

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 1

FOOD AND DRUG ADMINISTRATION (FDA) PUBLIC MEETING

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DRAFT GUIDANCE FOR INDUSTRY

Docket No. FDA-2018-D-3631

Tuesday, November 27, 2018
8:30 a.m.

Hilton Portland Downtown
921 SW Sixth Avenue
Portland, OR 97204

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 2

A P P E A R A N C E S

Kari Barrett

Advisor for Strategic Communications and Public Engagement, Office of Foods and Veterinary Medicine, FDA

Alexis Taylor

Director, Oregon Department of Agriculture

Jim Gorny

Senior Science Advisor for Produce Safety, Center for Food Safety and Applied Nutrition, FDA

Samir Assar

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

Karen Killinger

Consumer Safety Officer, Division of Produce Safety, Center for Food Safety and Applied Nutrition, FDA

Mary Tijerina

Consumer Safety Officer, Division of Produce Safety, Center for Food Safety and Applied Nutrition, FDA

Amber Nair

Consumer Safety Officer, Division of Produce Safety, Center for Food Safety and Applied Nutrition, FDA

Faith Critzer

Associate Professor/Produce Safety Extension Specialist, Washington State University

Ines Hanrahan

Executive Director, Washington State Tree fruit Research Commission

Sue Davis

Produce Safety Development Specialist, Oregon Department of Agriculture

Theresa Klamann

Regional FDA Produce Safety Network (PSN) Representative

Michelle Smith

Senior Policy Analyst, Division of Produce Safety,

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 3

Center for Food Safety and Applied Nutrition, FDA

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 4

C O N T E N T S

SPEAKER	PAGE
Kari Barrett	5
Alexis Taylor	6
Jim Gorny	10
Samir Assar	19
Karen Killinger	22
Mary Tijerina	31
Amber Nair	39
Jim Gorny	49
Faith Critzer	50
Ines Hanrahan	51
Sue Davis	52
Theresa Klaman	56
Open Public Questions	70
Michelle Smith	79
Amber Nair	88
Open Public Comments	101
Samir Assar	108
Michelle Smith	112
Amber Nair	113
Kari Barrett	114

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 5

P R O C E E D I N G S

MS. BARRETT: Good morning, everyone. I want to welcome you to today's FDA public meeting. This is our meeting focused on the draft guidance for standards for growing, harvesting, packing and holding of produce for human consumption. This is one of our Food Safety Modernization Act, or FSMA, guidances. My name is Kari Barrett, and I am at FDA, been there a while. I see a couple of familiar faces. I work with our stakeholders on all the FDA foods issues and have been running the FSMA public meetings for some time. So, again, it's good to see some familiar faces out here on the West Coast. I also do want to note, I want to thank everybody -- we have a large webcast audience today, so I want to thank the folks who are webcasting in as well.

We do always have housekeeping that has to be covered, so I'll try to do it fairly quickly. All of you hopefully received this folder when you came in from the registration desk. It does have the agenda and other important information, including the biographies for all of our speakers today, so I'm not going to repeat that when I bring people up to the podium. We'll just simply say names and titles and keep it short. For the web audience, you too should have access to the agenda, and the slides that are presented today will be posted on our website.

I also just want to note, we weren't anticipating anyone from the media here today, but if we do have someone, if you could please just register at the registration desk, we'd appreciate that.

Also wanted to note, at the end of the day we have time for public comment. We do have a few folks who are signed up to give that public comment. It's a little different than the Q&A; it's really an opportunity to make a statement for the record. And if you didn't sign up but you're interested in that opportunity, we do have -- we have time to do that. So, we can always connect with you at the break in the afternoon. But just, please, if you're interested in

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 6

that, it's not too late.

Also wanted to note, and I'm sorry to say, we don't have WiFi in the room. Maybe that's not a bad thing, because you'll pay attention. But if you're staying at the hotel, you should have it, but if you're not, I don't believe it's available. On the flip side, if you're not staying at the hotel and you drove in today, we do have discount parking and you can get that discount parking ticket at the registration desk outside the room.

And, also, always want to note, please take a moment to note where the exit signs are in the room. It's always just a good safety measure. And restrooms are on this floor. If you need any direction, the folks at registration can help you, and they can help you with any other questions that you might have throughout the day. Also, please do mute your cell phones. It's always awkward when they go off. If you have more than one phone, you know, turn them all off.

And we are having today's meeting transcribed. Our transcriber is virtual today, but you will hear me throughout the day, if you're asking a question, I'm just going to ask you to say your name and your affiliation, and that is for the transcriber. So, I want to thank you in advance for that.

And with that, I think that concludes most of the housekeeping. Again, if there's anything I didn't cover and you need assistance, the folks at the registration desk can help you out.

So, it's now my pleasure to really start the program. We do have two speakers to help kick this meeting off. Our first speaker is Alexis Taylor. She's the director of the Oregon Department of Agriculture, and she will welcome everyone to our meeting. And then we also have Jim Gorny, who is our senior science advisor for produce safety in our Center for Food Safety and Applied Nutrition at FDA. So, with that, Alexis, I'll turn it over to you.

MS. TAYLOR: Great. Thank you, Kari. Well, thank you very much for coming, and welcome. Welcome

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 7

to Oregon for our FDA partners. We appreciate greatly the opportunity to have one of the public meetings so close to home for many in our industry. And welcome to our produce farmers and associated industries who are joining us from Oregon and neighboring states.

I think and hope today will be very informative for everyone here, but equally important, to have your perspective, questions and concerns heard on the Produce Safety Rule draft guidance.

You know, it was interesting when I was reading some material in preparation for this meeting, this meeting space holds approximately 225 individuals. In Oregon, we produce roughly 225 unique and distinct agricultural commodities. That makes us one of the most diverse agricultural states in the country. Oregon has 26% of total land in the state in agricultural production, or about 16 million acres. We have just over 34,000 farmers and ranchers in Oregon, and just over 1,600 of them are expected to have to comply with the produce safety draft guidance that you are going to hear about today.

People are often surprised to learn that the average farm size in Oregon is 477 acres. Either you live on the west of the Cascades, where we are now, and that might seem a little big, or you live on the east side of the state, and that might seem a little small. But over 60% of farms are less than 50 acres. Those are our orchards in Hood River, our diversified vegetable farms here in the Willamette Valley. However, while the majority of farms in Oregon are small, the majority of land in agriculture in farms is over 500 acres. Eighty-eight percent of land in agricultural production in the state are in operations over 500 acres or more.

Oregon has a long history of agriculture in our state. We have over 1,200 century farms, so a farm that's been in the same family for 100 years or more, and 39 sesquicentennial farms, so a farm or ranch that's been in the same family for 150 years or more. That's actually pretty amazing when you think Oregon

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 8

has just been a state for 159 years. Over 96% of our farms in Oregon are family-owned and run, and nearly 40% of our farmers are women.

When asked for one word to describe ag in this state, it's diverse. We are diverse in size and scale, who's raising our food, the production systems that they use, and what we grow and produce. We are able to have that diversity because of several key factors, including the unique soil types in Oregon, the mild climate with a long growing season, particularly here in the Willamette Valley, and the availability of water in irrigation. And we also have diversity in that. When you compare the average participation across the state, if you go to the north coast and the average 88 inches a year; here in Portland we average 36; and over in Ontario, which is on the Idaho border, down in Southeast Oregon, they average 10. Because of that diversity, FDA has traveled multiple times to Oregon as the various Food Safety Modernization Act rules continue to be refined and developed. Even FDA Commissioner Gottlieb made several stops around the state earlier this year to meet with our specialty crop industry, to view an on-farm readiness review under FSMA in an orchard in Hood River.

As I mentioned, the majority of farms and ranches are family owned and operated, but the consolidation of farms that has been happening all over the country is also a trend we have seen here in Oregon. In the past 15 years we have lost over 5,800 farms and ranches, or just over 14%. And while we're losing operations, we're also losing land. Between 1995 -- excuse me, 1959 and 2012, Oregon lost almost 5,000 acres of farmland. In the last 15 years alone, we lost one million acres of farmland. I mention this because I think it highlights why it's so important for FDA to be with us here today in Oregon.

I have not met a farmer yet who doesn't care about food safety. They want to ensure what they are producing is safe, wholesome and abundant. However, the how in this instance is as critical to not

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 9

exacerbate that consolidation that we have already seen in Oregon and all over the country. I know tackling the first major food safety overhaul in 70 years has been -- is and has been no easy task. However, I also know states across the country have appreciated FDA's willingness to come to our homes, out in our fields, and see the realities of farming in our states, and maybe most importantly, adjust the rules and try to make them workable for farmers. Food safety is not advanced if the standards are not achievable.

Today I know you will hear about the implementation of the Produce Safety Rule in Oregon and around the country and the slightly unique approach that Oregon has taken to this implementation.

Currently, Oregon is only participating in what is known as Competition A funding. This funding is dedicated to outreach and education around the Food Safety Modernization Act, specifically, the Produce Safety Rule. With the complexity of multiple rules and continued engagement with our industry, we believe focusing on education of our growers all over the state should be where we put our effort as an agency, again, this being the first major overhaul of the food safety system in nearly 70 years, and the first time we are regulating to the farm level. To that end, ODA has hosted 12 Produce Safety Alliance grower training, reaching approximately 400 growers. Additionally, ODA has eight more grower trainings planned for this coming winter, which we anticipate will reach another 400 growers.

We are also continuing to staff up the program and just hired -- and a new produce safety manager started this week. We have multiple staff from ODA here today, and I just ask for a minute if they would stand so you all can see who is on our team for the department. Great, thank you.

We are lucky in Oregon that we have such a dynamic and innovative food industry. Because of that we are able to leverage the 225 unique and distinct agricultural products that we produce, and really

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 10

connect with consumers all over the world and in Oregon. Again, I would like to thank FDA for holding this meeting in Oregon, and for all of you for making time to attend it. I hope everyone finds it very informative and productive. Have a great day.

MR. GORNY: So, good morning, everybody, and thanks for joining us today at this FDA public meeting with regard to the Produce Safety Rule Compliance and Implementation Guidance that was recently published. You're going to hear multiple times that this is available in draft form. It's available and open for comment, and we really do value your comments.

When we first started drafting the produce safety rule at FDA, we had a number of meetings similar to this, and it's really important to reach out to stakeholders, and we found them very valuable to get folks' input. So, we really want to continue the dialogue and really get input on these guidance documents.

I'm Jim Gorny, as Kari pointed out. I'm the senior science advisor for produce safety at the FDA Center for Food Safety and Applied Nutrition. We are from the government; we do speak in acronyms, so we would call that CFSAN instead of the Center for Food Safety and Applied Nutrition. It's in College Park, Maryland, just outside of Washington DC.

It's a pleasure to be with you this morning and thank you, Director Taylor, really appreciate it. Really love being in beautiful Portland. It's a great city and a great state.

I think we all know that we all want to move the ball forward with regard to produce safety, and what I mean we, I mean produce farmers, buyers, cooperative extension agents, researchers and consumers. In short, we can do better. This year has been a really tough year with regard to produce safety outbreaks. Starting in the spring with an *E.coli* 0157:H7 outbreak that was associated with romaine lettuce, and we're currently experiencing another one as we speak. In spring it caused five deaths, over 200

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 11

people became ill, and it was the largest Shiga toxin-producing *E. coli* outbreak in more than a decade.

And then to this summer's cyclosporiasis outbreaks, and when I say outbreaks, I do mean plural, because there were a number of outbreaks associated with the cyclosporiasis illnesses including from, again, bagged salads to fresh cut vegetables. So, it was also very important in that the cyclosporiasis outbreak, the *Cyclospora* was also detected in samples of cilantro and romaine lettuce, and these were the first and second time that the parasite was found in domestically grown produce. That's an important finding, because up until now it's really been thought to be an imported produce issue. As I said earlier, I think it's all about pushing the ball forward, and we can do better.

So, FSMA isn't something new -- and, again, I'm sorry I'm using an acronym, Food Safety Modernization Act -- we call it FSMA for short -- and the Produce Safety Rule aren't something new. This first came to be law in 2011, and it amended the federal Food, Drug and Cosmetic Act when it was signed into law. FSMA is really written at the 50,000-foot level, the statute itself. The rule, the Produce Safety Rule, the Preventive Controls Rule, and other rules are really written at the 10,000-foot level and, really, what it comes down to the boots-on-the-ground level, these compliance and implementation guidances are absolutely critical for people to understand what compliance may look like.

So, today we come down to the boots-on-the-ground level to discuss the guidance, and its intended purpose is to really help produce farmers understand what compliance and implementation may look like, and I'm stressing the word "may," and I'll talk about that in a second.

