is really, really busy. And yes, we just appreciate your time. Your time coming out here and time you know meeting with us. There are a lot of sidebar discussions and there is really good opportunity to meet some of you out there. And please feel free to approach us after the public meeting. We've been more than happy to answer questions or just talk with you about the issues that you are facing. That's part of the reason why we're here.

So we heard a lot of interesting things today. Certainly issues and ideas that we absolutely need to take into account as we move forward with our regulatory approach around the Produce Safety Rule.

There were certainly a lot of questions about -- questions/comments about our kind of current position or where we might be going with certain areas of the rule that we've decided to revisit or reexamine and or we have enforcement discretion around. And those areas include water and farm definition and those are very important areas as I have said and we

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understand the need for answers in the case of water, and certainly, you know, there is a public health reason for us to decide on a position and move forward with it, as soon as possible and we are working on that. When I say we are having internal discussions I am saying that it's happening on a very frequent basis every day, it's really on the top of our minds. I would say, all three areas water, farm definition, written assurances which I didn't hear from you about today but that's another area that we are working on as well. And biological soil amendments is the last area that we're looking to resolve as quickly as possible.

We heard from the panel discussion, which I found very interesting. And I appreciate the panelists for being here and providing their perspectives. Really that the guidance is -- you know will be informative, when it's in its final form to kind of helping growers, the communities that they -- that some of the panelists work with. We heard from Chris and Roger that that it will be informative to the discussions that will be -- that they will be having with the group of farmers that they work with.

But also there's a recognition that it's even the final product isn't going to be -- isn't going to be the end product for them necessarily. But that final product can be a starting point in fact for other materials that could be generated that are more tailored to small growers or regions that, you know, just need a little bit more focus, understanding as to what the expectations are for complying and implementing the Produce Safety Rule.

We've definitely get, it's a big guidance and not everything in that guidance is applicable to everyone. So we certainly welcome efforts to develop add-ons or develop other materials based on this guidance moving forward. We certainly recognize that the language and the guidance is not easily understood by the entire community and we certainly try to provide the information -- the guidance information in

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the most -- a farmer friendly or user friendly way as possible as I mentioned at the beginning.

But -- and I think there are many cases where some of you can do that better than we can. And because you know -- you know the growers that you represent, you work with them. You know what is relatable to those growers and how they receive information and so forth. So we're really counting on you which makes it even more important that we get this final guidance right. So once we have this final guidance we're counting on you to utilize it to communicate with your -- if your -- for the growers that are out there, you know, maybe your colleagues or your workers, for those of you that represent growers, for you know those who communicating to those growers that you represent.

So again, it's -- we appreciate your comments in this session. We -- certainly we want to hear from you. We've got time. April 22nd is our closing date. But we always consider your comments. It's just that -- we'll officially consider them up until April 22nd but you can continue to provide us comments. We'll expect comments at any point. So we welcome your feedback as soon as possible and really help us -- help us get this guidance right. Again, we're appreciate you are being here.

MS. KILLINGER: Yeah, I'd like to echo some of the comments that Samir has already made but we absolutely appreciate the feedback that we've received today through your questions and comments and the panel discussion. And we've heard a lot of things that are helpful for us as we move forward. And it is our intent that the Draft Guidance provides useful and effective implementation strategies. And it was refreshing to hear that some of those are even commonsense approaches. That's what we're aiming for.

And so the goal of this meeting was to help us understand, did we get it right? And you guys have provided some comments that have helped us understand some areas, where maybe we are close to mark. I heard

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some positive comments about our discussion -- our discussion in chapter 1 of the definition of produce and describing more information on racks, and transitioning to a processed food as well as our description related to covered farms, and more examples and information about qualified exemptions and those calculations and examples around the calculations.

In Chapter 3, we heard some positive comments about the visitor awareness of policies that were helpful. And generally, we heard some positive comments about the examples, although I'll bring that up a little bit later. We also in Chapter 7 heard some positive comments related to the current content on cleaning and hand sanitizers. And so we absolutely appreciate hearing those positive comments. And we appreciate you submitting comments to the docket on those positive aspects. So we make sure that those concepts are retained in the final guidance as we move forward.

We also heard several areas, where you think we need to continue to improve this document. And some of those included topics around areas that were challenging for implementation such as interacting with harvest crews and how that can be done. And also examples that are more tailored towards small farms. And I think a specific example of high tunnels was mentioned.

And again, this is an area where your specific comments and detailed examples or detailed information on farm specific practices would be really helpful to us, so that we can consider including those types of examples. Some other topics where clarification maybe needed included on the harvestable part of the crop with regard to fruit set and flowering, as well as additional clarification on how to approach course materials and information related to dropped covered produce as well as cleaning. So on cleaning we had positive and some comments that areas need to be strengthened. So again, specific comments

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on that particular topic with details would be helpful so we know where to expand.

Given that the document is already along we want to make sure that we selectively choose those areas that you really feel are necessary to expand on in the document. And I also heard that some of the examples may have added some confusion. So we'd like to hear more specifics about what in those examples is confusing so we can help clarify that.

Just to wrap up some themes that I heard throughout the day. I think it was Commissioner Ball started off by saying that one of the important aspects of us moving forward is collaboration. And I think that we heard a lot of the panelists talk about the need to collaborate and that's why we're here today as well is to work together as we move forward with implementation.

We recognize that this is a process and the key to moving forward to achieve our food safety goals is by working together and collaborating and communicating to get this right.

So thanks everyone for being here and please do submit your comments to the docket.

MS. McDERMOTT: Thank you Samir and Karen. And again, thank you to everyone that came here today and to those that tuned in via webcast. We really appreciate your time and taking a day out of your schedule to attend this meeting.

Thank you to everyone at the FDA who helped in preparing and planning for this meeting. We look forward to continuing to work with all our stakeholders on FSMA Produce Safety implementation. And I hope everyone has a wonderful evening and safe travels. Thank you again.

(Applause)

(Whereupon, the meeting was concluded.)