You know, sometimes when you're engaged in a really tough task, whether it's pruning an orchard, which is a huge task, or a vineyard, or digging a ditch, sometimes you just have to stop, look back, see

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 12

where you've been, how much you've accomplished, look forward seeing how much you have to do, and kind of sometimes remind yourself as to why you're doing what you're doing and what the end goal is here. And I think, really, the Produce Safety Rule, it's really a four-step continuum with regard to implementation and design, and it's not going to happen in one fell swoop. It's not going to happen overnight where we're just going to click a switch and everybody's going to be compliant with FSMA and we're going to have fewer outbreaks and fewer recalls, and produce is going to be -- we're going to push the ball forward on food safety.

The four steps that I consistently, for those of you who know me, I've consistently talked about FSMA in four steps: awareness, understanding, implementation and verification. So, what do I mean by this? What I mean by awareness is understanding why you're doing what you're doing with regard to change. Change is hard, but we need to change, because the status quo just isn't working out so great right now with regard to these huge foodborne illness outbreaks associated with produce, and I'll talk about -- I'll talk about awareness a little bit more in a second.

What I mean by understanding is really understanding what produce growers, as a produce grower, what do you need to do to assure that what you're doing makes produce safe, and what's in the Produce Safety Rule to enhance produce safety?

Implementation is really getting on the do-it side. That's where you're going from, gee, I understand what's in the Produce Safety Rule to now I've got to start implementing it on a daily basis and understanding what that means specifically for your operation.

And verification, of course, is assuring that you know what's being done is actually happening. So, you think things are happening; verification is really about making sure they actually are happening. So, let me talk about each of these four steps very briefly.

Let me talk about awareness. So, why have we

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 13

all been working so hard on produce safety? Look, it's all about protecting consumers' health. Who are consumers? Well, they're us, of course. You know, if you have a family farm, you're eating the produce off of that farm as well. But when we go to the store and we go to purchase produce or any other food, just by looking at it you can't tell whether or not it's safe, and that's really why the FDA came into being in 1906 with the Pure Food and Drug Act. It's really to provide that assurances to consumers that the food that they're purchasing has appropriate oversight and it's being -- and it is safe. Our *raison d'être*, or our reason for existence, is to promote and protect public health. And one way is by setting enforceable standards and making sure everybody is following those rules. That's really our role at FDA.

FDA's goal envisioned and mandated by Congress is to reduce foodborne illnesses, as I mentioned earlier, reduce the number of recalls, and reduce -- and assure consumer confidence in the food supply. They all add up to protecting health. And, quite frankly, consumer fear has no place in the produce aisle. I mean, we want people to be able to go in there no matter where that produce is from, domestic, internationally sourced, conventional, organic, it doesn't matter; they should have no fear in purchasing that produce. They should know that it's safe.

The second reason with regard to awareness that we're doing this is promoting public health. I can think of no better way to promote and protect public health than by increasing per-capita produce consumption. Your mom was right, and we all know from the data now, that eating a diet rich in fruits and vegetables is an essential part of a healthy diet. By increasing per-capita consumption, it's probably one of our best tools that's available to reduce the incidents of some cancers, fight type 2 diabetes, and reduce and prevent obesity.

So, again, it doesn't matter what type of produce you consume, but certainly consuming more of it

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 14

is a really good thing. It doesn't matter whether it's conventional, organic, locally grown, commercially grown, imported, frozen, canned, it's all good.

The third reason for this awareness as to why we're doing what we're doing, it's all about produce farmers. So, reducing the financial impacts, the produce businesses because of a foodborne illness outbreak and recalls is an often overlooked but critical reason why the produce safety is so important. The rule coupled with compliance and enforcement efforts is really designed so that all suppliers in the US market, no matter where in the world they're located, play by the same set of rules and minimize produce contamination.

So, when even a single lot of contaminated produce is placed into commerce, everyone who sells that items is affected. The warehouses and distribution centers fill up, whether they're at retail or food service; the farmer gets the call, stop shipping product, even though they have absolutely nothing to do with the potential foodborne illness outbreak; and, basically, farmers and farmworkers have no work because there's nowhere to sell this product. So, it's really critical. We're only as strong as the weakest link in our food safety chain, so it's really important that everybody is doing their best to restore confidence to the food supply and assure that food is safe, particularly produce. So, the take-home message is that sound regulations and enforcement protect the good operators and the damage caused by produce businesses who are potentially cutting corners.

Second, let me talk a little bit about understanding. Understanding is what's really required of produce farmers in the Produce Safety Rule to enhance produce safety is really a critical step in the next process, and many of you have embarked on this already. Since the Produce Safety Rule was finalized in 2015, a coalition of industry, government and cooperative extensions have been working to educate and train growers across the country and across the world.

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 15

The foundation of this education and outreach is what's called the Produce Safety Alliance, which is at Cornell University and it provides a standardized curriculum. The curriculum is really agnostic: it doesn't matter whether you're convention, organic, commercial or a locally grown, it provides you key information with regard to what you need to do comply with the Produce Safety Rule. It doesn't mean that you may have special needs with regard to trying to understanding it, if you're an organic grower or a very small grower, and FDA has put a lot of time and energy and effort into funding various initiatives to help people understand and take that Produce Safety Alliance curriculum and translate it into localized needs, and that is currently ongoing.

We've currently reached through the Produce Safety Alliance over 27,000 growers, and it's all about the requirements of the Produce Safety Rule. We also, Director Taylor also mentioned a volunteering nonregulatory on-farm readiness review program are also being conducted by state departments of agriculture. I'd encourage you to really take advantage of that. I would consider that really the laboratory portion of the Produce Safety Alliance training. It really brings it to light, because you're actually on a farm, it's nonregulatory, and it really helps people put into motion what it looks like with regard to compliance and the complexities of the Produce Safety Rule and how to be in compliance. It's a very helpful program.

But simply understanding the needs of what needs to be done as required by the Produce Safety Rule really isn't enough. It really comes down to the third phase, which is what I'd like to talk about, really, and that's what we're here for today, which is implementation.

You can be coached on how to swim but it only becomes very real when you jump in the water. You can try your hardest, you know, with regard to understanding what you need to do, but you really need to turn that understanding into action, and that's not

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 16

always easy, right? I mean, I remember learning how to swim. Implementation is all about getting on the do-it side, and once you start, you may need further coaching to master the skills which you've learned about initially, and that's what this draft guidance we're here to talk about today is all about. It provides you guidance on how you may comply and appropriately implement the Produce Safety Rule when you encounter specific situations or circumstances on your produce farm. Does the draft guidance have the answer to every possible scenario in farming? Of course not. No, that simply isn't possible.

So, what it does do is it provides you with some examples, some concrete examples of what compliance may look like. In essence, again, it's coaching for produce farmers and inspectors on what compliance may look like on a produce farm.

So, why is this guidance so important? It's important because it gets everybody on the same page as to what we may expect to see on a produce farm that has successfully implemented the Produce Safety Rule. Does it mean that you're not -- if you're not doing what's in the guidance, does that mean that you're not in compliance with the Produce Safety Rule? The answer is a definite no, it doesn't mean that you're not in compliance, but you may have specific situations that don't fit the examples that are in the guidance. You may have chosen to address your farm-specific food safety challenges in an alternative but equally effective manner. So, I think we're going to have a robust discussion about this today as well.

So, let me step to the fourth step, which is verification, and this is really what people really want to talk about, I think, a lot, which is verification is just a way of saying that you and someone else, like government inspectors, can confirm that what we all know should be done to assure safe growing, harvesting, packing and holding of fresh produce is actually happening.

This proposed draft Produce Safety Rule

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 17

guidance plays an important role, again, to make sure that we're all on the same page with regard to what's being expected. I want to emphasize that the guidance is different from the Produce Safety Rule itself in that inspectors don't inspect based on the standard articulated -- I'm sorry, inspectors do inspected based on the standard articulated in the Produce Safety Rule. They don't inspect on whether or not a produce farmer is following guidance. Moreover, if an inspector comes across a commonly encountered situation you're addressing in a different manner than an example given in the guidance, it doesn't mean that you're out of compliance with the Produce Safety Rule. The inspectors are being trained to understand each individual farmer's approach may vary, but you should be ready to explain how you arrived at implementing your approach, and it has to make sense from a public health and safety perspective. So, that's really a critical aspect here with regard to implementation.

So, what is this draft produce safety guidance document all about? It's about removing guesswork for farmers. It's really intended to help farmers understand the Produce Safety Rule in a deeper way. Guidance helps everyone from produce farmers, buyers and regulators alike understand and envision with concrete examples how to implement the Produce Safety Rule. And it answers questions so produce farmers aren't left to guess what procedures, policies and practices they really need to have in place to meet the requirements.

And I'd like to make that point again, while the provisions of the Produce Safety Rule are regulatory requirements, the recommendations included in the guidance are just that: recommendations. But, again, you may choose to follow the examples in the guidance or you may choose another means of ensuring compliance with Produce Safety Rule requirements. The examples may not be relevant to every situation and should not be interpreted as being universally applicable. As you're all aware, on farms nothing is

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 18

universally applicable; it often just depends and it's complicated. Also, because this version is draft, we really encourage you to take a look at it, review it, and submit any questions or concerns you have about the document to the docket.

So, I encourage you to listen carefully today to the upcoming presentations by my FDA colleagues about what's been proposed in the draft compliance and implementation guidance, and please give us your feedback. Please be honest on how the guidance could be improved.

And last but not least, please let us at FDA know if there are any specific situations that need to further be addressed in the guidance document that are not currently included, and please consider sharing your perspective on what compliance to the Produce Safety Rule looks like in specific situations that you have on your farm or may have encountered and have questions about. We can only -- it's really up to you all to provide us with that information so that we can answer those questions in the most effective manner.

I thank you again for your time and your participation. I know it's a busy time of year with the holidays, and thank you for being here. I'll be around all day if you have any questions or would like to me, I'd be happy to do that. And with that I'll turn it back over to our moderator, Kari Barrett. Thank you, Kari.

MS. BARRETT: Thank you. I want to thank you both, and we're going to now switch the stage out and we'll bring up our first of our program speakers.

Alright. So, we are now going to begin really diving into the draft guidance, and to start us off we have our produce food safety expert from, again, our Center for Food Safety and Applied Nutrition, or CFSAN. We'll start with Samir Assar, who is our director, Division of Produce Safety, Center for Food Safety and Applied Nutrition. Following Samir will be Karen Killinger, who is a consumer safety officer in our Division of Produce Safety, and again at CFSAN, and

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 19

she'll provide an overview of the produce compliance and implementation guidance. And then we'll have Mary Tijerina, who is also a consumer safety officer, Division of Produce Safety at CFSAN, and provide an overview of the general provisions of chapter 1, and records in chapter 8 of the draft guidance. Did I get that all correct? Okay, great. Well, then, I'm going to hand it over to Samir.

MR. ASSAR: Good morning. Good morning. Thank you. I just want to again thank everyone for being here. I know this is a busy time of the year for everyone, and we certainly appreciate the time that you've taken to come out here in person, and also for the people that are joining in by webcast. It's a full day and we appreciate your interest in produce safety and particularly the guidance that we just issued.

As Kari mentioned, I am the director for the Division of Produce Safety at the Food and Drug Administration, and it's a pleasure for me to really kick off the overview of the Produce Safety Rule, which is also referred to as Standards for Growing, Harvesting, Packing and Holding of Produce for Human Consumption. And this is the draft guidance for industry that we're talking about today here, and I just want to get a tally. How many people have read the entire guidance so far? And I'm not going to call any of you out. Okay, for people on the webcast I'll say 50% of the audience. Well, we appreciate that, and you have time, and as a recurring theme here during today's discussion is, this is a draft guidance and we would fully appreciate your comments. As we've provided our current thinking in draft form, we really need to know from you about, you know, how best to comply and implement the rule in view of your context, in view of the context that you face and deal with on an everyday basis.

We know many of you have looked forward to this guidance, and we're excited to get it out in draft form, and we look forward to today's discussion and your comments on the draft.

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 20

And I'd like to thank the FDA staff who contributed to the draft guidance for their hard work and their commitment considering this guidance. Although focused on produce safety, it covered a wide range of topic areas. It touched on other topic areas that are important to consider as we move forward with implementing produce safety. So, I appreciate the FDA work on it, in particular, my staff worked very hard to consider the diversity among the farming community domestically and internationally. That is a point that I want to make sure everybody understands, is that this guidance is not only supposed to be useful for farmers that are here in the United States, but also for farmers that are outside of the United States that are offering produce for import into the United States. So, it's a challenge to address or to put forth guidance that is -- that accounts for the diversity of practices that we see across-the-board domestically and internationally.

And this is an important step as we continue to educate before and while we regulate, and we appreciate the input that we've received from stakeholders, state partners, educational partners, and other agencies as we continue to implement the Produce Safety Rule. And there's a lot of great thinking out there that we've utilized in this development process. We want to build in as much work, the best practices that we know that are going out there that are working, as well as the scientific information out there that should be considered as we inform our industry about how to comply and implement the rules. It's really important for us to do that and we definitely considered the existing information as we move forward with the development of this guidance.

Let me just review the steps towards implementation that we've taken so far. We've talked about the Food Safety Modernization Act, which is also referred as FSMA, which passed into law in 2011 and was directed to issue a rule to establish science-based minimum standards for safe production and harvesting of

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 21

fresh fruits and vegetables, or fruits and vegetables. We published this after the law was enacted. We published a proposed rule for standards for growing, harvesting, packing and holding for human consumption in January, on January 16, 2013. We issued that for comment.

And then, based on the stakeholder input we received through that proposed rule, and we received quite a few, thousands of comments, we issued a supplemental notice of proposed rulemaking that was published on September 29, 2014, which involved a limited reopening of the docket to really touch on specific aspects of the rule for us to receive additional stakeholder feedback.

And then on November 27, 2015, we published the final rule for standards, again, the Produce Safety Rule, which hopefully you're all very familiar with by this time, and this guidance is basically, again, a compliance and implementation guidance that is useful to implementing and complying with the Produce Safety Rule.

The Produce Safety Rule represents minimum standards for the safe production and harvesting of fresh fruits and vegetables. In many cases the rule requirements provide flexibility to comply in a way that accounts for specific conditions and risks on your farm. But, again, it doesn't -- there are specific situations that we need to hear from you about. Again, the farming practices that you work with on an everyday basis, or the conditions that you face on an everyday basis, these are the things that we need to build in as we work to finalize the rule -- I'm sorry, the guidance.

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

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 22

ensure that they have the information that they need. Releasing this draft guidance is a step towards helping farmers implement the rule. And when finalized, it will describe our current thinking.

Similar to the rule-making process, the guidance will be open for comments. Comments in this draft guidance may be submitted at any time, and we encourage submission of your comments by April 22, 2019, so we can take them into consideration as we work on finalizing -- putting out a final version of this guidance. And I'd like to note that our efforts on this guidance will not stop. After we finalize this guidance we recognize that there will be future needs, future needs in terms of complying and implementing the rule. We are going to be putting out other editions, potentially, of the compliance and implementation guidance, so the work does not stop here with this first edition of a compliance and implementation guidance. We will continue to engage the community, as we have in the past. And as was mentioned, we've been to the Pacific Northwest a few times and really learned a lot from, again, the conditions and practices that we've seen here and have become aware of as we've come out here. And we will look for future engagement opportunities to basically address the needs that are out there to help growers comply and implement the rule. That's a commitment that we've made throughout the entire stage of this rule-making process, and we will continue to make that commitment.

And with that, I would like to introduce Dr. Karen Killinger, who is the lead for this massive project, and she will give you the rest of the overview. Thank you.

MS. KILLINGER: Thank you, Samir. Good morning, everyone. Alright, raise your hands if you can hear me in the back. Awesome, alright. Well, it's a real pleasure to be back here in the Pacific Northwest, and to have the opportunity to talk with you more about the draft produce safety guidance for industry. So, let's start with reviewing the content

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

of the draft guidance.

As you can see on the slide, there are nine chapters, and they closely follow the subparts of the Produce Safety Rule. We will have presentations today on all of these chapters except chapter 9 on variances. I'd also like to mention some topics that are not covered in the draft guidance. At this time we are not choosing to issue guidance related to subpart Q, Compliance and Enforcement; subpart R on Withdrawal of a Qualified Exemption; and subparts E and B, with respect to Agricultural Water and Alternatives.

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

As we continue to work with stakeholders on issues related to agricultural water, we do not intend to enforce the agricultural water provisions in subpart E of the Produce Safety Rule for covered produce other than sprouts. Farms should continue to use good agricultural practices to protect and maintain their water sources, and to ensure that their food is not adulterated under the Food, Drug & Cosmetic Act.

Moving on to talking about sprouts. With respects to subpart M in the Produce Safety Rule, we released a draft guidance early last year that primarily was intended to assist sprout operations to comply with the sprout-specific requirements in 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 regarding other aspects of the Produce Safety Rule including these other subparts.

Finally, I'd like to note that this guidance does not address the farm definition. The current status is covered in the Guidance for Industry titled

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 24

Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practices and Preventive Control Produce Safety and/or Foreign Supplier Verification Programs, and that guidance was issued to state our intent not to enforce certain regulatory requirements, including aspects of the farm definition and written assurances.

Before we move on to talking about the draft produce safety guidance for industry in more detail, I'd like to take a few minutes to talk more in general about the purpose and content of a rule versus a guidance, and this is summarized in the table on the slide. As noted, in an FDA rule we have both the codified and the preamble. In the first column we describe some of the aspects of the codified. The codified states the specific legal requirements for the rule, and in many cases the legal requirements use the word "must." The codified is a numbered section towards the end of the document. It's also important to note that most rules provide definitions for certain terms.

Moving on to the second column, which covers the rule preamble, which is often the bulk of the document. The preamble helps describe our thinking as we develop the rule, describes the rationale for the provisions in the rule, and for a final rule provides responses to comments that we received on the proposed rule.

Now let's move on to talking about some of the aspects of a guidance document as summarized in the third column on the slide. Guidance documents contain nonbinding recommendations to help understand how to comply with the rule requirements. When finalized, a guidance document describes our current thinking and in some cases, as Samir indicated, we update them from time to time. Our recommendations in the guidance usually use the word "should" or "recommend," and in a guidance document use of the word "must" or the citation of a specific provision number indicates a rule requirement. We typically issue a draft guidance

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 25

first and seek comments, and as has been mentioned several times and we'll mention several more today, we'd encourage you to submit your comments by April 22, 2019, so we can take your comments into consideration as we prepare the final guidance.

Now let's move on to talking about the draft produce safety guidance for industry, and I'd like to review some of the approaches that we used as we worked on the guidance, and also discuss some concepts from the background and introduction of the document.

Regarding our overall approach, we made an effort to keep in mind the diversity of the farming community as we prepared the guidance, which Samir referenced earlier. We understand that there's operational differences that need to be accounted for, as well as differences in understanding awareness of food safety concepts. As a starting point, we reviewed the comments from the final rule in the preamble, and we also reviewed recent scientific literature as appropriate. We also considered materials that were available from other organizations and educational groups.

We made an effort to communicate within FDA as well as with other agencies to consider efforts where the rule impacts or could be impacted by the rule to assist in the development of consistent approaches across-the-board. We also had the opportunity to work with commissions of state representatives appointed by NASDA, AFDO and AFHTO (ph) to receive feedback on the guidance.

As Samir mentioned, our engagement with stakeholders continues to be important after the final rule published, and we really appreciate the opportunity to engage with stakeholders at meetings, listening sessions and educational farm tours. And all of that information has been helpful to us.

Another important way to communicate with us since the final rule published has been through the Technical Assistance Network, or TAN. I understand that some of you may be frustrated with our response

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 26

time with respect to TAN inquiries, and we work to streamline our process, and our response time continues to improve. But please keep in mind that TAN inquiries allow us to review your questions and understand farm-specific scenarios. The TAN inquiries were really an important source of information for us as we considered the draft guidance language.

Moving on, I'd like to talk about some of the concepts in the background and introduction of the draft guidance. First, I want to emphasize, as has been mentioned several times this morning, the draft guidance is intended to provide our recommendations to comply with the rule requirements. These are nonbinding recommendations. In many cases the rule requirements are flexible, so there may be one way or more than one way to comply with a given provision. You can use alternative approaches as long as it satisfies the requirements in applicable statutes and regulations.

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

The introduction also mentions that the guidance is intended to help the owner, operator or agent in charge of a covered farm to comply with the rule, that is, you, as defined in the guidance -- or as defined in the rule. So, many of the recommendations are framed as "you should" or "we recommend," to note that something is recommended but not required. It's important to note that the guidance does not provide all of the definitions in the rule, so it may be helpful to review the rule definitions as you go over the guidance language, and in your packets today you received a copy of the definitions from the *Federal Register* notice. For the most current version of the

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

definitions, please see the Code of Federal Regulations.

Now I'd like to move on to talking about some of the topics that are consistent across many of the chapters. As mentioned previously, 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 or practices, keeping in mind the framework of the rule to identify a way to meet the requirement that best fits your operation. The draft guidance also mentions that it's important to consider the extent of your practices, so you also need to consider infrequent practices as well as changes that may occur on your farm to ensure that these practices or changes are considered as you account for those practices or changes in order to comply with the rule.

In several chapters we provide recommendations for key components, so you may see a bulleted list at the beginning of the chapter or the beginning of a section to help summarize key recommendations to move forward with implementation, and we hope you find these summaries helpful. We also made an effort to include several examples in a chapter to illustrate specific concepts. There's over 51 specific examples that use a numbering system within each chapter, and there's even more examples embedded in the narrative.

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

We'd appreciate your comments on these overall approaches and whether you find them helpful to emphasize key points and provide specific examples.

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 28

In addition to the guidance itself, we have some other resources that we'd like for you to be aware of. First, we have a webpage for the draft guidance, and that's provided in the upper right-hand corner of the slide, and the draft guidance is available for downloading there. In addition to the draft guidance itself, we also developed at-a-glance overviews for each chapter. These overviews provide summaries of important aspects of each chapter, and we also have a summary of key terms. These at-a-glance overviews are also available at the draft guidance webpage and they are available for download as a group.

Moving on, we also have a couple of factsheets available at our Produce Safety Rule Final webpage, which is also provided on the slide, and those factsheets relate to rarely consumed raw produce, and everyone's favorite acronym, biological soil amendments of animal origin, or BSAAOs.

As I mentioned earlier, another important way to communicate with us is through the Technical Assistance Network, so we provide more information on the TAN, on the slide, and if you have questions about the interpretation or applicability of the Produce Safety Rule to your farm or your practices, the TAN continues to be a helpful way to receive questions.

I'd also like to note that we've expanded our staff to work on produce safety, and with the hiring of the Produce Safety Network, or PSN staff, spanning both the Center for Food Safety and Applied Nutrition and Office of Regulatory Affairs. We have approximately seven CFSAN and 16 ORA Produce Safety Network staff members who are regionally based to collaborate and communicate with regional partners to support and help with high levels of compliance in the farming community.

And I'd like to take the opportunity to identify a few PSN members. First I'd like to acknowledge Theresa Klamann from the Division of Produce Safety and a member of the Produce Safety Network staff. She's there in the back. She'll be joining us

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 29

for a panel later today.

I'd also like to recognize a couple of regional PSN staff here in the Northwest, and that's Dr. Stelios Viazis, also with the Division of Produce Safety, and Kate Allen, with the Produce Safety Network. Unfortunately, they will not be able to join us for the panel today, as they're working on an ongoing investigation.

With respect to other resources, we also have some other draft guidances. We've issued several draft guidances related to produce, and three of them are highlighted here on the slide. The first is the Small Entity Compliance Guidance, which is intended to help small entities in complying with the rule, and this guidance summarizes some of the definitions in the Produce Safety Rule as well as the requirements of the Produce Safety Rule.

Next, as I mentioned earlier, we issued a draft guidance related to sprouts last year to assist sprout operations with compliance with the sprout-specific requirements of 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 the requirements for current good manufacturing practices, and hazard analysis and preventive controls.

We also intend to publish other guidance documents for produce, including an updated version of the Guide to Minimize Microbial Hazards for Fresh Fruits and Vegetables, and a draft guidance related to alternate curricula. We also intend to post updates and new questions to the TAN frequently asked questions on the Produce Safety Rule website.

So, what are the next steps for the draft guidance? As we mentioned earlier, this is one of four public meetings to discuss the draft guidance, listen to your questions and comments, and understand your initial response to the draft guidance. Most importantly, you have the opportunity to share your

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 30

thoughts with us by commenting on the draft guidance. These comments must be submitted to the docket for our consideration and, as mentioned, we encourage those comments to be submitted by April 22, 2019, so we can consider them as we begin work on the final guidance.

There are several ways to access the docket. One way is to go to the *Federal Register* notice and that's the first website that's listed on the slide there. And you can access the *Federal Register* notice to get more information on how to comment both electronically as well as written submissions, and more information if you'd like to provide confidential information in your comment.

I'd like to note that in the *Federal Register* notice we have some specific questions where we ask for comments, information and data, and we'll mention these questions in the presentations for chapter 5 on Domesticated and Wild Animals, in chapter 7 for Equipment, Buildings, Tools and Sanitation later today. In your packet you have a copy of the *Federal Register* notice and, again, that would provide you with the specific questions where we seek comment information or data, so I hope you'll take a look at those.

I'd like to take a minute to talk about what's helpful to us when you provide a comment. We welcome your comments both on positive aspects of the guidance as well as what you'd like to see changed. Commenting on positive aspects of the guidance helps emphasize that certain language should be retained. We also appreciate substantive comments where you'd like to see changes in the draft guidance. Please submit comments with enough specificity, details or examples to describe how it relates to farm-specific practices or conditions and other options that you think would fit to align with compliance with the requirements.

As I mentioned earlier, there are several ways to access the docket, and the slide provides the website to go to, www.regulations.gov, and you have the option to enter the docket number for the draft guidance, or there's a direct link to the draft

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 31

guidance so that you may submit your comments electronically or learn more about providing written comments.

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 our Seafood HACCP guidance, which is now in our fourth edition. It's important to us that the guidance continue to reflect our current thinking as we learn from each other through the implementation process, and that it continues to reflect currently available scientific information. We may also choose to issue other, more targeted draft guidance documents.

We look forward to continuing our engagement with you on the draft guidance as we move forward with implementation, and we look forward to hearing from you today. If you have questions related to this presentation, please hold on to them for the Q&A session at the end of the morning session, and we'll now move into our presentations on the draft guidance chapters. Please keep in mind that these presentations are overviews. We can't cover all the topics in our presentations today, but we thank you for the opportunity to share more information with you on the draft Produce Safety Guidance for Industry. We look forward to the discussions today. Thanks.

MS. TIJERINA: Hello and good morning. My name is Mary Tijerina, and I'm with the Division of Produce Safety, the Fresh Produce branch. Again, I would like to thank everyone for your interest and your participation today.

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

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 32

early in our discussion today.

Now, let's start with an overview of the content in chapter 1. We recommend that you consider the topics discussed in this chapter in the order that they are presented. Starting with section 1, Produce, then section 2, Raw Agricultural Commodity, and following with the sections on covered produce, covered farms and covered activities. Please note that the section numbers and titles are listed on this slide, and are provided on later slides to give a sense of where the information is located.

As we were writing this chapter, we aimed to provide clarification about these topics to help you determine whether the requirements of the Produce Safety Rule applied to your farm and to your produce. We were also mindful of the numerous questions that we've received through the TAN and that were relevant to this chapter. Generally, the Produce Safety Rule applies when three conditions are present: covered produce, covered farm, and covered activities. Note that under the Covered Produce section there are subsections that discuss produce that is not covered, which will be discussed in this presentation. Additionally, some produce may be eligible for exemption by commercial processing that adequately reduces the presence of microorganisms of public health significance, which we will refer to as the commercial processing exemption.

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

We have heard from stakeholders that having a tool to assist in determining whether your farm and your produce are covered by the Produce Safety Rule is important. This figure is available on page 8 of the draft guidance and a link to a PDF version available on the draft guidance webpage is also provided. I won't take the time to walk through each step, but this is an updated figure summarizing the steps in the order recommended in the draft guidance. We do hope you will

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 33

find this to be a useful tool and welcome your comments on it.

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

We received several comments on the rule about the term "produce" and food that is covered by the rule, and we've received numerous TAN inquiries on these topics. Thank you to those of you who submitted TAN inquiries on this topic so we can understand your farm situation and your questions. While we cannot address every scenario, we include 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, such as biofuels, clothing, animal food, or only for the propagation of a crop are not subject to the Produce Safety Rule.

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

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

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

them into a processed food.

Next, you should consider whether your food is covered produce, which is addressed in section 3. The topics listed on the slide describe produce that is not covered by the Produce Safety Rule or may be eligible for an exemption. 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 intend to consider upgrading the list of rarely consumed raw commodities in the future as appropriate. Any changes to the RCR list would require rulemaking and cannot be adjusted through comments on the draft guidance.

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

Moving on, we discussed three conditions that you must meet to be eligible for the commercial processing exemption, which are reviewed on the slide. First, the produce must receive commercial processing that adequately reduces microorganisms of public health significance, such as processing that meets the requirements of the low acid canned foods regulation, the juice HACCP regulation, or a validated process to eliminate spore-forming microorganisms. We recognize through stakeholder comments that there was a need to clarify the types of commercial processing steps that adequately reduced microorganisms of public health significance, so we mention in the draft guidance that freezing and washing are commercial processes that

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 35

generally do not significantly reduce the presence of microorganisms. Keep in mind that only a portion of your produce may be eligible for the commercial processing exemption. For example, if some of your produce receives adequate commercial processing, but then some of your produce is also sold into the fresh market.

Another aspect of the commercial processing exemption is disclosure. The draft guidance discusses that a disclosure statement can be provided in a variety of documents that accompany the produce, such as labels, bills of lading, freight bills, or other documents associated with shipment of the produce in order to communicate that the produce has not been processed to adequately reduce the presence of microorganisms of public health significance. You must also maintain documentation of your disclosures. You can keep records of your disclosure statements in several forms, such as by keeping a sample disclosure and a list of associated shipments or copies of documentation for each shipment.

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

Let's move on to the last two sections of this chapter. First, covered farms include farms and mixed-type facilities. Some farms may not be covered because they are under the \$25,000 threshold, and some farms may be eligible for a qualified exemption. We were aware that there were some comments on the rule, and many TANS related to what sales to include in your calculations. So, to assist you in determining whether your farm is above or below the \$25,000 threshold, the draft guidance describes the types of produce sales that should be included in your calculations, such as all produce sold, not just covered produce, in the applicable three years.

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 36

Produce sales, for example, at farmers markets, direct-to-consumers, or online sales would also be included. Keep in mind the calculation includes the previous three years. If 2018 is the applicable year, total produce sales for 2015, '16 and 2017 would be included in the calculation. Farms that exceed the \$25,000 threshold may be eligible for the qualified exemption.

For the qualified exemption calculations, all food sales must be included, not just produce sales. We were also aware of TAN inquiries on what to include in these calculations as well. The draft guidance mentions that livestock sales are included in food sales, as well as sales of hay, grains, wine, and other foods. In the draft guidance we provide several example calculations related to both the \$25,000 threshold and qualified exemptions to demonstrate how these calculations would be performed in specific scenarios.

We look forward to your comments on these examples to illustrate how to perform the calculations. Note that farms that are eligible for qualified exemption remain subject to modified requirements under the Produce Safety Rule.

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

And this concludes our overview of chapter 1, so now let's move on to chapter 8.

The topics on the slide lists 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 the slide and are provided on later slides to provide a sense of where the information is located.

This chapter provides a brief expansion on

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 37

certain topics as many of the requirements are generally self-explanatory. As we worked on the draft guidance, we targeted providing clarification about the rule requirement and providing our current thinking on topics based on comments on the Produce Safety Rule, stakeholder questions, and input through our engagement with educational partners.

Records keep track of measures to minimize the risk of hazards, help identify patterns and document compliance. Based on our inspection of sprout operations, we observed some challenges with keeping records required by the Produce Safety Rule. It's important to develop a strategy for keeping the required records.

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

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

Your records must list the farm name and location. The location should include a postal address or a physical location. Your records must also include, as applicable, the location of the growing area or other activity area. The draft guidance recommends establishing a system to document locations applicable to your records. You may already have identifiers that work best to meet this requirement, such as on-farm maps that have unique names for fields or buildings. Required records must include actual values and observations, and these records should be accurate without rounding or generalization. For example, records stating "pass" or "ok" or ">6" do not accurately reflect an actual value or observation, and

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 38

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

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

Our next topic is Review by a Supervisor or Responsible Party. Supervisory review of records is important to ensure the completeness of the records, accuracy, and that any necessary corrective measures are performed. The draft guidance recommends that supervisors should look for any unexpected results and follow up as needed. Generally, we believe record review should occur within one week after the record is created. In some cases, of course, a shorter or longer time frame may be more appropriate.

The draft guidance describes some examples of ways to comply with the requirements for records storage and format in sections 2 and 5. We also discuss 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 in a single site, such as at the farm's main office.

In regard to record format, there are several options, and some are listed on the slide. Keep in mind that the records should be sufficient to determine if the original record was changed. Paper or electronic records or a combination can be used. With respect to use of existing records, if the existing records contain some of the required information, you can keep additional information required for compliance separately or in combination with the existing records.

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 39

For example, if a record received from a third party does not include the farm's name and location, you could record this information separately or add it to the existing record.

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

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

This was a brief summary of the topics covered in the draft guidance for chapter 1 and chapter 8. We look forward to your comment on the content of these chapters. If you have questions or comments, please hold onto them. We welcome questions related to chapters 1 and 8 at the question session right before lunch. If you have comments on these chapters, we look forward to hearing them in the comment section this afternoon. And, once again, thank you for your attention.

MS. BARRETT: Alright. Well, it is time for our first break, and it looks like we're a little bit ahead. Do I have a little flexibility to start at 10 after instead of quarter after? I'm looking --

MS. NAIR: Yes.

MS. BARRETT: Okay. So, why don't we go ahead and break now and we'll meet again at 10:10.

[Break]

MS. BARRETT: Okay, welcome back, and we will continue to review a couple of chapters from the draft guidance. We have Amber Nair, who is a consumer safety officer, Division of Produce Safety, again for our Center for Food Safety and Applied Nutrition, or CFSAN. Amber?

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 40

MS. NAIR: Hello and good morning. I'm Amber Nair from the Division of Produce Safety, Fresh Produce branch. It's a pleasure to be with you today to discuss recommendations in the draft guidance. Really, it's at chapter 2, Personnel Qualifications and Training, and chapter 3, Health and Hygiene.

Okay, let's start with chapter 2 of the draft guidance. This slide lists the sections of the draft guidance related to personnel qualifications and training. We don't have time to discuss all of these sections today, so we selected a few to highlight in more detail. Please note the section numbers and titles are listed on the slide and are provided on later slides to provide a sense of where the information is located in the draft guidance.

As we worked on this chapter, we targeted providing recommendations and examples to describe options for implementation on the farm. We considered stakeholder comments, TAN inquiries, and our engagement with educational partners as we developed this chapter. The recommendations in this chapter will help you to evaluate personnel assigned duties, identify personnel subject to the qualifications and training requirements, evaluate whether personnel have the necessary qualifications to perform their duties, and provide training at frequencies to comply with the rule, among other topics.

On this slide we cover two sections of chapter 2. Section 1, Evaluating Personnel's Assigned Duties, and section 8, Supervision to Ensure Compliance with the Requirements of the Produce Safety Rule. For these topics, we took into consideration some of the TAN inquiries that we received, as well as stakeholder comments. In section 1, we recommend the owner, operator, or agent in charge of a covered farm review the assigned duties of all of your personnel and observe them to help you identify the personnel subject to the qualifications and training requirements. As a reminder, all personnel who handle covered produce or food contact surfaces, or who are engaged in the

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

supervision thereof, must have a combination of education, training and experience necessary to perform their assigned duties in compliance with the Produce Safety Rule.

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

Moving on to section 8 of chapter 2, Supervision to Ensure Compliance. For this topic, we also recommend evaluating your operations and ensuring that you identify personnel to supervise each aspect of your operation for compliance. As a reminder, you must assign personnel to supervise your operation 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, contracted, or other personnel. The assigned personnel play an integral role in ensuring food safety.

The owner, operator, or agent in charge of a covered farm should also ensure that assigned personnel are aware of their role in recognizing and ensuring the correction of deviations from your food safety procedures and the requirements of the Produce Safety Rule.

It's important to note that the Produce Safety Rule specifies requirements for personnel qualifications and training. We'll next move into some of the draft recommendations related to personnel qualifications covered in section 2 of chapter 2.

For personnel that handle covered produce or food contact surfaces, or those engaged in the supervision thereof, the owner, operator, or agent in

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 42

charge of a covered farm should evaluate whether these personnel have a combination of education, training and experience to perform their assigned duties.

Appropriate qualifications prepare them to perform their assigned duties in a way that meets the requirements of the Produce Safety Rule. They should also be able to apply their knowledge when performing their job duties. The draft guidance provides several examples about evaluating the education, training and experience of farm workers and supervisors. Your evaluation can help you decide if additional steps need to be taken in order to ensure they have appropriate qualifications for their assigned duties.

Now that we've discussed some of the recommendations for personnel qualifications, let's move into some of the general recommendations for training. This slide discusses content in sections 3 and 4 relating to training frequency and easily understandable training in chapter 2. In these sections we are aware of stakeholder comments from the rule and expanded our discussion on some of these topics. First let's discuss section 3 on training frequency.

As a reminder, you are required to provide training upon hiring periodically thereafter, at least once annually and as necessary and appropriate in light of observations or information indicating personnel are not meeting the requirements of the rule. Training helps provide personnel with the knowledge base to promote safe practices and minimize the potential for contamination and foodborne illness. There is a great deal of flexibility in how you arrange the timing and frequency of periodic training as long as it occurs at least once annually.

Factors to consider when determining timing of training include the type, number and timing of your crops, and timing of hiring and initial training of personnel. Several examples are included in the draft guidance to illustrate the flexibility around implementing the required training. Some of the

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

examples illustrate options for periodic refresher training.

Moving on to section 4 of chapter 2, Easily Understandable Training. The slide reviews some of the recommendations around making sure the training is easily understood. The draft guidance discusses several considerations on the topic including structuring shorter or longer training sessions depending on the type and depth of information being presented. In some cases, delivering training at or near workstations can be useful to connect with specific job duties.

Add demonstrations or use visual aids during the training. Hands-on activities can be helpful 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 in the draft guidance. For these sections, we were aware of stakeholder comments from the rule as well as information from our educational partners. The draft guidance discusses that training should focus on principles that will help personnel understand how to perform their assigned 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 routes of contamination so they can recognize how on-farm practices can result in contamination. Training should also include your farm's food safety procedures so personnel are aware of them.

Next, the draft guidance discusses recommendations and examples relating to the required minimum training topics. Training personnel who handle covered produce or food contact surfaces, or those who are engaged in the supervision thereof on food hygiene

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 44

and food safety provides a knowledge base to help ensure compliance. The draft guidance recommends that the following training topics should be included: relevant sources of foodborne pathogens, such as humans, animals and their waste; routes of contamination, such as animals and pests contaminating covered produce or food contact surfaces; or handling an untreated biological soil amendment of animal origin in a way that it contacts covered produce during an application.

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

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

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

This wraps up our overview of chapter 2, and we'll move on to discussing chapter 3.

Chapter 3 discusses recommendations related to health and hygiene in the draft guidance. In this

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 45

chapter we are aware of stakeholder comments from the rule, expanded on some concepts, and provided examples to illustrate the options for compliance. This chapter is divided into three main sections, which are listed on the slide.

Again, in this section, numbers and titles are listed on the slide and are provided on later slides to provide a sense of where the information is located. I'd like to point out that at the beginning of sections 1 and 2, there is an overview and a summary of some of the key recommendations for each section. We hope you find these 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 and supervisors or responsible parties to prevent contamination through hygienic practices. In sections 1 and 2, this chapter discusses recommendations directed at the owner, operator or agent in charge of a covered farm, as well as recommendations directed at supervisors or responsible parties, and at farm personnel to prevent contamination through hygienic practices.

Now let's talk about the content in section 1 of chapter 3. The main bullets on the next two slides list the subsection topics. In the first subsection the draft guidance reviews the signs and symptoms of applicable health conditions. These can include vomiting, diarrhea, abdominal cramps, sore throat with fever, jaundice and open wounds. Hopefully, none of you have experienced those. 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 can include full-time, part-time, contracted personnel, volunteers and visitors.

In the subsection on self-identification of applicable health conditions, the draft guidance

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

recommends that you should ensure that personnel who have the potential to contaminate covered produce or food contact surfaces can identify applicable health conditions. There is also discussion of training requirements and recommendations related to health and hygiene topics. As a reminder, the owner, operator or agent in charge of a covered farm must instruct personnel to notify their supervisors or responsible party if they have, or if there is a reasonable possibility that they have an applicable health condition.

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

Moving on, let's discuss more of the content related to preventing ill or infected persons from contaminating covered produce. The role of supervisors and responsible parties is important for the implementation of health and hygiene practices. The draft guidance recommends that the owner, operator or agent in charge of a covered farm should ensure that supervisors and responsible parties are aware of their responsibilities regarding the health and personal hygiene requirements of the Produce Safety Rule.

Now let's discuss some of the content in the section on Adjusting Reports of Applicable Health Conditions. In this section, the 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

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 47

assist in making decisions about excluding or reassigning workers with applicable health conditions.

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

Moving on to section 2, Hygienic Practices. In this section we are 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 such contamination. This requirement is not limited to personnel who handle covered produce and food contact surfaces, but also applies to others who work in the operation.

The draft guidance provides a list of recommendations at the beginning of the section to help identify steps for implementation, and they are listed on the slide. There is a recommendation that you should ensure that all applicable personnel are aware of hygienic practices, requirements, and can identify and correct or report unhygienic practices.

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

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

Continuing on, the main bullets on the 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

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 48

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

Moving on to the role of supervisors. The draft guidance recommends that supervisors or other responsible parties should ensure that other personnel consistently follow hygienic practices on your farm. As 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), including maintaining adequate personnel cleanliness through handwashing and using gloves.

Now let's discuss section 3 of chapter 3, Measures to Prevent Visitors from Contaminating Covered Produce and Food Contact Surfaces. As we worked on this section, we were mindful of stakeholder comments from the rule. Keep in mind that the term "visitor" is defined in the Produce Safety Rule. The draft guidance recommends that the owner, operator or agent in charge of a covered farm evaluate the different types of visitors and their interaction with covered produce and food contact surfaces to determine appropriate approaches. There is flexibility in how to meet the requirements. In the draft guidance it describes options and examples on possible implementation strategies. As a reminder, you must make toilet and handwashing facilities accessible to visitors, and you

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 49

should inform visitors of the location of accessible toilet and handwashing facilities.

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

MS. BARRETT: Jim, we're about 10 minutes, but is your panel all here and we'll go ahead and move to that. Pleased to bring Jim Gorny back up to the podium. As noted earlier, Jim is a senior science advisor for produce safety in our Center for Food Safety and Applied Nutrition, and Jim's going to moderate today's panel discussion with external stakeholders. So, I'm just going to turn it over to you, Jim. Thank you.

MR. GORNY: Thank you very much, Kari. So, as I noted in my opening remarks, FDA can't do this -- please come on up. We can't do it ourselves, and this is really a grouping of folks from industry, government and academia to really help provide a little context to the guidance that we're discussing today. And I do want to try and keep the discussion related to the guidance itself and not get into the weeds with regard to compliance and enforcement with regard to all kinds of details related to that.

So, what we've done is I've asked them a series of questions, and the first one that I'd like to do is just have them introduce themselves a little bit, who their organization is, and what's their role with regard to the Produce Safety Rule, and how are they going to potentially be using the draft guidance document. So, I'm going to start first with Faith Critzer from Washington State University. Faith and I have worked together for a long time on produce safety; Ines Hanrahan from Washington State Tree fruit Research; Sue Davis from Oregon Department of Ag; and that is definitely not Stelios; that is Theresa Klamann of our Produce Safety Network.

So, why don't you go ahead, Faith, and just

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 50

talk a little bit about who your organization is and what's your role in this thing called produce safety.

MS. CRITZER: So, my name is Faith Critzer, as Jim said, and I have just joined WSU in January of this year. Sorry for my voice. It doesn't hurt, it just sounds bad. I am a produce safety extension specialist with Washington State, so many of you are familiar with the extension's role in that we try and take client-based information and make it available to growers. Prior to this I was at the University of Tennessee, where I was in a similar role, but essentially for anything people could sell that was related to food. So, my concentration now is much more focused on produce given the production size and scale within Washington State.

My role with the Produce Safety Rule is really trying to, first off, make sure that growers have -- are able to be compliant by getting the PSA curriculum training, making that available, working with Washington State Department of Agriculture, who is using their funding stream from the FDA to gratefully subsidize those trainings so that we make them affordable to all those who would like to participate.

I think that's a really nice connection, because you can really easily begin to understand where people's questions are, and that makes you think a little bit more, because our job is not to develop, you know, regulatory interpretation, but more so read into the preamble and documents such as this to help them make sure that they are complaint, because it's always, hey, I'm doing this; that's fine, right? You know, in my role beyond that, I also participate in on-farm readiness reviews. I'm going to be a participant in the TAN that is being developed more so --

MR. GORNY: Why don't you explain what a TAN is?

MS. CRITZER: So, a TAN is Technical Assistance Network, and I was part of a TAN for the preventive controls regulation, which is food manufacturing sector, and there's two different TANs.

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 51

There's FDA TAN, and then there's also -- which is more so for regulatory interpretation questions. And the Produce Safety Network and PSA have basically tried to develop a similar avenue for people who have more, not regulatory interpretation, but just general, okay, things that they would normally go through extension for. And so going to work with other subject matter experts across the United States and help answer questions that arrive to us from that avenue stream, where people post questions online.

Beyond that, a lot of what we do in extension is helping people who are just starting out. Larger entities tend to have a lot more resources in, you know, human capital that are really well trained and have maybe specific questions for you, but when people first start out, they don't know what they don't know. And so trying to help them get their bearings and not overwhelm them in work them through a progression of knowledge.

MR. GORNY: So, it sounds like the guidance would help you answer specific questions, and during the PSA training?

MS. CRITZER: Yeah, guidance documents are always great for, again, we can't make up regulatory interpretation, and so it's always nice to refer to a guidance document. It also gives those growers and packers that you're working with a lot more assurance as far as it's not just my personal interpretation.

MR. GORNY: Right. Exactly.

MS. CRITZER: It's actually what the regulatory authorities are going to be looking for.

MR. GORNY: Thanks for that overview. Ines, maybe you can talk a little bit about the Washington State Tree fruit Research Commission.

MS. HANRAHAN: Hello. I'm Ines Hanrahan, and the Washington State Tree fruit Research Commission is a commodity organization, and starting about eight to nine years ago, we were keenly aware that FSMA was coming and that we probably had some research needs. We are financed by the tree fruit producer in

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 52

Washington State, so apples, pears, cherries and softwood growers. And up until then the focus has been more on production issues, but starting then we started to recognize that there would be a need for some specific research, and at that time we identified agriculture water probably as one of our biggest spots. So, we initiated several research projects related to specifically *E.coli* in water in our agricultural water systems.

Then, in 2015, we had the *Listeria* outbreak for caramel apples and it totally shifted our focus in terms of research. Since then, we've really focused a lot more on finding research related to how to control *Listeria* in the packing environment and in the storage environment, so not so much basically research directly related to FSMA implementation. The one thing we are still really cooperating with is the food safety and security on trying to figure out how to make it easier for folks to comply with potential water regulations related to water sampling, understanding how our systems work, what are the dangers, and are the ways to cooperate and reduce the number of samples while not basically creating any dangerous situation for folks.

We are working with a lot of collaborators, with Washington State University, our local land-grant university, with regional specialists, and along the West Coast, especially UC-Davis. We've been trying to leverage funds by trying to be actively involved in the Specialty Crop Research Initiative process, also leveraging state block grant money which in Washington State can be used for research.

We have been partners in research with the Center for Produce Safety again to align ourselves with more experts. We are realizing we are not having a lot of microbiologists. For example, I am by training a horticulturist, agriculture engineer and post I was physiologist, and now basically, per se, I became a microbiologist, but I haven't been trained formally in this, and that happens to a lot of folks.

And we are also having an advantage in our

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 53

region in that we have a strong land-grant university, and Faith is a fantastic collaborator. And then we have three industry organizations that basically represent policy, grower education and research, and we are very closely aligned and we're trying to do all of our activities consolidated. So, we have the Northwest Horticulture Council, the Tree Fruit Association and Tree Fruit Research Commission, so that's like a good trifecta in addition to WSU, and that has really helped us move things forward in a consolidated way, and consolidate what we really need and use our money and resources more effectively.

MR. GORNY: So, who is doing education and outreach in the state of Washington with the PSA curriculum?

MS. HANRAHAN: Yeah, we'll talk about this in a little bit, but I can mention it now. So, what we did is we realized that the general PSA curriculum is a general curriculum that would be probably really useful for our -- especially we got several thousand growers to have more specific training that is more related to tree fruit. So, we had one of the first train-the-trainer workshops, so we trained industry personnel to be a trainer. So, our focus has been to try and have each PSA training with some official PSA trainer, some sort of extension person, and some industry trainer all working together on those trainings. And we've had over a dozen of those trainings, and we can offer them at real sharp discounts, \$25 apiece, because the Tree Fruit Association was able to get some grant money through the State Department of Ag. So, again, it's all kinds of people working together for the same common goal of trying to educate people, get them up to speed, and give them the information base that they actually can use.

MR. GORNY: It's often very situation-specific, so we'll come back to the research question, because I know both of you are very interested in that.

Next up is Sue Davis from the Oregon Department of Agriculture, and maybe you can explain, Sue, a little

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 54

bit about what ODA -- I'll use an acronym again -- what ODA's role is in all this.

MS. DAVIS: Sure, that sounds great. So, like, as mentioned, I'm Sue Davis. In a produce safety development specialist for the Oregon Department of Agriculture, and as was mentioned by Director Taylor earlier this morning, Oregon is in a unique role in that we are taking education and outreach as our only piece of the funding related to the Produce Safety Rule. So, we are working under a five-year cooperative agreement to do education and outreach statewide. We're in our third year, and I'm the PI on the grant, which means that I do all the administration, and I think through how to build that sort of cadre of trainers that we can put out in the field to be responsive to farms' needs for training. I also work on our on-farm readiness reviews. Partly, that means doing internal training, helping our growers understand what an on-farm readiness review is and how it fits into this whole program.

We also have recently created a great relationship with Oregon State University, so we now have a sub-award with a team of five people at Oregon State University that are working closely with us, again, to push out education and opportunities in different regions around the state related to the rule essentially with the goal of helping farms understand and comply with the rule.

We also recently added staff to our team, which will be very helpful for us. So, I'm actually located in one of our field offices in the Columbia River Gorge, and we recently hired a natural resource specialist in the Salem office, and we now have a new produce safety program manager joining us as well.

MR. GORNY: Well, thank you for that explanation. Thank you very much. So, our next panelist is Theresa Klaman, and she is part of our Produce Safety Network. And, Theresa, maybe you can tie it all together for us. What's the role of the Produce Safety Network, and there seems to be two

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 55

different flavors of Produce Safety Network with regard to our Office of Regulatory Affairs and our -- I'll say it again, CFSAN, Center for Food Safety and Applied Nutrition. So, what are the roles and how do you work with the states, and what does this guidance mean to you all?

MS. KLAMAN: So, with the implementation of FSMA, FDA recognized the need to establish the Produce Safety Network, and the goal was to have education in high rates of compliance with industry in regards to the Produce Safety Rule. So, the Produce Safety Network is comprised of staff persons from CFSAN, Center for Food Safety and Applied Nutrition, and Office of Regulatory Affairs' staff, and we are regionally located. I, myself, am located in the North Central region and stationed in Minneapolis, Minnesota, and I am sitting in for Stelios, my colleague, Stelios Viazis, who is the Northwestern regional representative.

We are regionally located so that we can be in tune with those specific issues that affect our areas that we can be familiar with the irrigation districts, the weather patterns, the commodity-specific concerns in those areas. We collaborate and communicate with our domestic regional and international partners to build on those existing produce safety -- build on the existing produce safety infrastructure, and CFSAN Produce Safety Network is predominantly responsible for providing the technical assistance and outreach and education training to our state counterparts, our cooperative extension partners, and other stakeholders.

Conversely, the Office of Regulatory Affairs Produce Safety Network in the Northwest, that would be Kate Allen, is responsible for for-cause investigations. They also will be conducting foreign inspections. And for those states that have chosen not to implement an enforcement and inspection program such as Oregon, the ORA PSN will be doing inspections within the state. For a state like Washington or Idaho that has elected to implement what's commonly known as

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 56

Competition B, which is the enforcement and inspection piece, the state inspectors will be doing those inspections. So, the team works together so that we can build and help support our counterparts within each region.

MR. GORNY: So, if somebody in industry has a question, can they call the Produce Safety Network CFSAN person in their region and get an answer? And how does the guidance help them answer those questions?

MS. KLAMAN: So, what the CFSAN Produce Safety Network, we are a live resource. People can reach out to us either by phone call or email, and we would be using the guidance to look towards what the current thinking, what the recommendations are, and try to help people become compliant with the regulation. If we cannot answer a question directly, we do go to our subject matter experts within the Division of Produce Safety and turn to them for additional guidance. In some cases we do have to refer people back to the Technical Assistance Network because it's a policy implementation question.

MR. GORNY: Or it could be submitted to the
TAN --

MS. KLAMAN: Yes, that's what I meant.

MR. GORNY: And it helps inform. Absolutely, you're right on target. So, a bit of a spoiler alert. We haven't been able to go through the complete guidance yet, but I was just going to ask the panelists, I know that many of them -- I hope that all of them have read it through in its entirety. I'm just going to ask them if they found anything within the guidance that was a wow moment, like, wow, that really helps explain, you know, that's in compliance and that really helps me understand that because I get that question all the time from folks in industry. So, I'll again start with Faith, because you do a lot of education outreach and I'm sure you get a lot of questions.

MS. CRITZER: Yeah, a lot of questions, and I think, again, since an extension, we work with a lot of

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 57

small to medium size growers who ultimately may be exempt, are taking a qualified exemption many times. I thought that piece in the guidance document was very well spelled out, because it's not just a single dollar amount. It's really -- you have to account for inflation, you're taking the average over three years; what happens when you're just starting out? I thought that that was really nice, nicely done, and I think it will help people have another resource they can refer to if they're looking towards taking one of those exemptions or exclusions and really understand exactly what it means to be in compliance with documentation they'll need to keep for that.

For the other piece that I really had questions on, it was what -- how does the FDA view, if you're bringing contract harvesters, and who owns the burden of training and documenting training, things along those lines for those entities? And so I thought that the guidance document was really nice in the way it was spelled out, that really has to be owned by the farm; they're not separate entities that are then going to be inspected separately, or things along those lines. And they may provide the training but you have to keep documentation. So, I thought that was very nicely laid out and something we've had come up in training.

MR. GORNY: Good answer. Thank you very much. Ines, your thoughts on anything that wowed you and thought, wow, that clears that up for you?

MS. HANRAHAN: Yeah. I think, Jim, for you it's not a surprise that a lot of the feedback we get from the growers is they're very willing to comply and they wish just to get a to-do list and then just check it off and be done with it. And that's really frustrating for them to have -- basically, to have no clear instructions and to have basically the responsibility of thinking through their own situation. So, that's -- we get this feedback all the time, "Please, just tell me what to do, I'll do it and I'll be done with it." It's just not as simple in this

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

case.

MR. GORNY: Right.

MS. HANRAHAN: So, what I really liked were some of the checklists, especially as they pertain to the personnel qualifications and training in the packinghouse, I really think they will be useful and really helpful. They are really close to this. "Give me what to do and I'll do it," and so I think growers will really enjoy those, or really find them useful.

I also think that these at-a-glance overviews that you have -- that FDA has posted on the web, they're very useful because they basically -- they're shorter documents and they pull out the main things, if somebody just wants to read through those, and those are real -- I thought they were really helpful and well written and available already, which is nice.

And I also thought the domesticated and wild animal section -- we haven't talked about this -- I thought this was very well done, that it clarified a lot of things and had really good examples. The only thing that I would say in that section that we probably need a lot more guidance on is how to establish no harvest zones, really more specific guidance and examples of how to best do this. Because there's, I mean, you know, there's a lot of different situations.

MR. GORNY: Absolutely. Thank you, Ines. And just for those of you who aren't aware, FDA published the entire guidance document, which is quite lengthy and quite detailed, about 140 pages or so. And there are at-a-glance publications. They're basically almost like a cliff note or shortened version. They're about three to five page at most, and they really excerpt the key meat of the message out of each of these chapters, and those are available online as well. So, if you don't want to read the full thing, the full guidance document or draft, I'd encourage you to go and look for these at-a-glance documents, and I'm glad to hear that they were very useful.

So, Sue, you guys do a lot of education and outreach here in Oregon, again, and what was the wow

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 59

moment for you? What was helpful?

MS. DAVIS: I would say there were two things that we would point out, and I would say they're wow, but wow, can we have some more information, too.

MR. GORNY: Okay, fair enough.

MS. DAVIS: First one is related to visitor policies. So, in our on-farm readiness reviews, we have found that often a visitor policy either doesn't exist or isn't broad enough, written broadly enough or maybe it's not really being used.

MR. GORNY: Uh-huh.

MS. DAVIS: So, one of the comments that we came up with in looking at the guidance was that it seems like the visitor, the responsibility for ensuring that your visitors completely understand and comply with the food safety policies on the farm have been maybe elevated beyond what we had understood it to be. And so that's helpful for us just in terms of emphasizing that in our education and outreach. And then, also, just a little more clarity, I guess, about are we interpreting this correctly? Is it almost as if a visitor needs to be at the same level as an employee in terms of their understanding and compliance with that portion of operations on the farm?

MR. GORNY: Good point. Good point.

MS. DAVIS: The other thing, actually, is something that, Faith, you mentioned, and it's related to the burden of responsibility for training when you have different operators on one piece of ground. So, you've got the folks who are growing the product, you've got people coming in who maybe contract harvesters, for instance. And as we read the guidance, there was an aha moment, which is that a contractor can be on farm, be conducting a covered activity but not be a covered farm in that moment, rather, it's still that initial farm that would be responsible. But then later in the guidance it looked like there was some gray area around could and should in terms of responsibility for training.

MR. GORNY: Right. So, Theresa, I'm sorry,

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 60

but you don't get to opine on this because you're part of the FDA team. It's all wonderful, right?

MS. KLAMAN: I'm really happy with the guidance, to be honest with you. We get a lot of frequently asked questions. I have 12 states that I personally am responsible for, and I can tell you that I think this will help a lot of people. As they ask those questions, I can now turn them to the guidance, help walk them through the guidance and show them where to find the answers themselves.

MR. GORNY: Again, it gets everybody on the same page, so whether you're a grower or a buyer, a regulator, it doesn't matter. So, I'm sure you came here not just to praise FDA, but to point out some areas where we could improve the guidance. So, Faith, I'll turn to you again, just going down the line with regard to areas. As Samir mentioned, Dr. Assar mentioned that we are a science and risk-based organization and we want those rules to be based on science and risk-based. So, are there areas where we could use additional guidance with regard to certain procedures, policies and practices? And is there a need for research in any of these areas, because, again, it has to be science-based and risk-based. So, thoughts on that?

MS. CRITZER: Yeah, I would say that this is probably going to be echoed as we go down the line, but ag water is where people have the most --

MR. GORNY: If you notice, it's conspicuously absent for some reason --

MS. CRITZER: Well, there's a good reason for that.

MR. GORNY: -- because we're revisiting that, absolutely.

MS. CRITZER: Yeah, there's a good reason for that, so definitely as those details are determined, having that document readily available would help put people more at ease.

MR. GORNY: Absolutely.

MS. CRITZER: The other piece that I would say

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 61

within Washington, we have hops growers and grape juice or wine, grape growers who are ultimately going to be taking the commercial processing exemption, other entities that may go into a validated kill step process. I think the guidance document as very clear as far as what they need to do with the exception of written assurances, which again are enforcement discretion, so really getting detailed around, you know, how is that going to look, and letting them think through how troublesome or problematic their current process may be and how it may need to be changed, and then giving guidance on that as well. Yeah, I think that the --

MR. GORNY: You talked a lot about structural changes, like who's in, who's out, how to deal with that. Anything specific about on-farm procedures, policies, practices?

MS. CRITZER: You know, I think that it was fairly -- when I read through everything, I thought that if I was sitting in a grower's shoes or packer's shoes, I would understand who owns this -- who has to take care of this. You know, maybe a little bit with the visitor policy, I think that ultimately people may just decide not to let visitors on their farm if it becomes too hard to manage at the end of the day.

MR. GORNY: And any researchable moments? I mean, like wow, --

MS. CRITZER: Oh, for sure. When it comes to research, I think that many times we're left in a void. If people ask us what do I need to do, we do not have a study group to refer to to even start to draw some science-based best practices. Agricultural water is a big one, of course. The setback distance, as Ines alluded to for fecal contamination are huge, and it's -- everything's different, right?

MR. GORNY: Right.

MS. CRITZER: Fecal contamination from birds versus from, you know, heavy density, you know, wild hogs in your fields, and letting growers -- kind of give them some better guidelines for what they need to

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 62

be doing to avoid subsequent crop contamination.

MR. GORNY: Sort of domesticated animal operations, and it's obviously more than just about setback distances, but it is uphill, downhill, upwind, downwind, you know, a lot of complicating factors, that it's not as simple as just --

MS. CRITZER: Unfortunately, not all produce farms are up on top of a hill, and so it's nice to look at that. The other thing that I would mention, I think was not really referenced because it's a hard thing to lock down is that what's the role bioaerosols and how can you mitigate potential contamination from bioaerosols onto your crops? Because as we get more, you know, at the beginning of opening statements, you know, we're getting more and more confined agricultural production --

MR. GORNY: Right, right.

MS. CRITZER: -- we're going to have, you know, either farms with, you know, animal production next to them or within their own operation, and how do they mitigate that risk effectively?

MR. GORNY: So, what I'm hearing in those statements is there's general awareness that there's a potential hazard there, but there needs to be more explicit direction as to how to address with regard to preventive measures to address those issues?

MS. CRITZER: Correct.

MR. GORNY: And it has to be science and risk-based.

MS. CRITZER: Right.

MR. GORNY: Ines, this is your keystone issue, research, and so what's missing and what potential research needs to be done for that science and risk-based preventive measures?

MS. HANRAHAN: Yeah, so I would say, I'm going to echo what Faith said, really growers would like guidance on ag (inaudible). And I think another good point will be that we will face, as we are trying to help growers understand the guidance, is to really emphasize that this is just guidance and that this

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 63

doesn't mean you have to do it like what it says. And that will be a big uphill battle, because folks, again, they would like to have clear recommendations and just do that and call it good. This whole concept of having a food safety attitude, a food safety mindset, I think that concept, working on this concept will be of utmost importance.

What really helped us, for example, is to make some videos, so we did some videos that are basically just teaching good agricultural practices in our industry settings in English and in Spanish, because we are also talking about target language. And that has really helped elevate this general understanding of the why and the food safety awareness in some of our packing operations. So, I think it's something that would be really useful to do for a lot of other scenarios, because that's really hard to really get to this.

Then I would say another thing, as best as we can have lists of acceptable practices, because that will also help, and that way people can choose, okay, I'm doing this, okay, this is a concern, acceptable practice. And if they're using alternative methods, create a checklist so that they know they have all the documentations in line of what FDA might ask for if they're using an alternative method, which is totally fine, but then, again, have a checklist. This is the kind of things you need to consider or having read, even, if somebody comes to inspect you, that I did not see this.

There is one very specific thing that I thought was a little bit misleading, and that is related to modified atmosphere packaging and *Clostridium botulinum* that was, I think, more geared towards mushroom growers, but it can be a really big problem when you have low oxygen in your package. But for anything, any product that is a climacteric product, so it is a product that ripens after it's harvested, for example, apples and pears, but also cherry, it is really nice to have low atmosphere or low

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 64

oxygen in the atmosphere, and it doesn't pose any specific risk. So, this specific section, I think, there potentially be quite a few comments because, basically, if you don't read it correctly or if somebody just glances at it, they could basically interpret this as CA storage as something bad and you should not be doing it, or MAP bags. So, this was a little bit misleading, I think, that could be revisited.

In terms of research questions, I think what's been really obvious in any of the recent outbreaks is that we really are still lacking good testing, basically testing methodology for any kind of potential contaminants. For example, we had a situation where we wanted to test for a virus, and the best method available is 60% accurate and takes forever. Well, it's neither cheap nor it's fast nor it's accurate, so I think there's a big need to push in the research community to have those methods developed that would really help us to even identify our hazards correctly and that could help everybody, I think.

I also think cheap water disinfection is probably still a big issue to focus on because we are still using nonpotable water to irrigate our crops and that won't get away -- that won't go away at all. Now knowing that there is new, potentially new contaminants like cyclospora that is really an emerging research area, what are those things so that we can be prepared, because it will happen to us, right?

And, let's see here. And I would say as a region, and I mentioned this already, we have focused on how to best -- and I guess I'm German, this brings out the German in me -- how to best and most economically sample water so that we don't have to redo this process over and over again. I think that would be something that's very practical and the extension can have a really big role.

MR. GORNY: Okay. So, what I heard in your comments, there was a lot there, so thank you very much for sharing your thoughts. But one is a means of

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 65

getting information to people, including this guidance. So, I heard things like, you know, we all carry a cell phone around; videos are very important, two-minute snippets. Cornell University in the past has developed photo novellas for people to use to train workers. There are materials for tailgate meetings for employees. All very important that we've got to take this guidance now and really get it out into the hands of workers and management. That's really a key aspect.

MS. HANRAHAN: Yeah, I have one other thing that I think I want to mention, and this is, okay, all of us are, we can say what we should do, but we should also do what we say. I mean, for example, how many of us, as we went to the bathroom during break, did exactly the right procedure for handwashing? So, if we are expecting anybody to do the right thing, we have to do the right thing ourselves. I think this sounds really trivial, but I think this is the truth. People watch what you do. They don't care what you say, they watch what you do, and I think that is something for all of us to consider, and to be passionate about these things and not just -- yeah, I mean, words are cheap. Do it and be passionate about it, I think that carries a lot, and relate it to why it means something to people that are actually having to do this. It doesn't have to cost a lot of money.

MR. GORNY: I also heard your, you know, topic was alternatives and how to evaluate alternatives. I think that's a very valid concern, and especially for someone like yourself in the Washington Tree Fruit Research, because you have very unique climatic conditions, specific crops that are unique to your area. I also heard about modified atmosphere packaging. We look forward to you providing those comments so we can tighten that up. And, again, pathogen testing to identify hazards, and making sure that they are validated methods for whatever you're testing, whether it be a food contact surface or a specific fruit or vegetable is really critical. So, a lot of opportunity for research to provide better

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 66

guidance.

MS. HANRAHAN: And I forgot to mention one other thing that I think affects a lot of folks, and this is I didn't see a lot of specific recommendations for organic producers, and this is an ever-growing segment of our industry, so this would be another opportunity to really make sure we are not forgetting about those producers.

MR. GORNY: Right. And, again, we have to be aware of those specific procedures, policies and practices associated with organic production that are potentially very different than conventional, so that's great. Sue, did you have any comments with regard to, you know, need more explanations here in this particular section?

MS. DAVIS: Other things that we felt like the guidance could include, and this is kind of a wish list that I've been told I won't be getting, but just commodity-specific items, and I guess I'll use tree fruit as an example since that's the region that I live in. For example, there is tree fruit versus row crop. So, tree fruit, they sort of have more protection built into the way they're grown. It's generally off the ground, it's irrigated in some cases by drip tape, and it's stored with pretty good diet periods. So, that in comparison to, like, cucumbers or strawberries, something like that, it would be -- again, I know it's a lot to ask for every commodity to have its own sort of set of risk issues, but that's one thing that has come up in our work.

Also, let's see, some notes just -- it would be helpful if we could better understand the impact of wildlife beyond the way the rule is written. Since we know we can't entirely exclude wildlife and we're at this point primarily looking at sort of visual signs of contamination, some additional insight into sort of the more systemic ways that wildlife can have an impact on food safety.

I also have sanitizers, so we're looking for efficacy in real world scenarios and food contact

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 67

surface types. Also, insight into recirculated water. That's actually also related to more research.

MR. GORNY: So, one of the things you've touched on was commodity-specific guidance, and as I've traveled around the country and around the world to look at produce operations, they're all potentially very unique, but they can oftentimes be lumped, like tree fruit, row crops. So, again, I would encourage industry, academia, to work with FDA, with state government, to potentially develop commodity-specific guidance, because nobody knows your operations better than you do. And for FDA to -- I don't think we can take the lead in that area but can potentially provide some technical assistance with regard to making sure that it makes sense and meets the end goal of Produce Safety Rule. But, again, I think it's a really important aspect. And, again, I don't think we need to split down to individual crops, but, boy, if we could just get some more -- and even regionally-specific, because your climatic conditions and your growing practices. Like, you know, we all have this bucolic idea of what an apple orchard looks like. Well, nowadays we know that they're trellised. They're completely different than what you would think of as an apple orchard being. So, there's changing practices as well, and I think we really need that in-depth, inside local knowledge to help make and interpret with new guidance, like this one, specifics that can really help the situations.

So, I'm going to go down the row one more time, if there is any last comments that, you know, you want to just throw out there with regard to the guidance document, because I think we're pretty much -- we're okay on time, and then we'll go to open comments, I believe, right, Kari? Yeah, we'll go to questions and answers. So, any other comments? Just jump in. I'm not going to go down the line here and put you on the spot, but if there's any other last comments that you wanted to throw out there, something you wanted to talk about but didn't quite have an opportunity?

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 68

MS. CRITZER: I would just urge, you know, those that are listening to the webcast or are present to, you know, this is -- you're fully vested in this right? So, make your comments available. That's the only way to improve the process, to give your input, and that's the only way it's going to be considered.

I really applaud the FDA for the way the guidance document was written. I think it's very nice that they took into consideration questions they had already been asked basically about a TAN, and that really helped shape the guidance document, so I think that's very good. But I'd encourage people, I know it's a long document, I know it's hard to find time when you're trying to wear so many hats, but really make time. This is very important for your voice to be heard.

MR. GORNY: Great, thanks, Faith.

MS. HANRAHAN: I'm going to take a little bit of a different step and I would like to bring up that from a research perspective, our, basically, especially for fresh products, we've been under the auspice of basically trying to find a kill step without killing our product so it would make it inedible. But this might not be the right approach anymore, so this is maybe an awesome opening for a bigger discussion of what would be the right approach for those kinds of research questions? Is a kill step still what we want or have we moved on and do we need something else instead?

MR. GORNY: Right. That's what makes it difficult, right, with regard to produce, it's a hurdle approach with regard to lowering risk and preventing contamination.

MS. HANRAHAN: Yes, yes.

MR. GORNY: We don't have any way to clean it up at the end of the day and make sure it's absolutely safe.

MS. HANRAHAN: Exactly, yeah.

MR. GORNY: What are those little hurdles, I think is what you're asking, or do we --

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 69

MS. HANRAHAN: Well, we're working on the hurdle approach right now, but ultimately if you have a real situation where there's a contamination, that doesn't help you, either. So, this is really, like, if you're having a contamination event, I think right now there's no way to test yourself out or to do anything else. Even if you had a kill step, that would not -- that would not make your situation better. So, right now the best approach is the prevention of the contamination in the first place, but I think there's room for discussion of what are other ways to potentially make sure that we can ensure we don't have to throw away good product, because we have to think of food waste as well.

MR. GORNY: Exactly.

MS. HANRAHAN: There's a lot of things to consider, and this is more of a very general question that I think we need to address, because we need to be responsible as stewards of the food that we're producing.

MR. GORNY: Good point. Sue? Sue, any thoughts?

MS. DAVIS: Well, I guess what I would say now is simply just that we really appreciate all the active engagement that we've had with FDA. We've been very fortunate to be able to do educational water tours a couple of times in our region with a variety of staff from FDA, and then we also were able to host Commissioner Scott Gottlieb for the on-farm readiness review in the region. So, it's very helpful for us to be able to convey FDA's educating while regulating. It's very helpful to help our producers kind of get a feel for how this is going to roll out.

MR. GORNY: Thanks for those thoughts. Theresa, any closing thoughts you want to throw in there?

MS. KLAMAN: I'd just encourage you all, if you do have general questions outside of the guidance to reach out to your Produce Safety Network individuals in your states. Here, Stelios Viazis is the CFSAN

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 70

produce safety regional representative, and Kate Allen is the Office of Regulatory Affairs produce safety individual.

MR. GORNY: If you could please join me in thanking our panelists. I think they did a great job and really appreciate it. And I'm going to turn it back over to Kari, and I think we're going to go to questions and answers, I believe. So, again, thank you very much for your answers.

MS. BARRETT: Alright. Well, we are going to move on now to hopefully a more interactive session with you all participating as we go into the questions and answers. And what we'd like to do in this morning session is really focus on the content that we've presented to date in our schedule. So, we really would be looking at the various chapters that are noted in the agenda. And then this afternoon we'll have another opportunity for Q&A where we can discuss the additional content that will be presented early in the afternoon.

So, to work through the Q&A process, just a few things to think about. We do have a microphone here. When you have a question, you're just welcome to come up. We don't want to have a big line, so if you want to -- you know, it's up to you if you see somebody up there to come up, or just stand behind them, whatever you're comfortable with. We ask when you start with your question, again, if you'll say your name and affiliation, we'd appreciate that for the record. And, if possible, to direct your question to a specific speaker, if you know who that person is. If not, you can just generally ask and the panel will figure that out of who the best person to respond is. And I think with that we can go ahead and get started. So, if someone has a question, please feel free to come up to the microphone. I'm sure that there are a few questions out there. Thank you.

MR. NIKOLICH: George Nikolich with Gerawan Farming. We're a stone fruit grower, packer, shipper in Fresno, California. Just a point of clarification with regard to Produce Safety Rule versus Preventive

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 71

Controls Rule. There was a note at the beginning that it wasn't addressed in one of the subsections, but I was curious. Does that mean, then, that if one claims that they're subject to the Produce Safety Rule rather than the Preventive Controls Rule, that that claim won't be challenged, at least for the time being?

MR. ASSAR: So, I think you're referring to the enforcement discretion that we have around the farm definition, right?

MR. NIKOLICH: Right. When you say that you're not going to enforce that, is that what that means?

MR. ASSAR: So, it really depends on the activities that you're doing, which we talk again about if you're doing packing activities with -- involving raw agricultural commodities, then, yes, you could essentially follow the Produce Safety Rule and be aligned with this enforcement discretion that we put out there.

MR. NIKOLICH: Yeah, there's a little bit of a gray area with respect to ownership that I think you are still working on?

MR. ASSAR: Same thing, right, exactly.

MR. NIKOLICH: And so it's not clear at this point, so that if one would make the decision, you know, that they fall one way rather than the other, that is challenging that such a decision is not going to be something that you'll be doing or you still will be looking at that?

MR. ASSAR: Yeah, the ownership issue is definitely one of the primary issues that we're looking at with respect to the farm definition. And, again, as we do this enforcement discretion, and while we, you know, essentially address this issue around the farm definition, then, again, we're allowing and will not be enforcing the preventive controls regulation around those operations that are affected by the ownership area, and those operations would simply need to comply with the Produce Safety Rule provisions.

MR. NIKOLICH: Okay, thank you.

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 72

MS. BARRETT: Okay. Well, thanks for kicking us off. How about another question?

AUDIENCE MEMBER: (Microphone inaccessible.)

MS. BARRETT: I'm not sure we have the right group to talk about it. Understood, though, it's certainly the topic of the day. Yes, again, if you'll say your name and affiliation.

MR. REITZ: Stuart Reitz. I'm with Oregon State University, and this perhaps isn't so much a question but a comment in terms of formatting. So, there's, from the adult education standpoint. So, people, as they read through the guidance, they see at the beginning that says the definition of "should," should the recommendations, encouraging people to do these practices. When you get into a number of the examples, some of them list out a must as something that's required to do, and then several shoulds. I think, again, from just how interacting with adults and how they learn things, they tend to assume all of those shoulds are requirements, and so how do we format things to separate those out? And part of it is, I think, growers, as somebody earlier said, they would like to see a checklist. I've done this, I am compliant, I'm good to go. I think they struggle with the interpretation of the shoulds; you know, what do I have to do to be compliant?

MR. ASSAR: Yeah. No, that's an interesting point, and it was a challenge for us as we developed the guidance, as there was a need to certainly anchor our recommendations on the requirements of the rule, and in those cases we used "must" when it was anchored -- when we were basically reciting the rule requirements, we obviously used the language that's more kind of a determinative and definitive "must." And we tried to make sure that there was a good delineation of those requirements that we -- you know, it's hard to talk about recommendations in a vacuum; you need to anchor them onto requirements. So, delineating the "must" from the "should," and we tried to emphasize the -- you know, these are shoulds and

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 73

these are recommendations, but I understand that there could be some confusion around what exactly the expectations are. Are all the shoulds -- when we say should, is that a must? And really kind of making sure that there's clarity around those two areas, and we appreciate that feedback.

MS. KLAMAN: I guess, too, I mean, a good place to offer comment if you have some suggestions.

MR. REITZ: Absolutely.

MS. KILLINGER: Yeah, we'd like to hear your suggestions if you have other ideas on how to delineate the shoulds in a way that you feel would be more clear, but certainly when we say should we intend it to be a recommendation. And I'd like to revisit the fact that there are -- you can use an alternative approach, so we've built flexibility into those shoulds, so that's not the only way to do something; that's a recommendation and in some cases we provide different options for recommendations.

MR. REITZ: And there are sections in there for one of the training examples that says should, should, should, there is no must. So, again, I'm just -- as an educator I'm kind of struggling with how to let people know what it is they need to do. I think everybody understands the goal of having safe produce, but on the flip side it's like, well, okay, what do I need to do to comply with the regulation.

MS. BARRETT: Yeah, thank you. Other questions or comments?

MS. WIGGINS: Hi. I'm Jamie Wiggins with the Northwest. My question is probably for maybe Mary or anyone, but it's regarding RACs, and I think there are some growers and harvesters that have some unique harvesting methods that may not know for sure if they fall in that kind of a gray area of a RAC or a processed food. And so I know the guidance does address, I guess, a couple examples of, you know, the differences between a RAC or a processed food. So, I was wondering where should they go to get some direct guidance or technical support if they have -- if they

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 74

feel like they're in that gray area or not sure if PSR applies to them or not?

MS. KLAMAN: There is a small entity, a guidance that does parse out the different activities that would be more for farms, and also that would push someone over possibly to be covered under the PC rule. And that has a lot more information, so I would recommend that if you do have questions to look at the small entity compliance guidance.

MS. KILLINGER: There is also the classification guidance as well that would probably help.

MS. WIGGINS: There's a classification?

MS. KLAMAN: Yeah, there's a classification of activities. It's a long name, but basically is the -- it provides more guidance on what types of activities would be considered.

MS. KILLINGER: Either farm activities or not. And both of those are available currently on our website, and also if you just Google, they'll probably pop up also.

MS. WIGGINS: Okay, great. Thank you.

MS. BARRETT: Thank you for your question. Other questions?

MR. GERLACH: Bill Gerlach, World Variety Produce. I think it's very commendable that FDA is actually considering self-reporting of health issues for employees, but given the moral hazard, don't you think that's going to be more on the supervisor to identify that than those that are depending on an hourly wage?

MS. KILLINGER: Well, yeah. That's why we try to emphasize that it's important to have supervisors that are able to supervise each aspect of the operation to really be able to identify health conditions that could be hazardous. So, it's really a team effort. You know, you have some responsibility that is on the personnel, the food handlers or those who are contacting food contact surfaces, but also the supervisors to watch out for those employees. And,

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 75

also have the option of offering employees other duties for the day or for the week, where they won't be in jeopardy of contaminating somebody's produce, covered produce or food contact surfaces. So, yeah, it's a team effort on both the personnel and the supervisor side, but also on being able to offer some options so that they can still maintain a safe work environment.

MR. GERLACH: It's probably important to have supervisors of both genders, too, just to kind of know what's going on in each bathroom, when they're taking breaks and --

MS. KILLINGER: That's a great suggestion.

MR. GERLACH: The other thing that I just want to commend the FDA for taking a side, given what's happening right now, with taking the time with egg, water and setbacks, because it's really critical leafy greens industry.

MS. BARRETT: Thank you for your comment.

MR. DILL: Hi. I'm Mike Dill with Organically Grown Company, and I have a question just about labeling, like product labeling on produce boxes, whether it's bulk packaging or even retail-ready packaging. When I look through the rule and the guidance, and I haven't read the whole thing yet, but is there a section on labeling that talks about best practices beyond just having the name of a business on the label? Because when I've looked at it, I haven't seen anything about lot numbers or harvest dates or anything like that, so am I not seeing that correctly?

MR. ASSAR: We have not addressed, you know, those aspects of labeling in the Produce Safety Rule or in the guidance, so you haven't seen it for a reason, yes.

MR. DILL: Okay. And that was part of our initial comments in the very beginning was that we should have some kind of clear rules and requirements for labeling, and I think as we see right now with romaine, maybe that would be useful.

MS. BARRETT: Yeah, and please do offer -- continue to offer the comments.

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 76

MR. DILL: Thank you.

MS. BARRETT: Thank you.

MS. STANGER: Hello. Toni Stanger, Indigenous Food and Agriculture Initiative, University of Arkansas, and I have a couple, one suggestion and then one question. Suggestion, and I was just in Atlanta, Georgia with the Produce Safety Alliance, and we -- this issue came up, but it was providing -- is there any -- well, we see a need in the field, I guess you would say, but in Washington, do you see the need or the future for funding or any type of assistance to do -- train the trainer in other languages?

MR. ASSAR: Absolutely. We definitely recognize that there's a need not only -- well, I would say across-the-board for the domestic producers, because there are, you know, we're certainly aware of that farmers and farmworkers speak languages besides English, including Spanish. There's a diversity of languages that are essentially being communicated at the farm level, and it's important for those farmworkers to understand what the food safety policies are, the regulation, the guidance, and so forth. So, we definitely recognize that need. And on the international front, the foreign front, there's a long list of languages that we are working on translating. The one that we did translate was, well, the PSA curriculum, we translated that to Spanish, and that's obviously -- that's applicable for the domestic population as well as to Spanish-speaking countries. And we do, we have a prioritized list of languages that we're looking to translate either through work with the Produce Safety Alliance and/or through -- we have a Joint Institute of Food Safety and Applied Nutrition that's leading a produce international partnership group, and so there may be some translations done by them to address the needs that are out there. But, yes, ideally we want to get as much translated material out there as possible so that folks understand what it is our expectations are with respect to requirements and guidance. And we're doing that in a prioritized

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 77

manner based on the needs.

MS. STANGER: And to note the request was for a lead trainer.

MR. ASSAR: Right.

MS. STANGER: To make sure that the cadre of lead trainers are understanding and then able to reiterate those needs to the communities in the language that is their first language.

MR. ASSAR: Absolutely.

MS. STANGER: Okay. Then the other thing I want to mention, that in recordkeeping, we're having issues or we're identifying issues where it's the education as well as language can be a barrier, but also the cultural or spiritual component that aren't identified in the rule at all or in the act or any language or negotiations leading up to this, which for tribal communities is a big concern. Because for many tribal communities, almost every tribal and indigenous community in the United States, their food and the food that they participate in today is often tied to their creation stories, which is a spiritual, what you would, I guess, parlay into a religious kind of identification to that food. So, there are going to be issues in where some of this cannot be talked about because it is confidential, or where we talk about identifying any recordkeeping, identifying different parts of where you're growing. I'm not just talking about something small; I'm talking about the Navajo Nation has over 16 million acres of land, just the tribe itself, which is in Oregon. We're talking about 16 million acres of agriculture here in Oregon, 1.6% of land is tribal land. But for Navajo, NAPI, they're the largest condensed farm in the country, and a portion of their farm is dedicated to traditional crops. So, understanding that there are going to be some gaps in recordkeeping, but it's related to cultural confidentiality. So, having those types of exemptions are understanding those needs. Thank you.

MR. ASSAR: Thank you.

MS. BARRETT: Yeah, that sounds like an area

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 78

definitely for comments. Thank you. Other questions? Okay.

MS. PALACIOS: I'm Michelle Palacios with the Oregon Hop Commission, and as an industry, we believe that hops belong on the rarely consumed raw list. We have submitted comment through TAN and had direct communications with FDA. In the meantime, our growers are working to be compliant because we do fall under the produce rule. But my question is, you have stated today and it is our understanding that we cannot be added through this guidance to the rarely consumed raw list, but knowing that, what is FDA's timeline to go into rulemaking for hops and other commodities that believe we've been erroneously left off that list?

MR. ASSAR: Yeah, and so obviously we're aware of the concerns, and thanks to our stakeholders that are representing hops, and we've heard similar concerns from the wine grape industry as well. And so this is an important area for us, and I can't give a specific timeline, but I can tell you that we are actively, you know, working with the information that we have available to us around those issues, around those commodities, and looking to address, you know, really, again, our Produce Safety Rule is risk-based, and if we -- if information becomes available to us that there are practices or commodities for which, you know, the risk isn't as high, then we absolutely need to take that into account in terms of our regulatory approach. And so that's -- and that's what we're doing right now, essentially, in working to address the issues that we've heard about for commodities that express concern to us, including hops and wine grapes. I can't give you a specific timeline.

MS. PALACIOS: Everyone wants a timeline, right? Well, it's reassuring to hear those comments.

MR. ASSAR: Absolutely.

MS. BARRETT: Thank you. Other questions? Comments on what you heard this morning? It's early. I'm going to look at my lead and we could break for lunch. Is there any way -- I know earlier we thought

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 79

we would still come back at 1:30. Is there any way to come back at 1:15, looking at our crew? We're good? I know we have the webcast audience, so, folks, we will adjourn now for lunch and we'd like to start at 1:15.

[Lunch break]

MS. BARRETT: I want to welcome everybody back after lunch. I hope everyone had a good, nutritious lunch. Alright. So, we're going to go back to having our produce safety experts walk through a number of the chapters of the draft guidance, and we're going to start with Michelle Smith, who is the senior policy analyst, Division of Produce Safety for Center for Food Safety and Applied Nutrition at FDA. Michelle is going to discuss the Biological Soil Amendments of Animal Origin and Human Waste, which is chapter 4, as well as Domesticated and Wild Animals, chapter 5. Then Michelle will be followed by Amber, who you heard from this morning. She's, again, Amber Nair, Consumer Safety Officer, Division of Produce Safety, Center for Food Safety and Applied Nutrition, FDA. And this afternoon Amber is going to speak on Growing, Harvesting, Packing and Holding Activities, which is chapter 6, and Equipment, Tools, Building and Sanitation, chapter 7. So, with that, Michelle?

MS. SMITH: Okay, thank you, Kari, and thanks everyone in the room for coming back from lunch. And thanks everyone on the webinar for tuning in. You've got the luxury of being able to eat lunch at the same time as you listen.

Now, as Kari said, I am going to be covering, as soon as I find the clicker -- I'm going to be covering chapter 4, Biological Soil Amendments of Animal Origin, also known as BSAAO, and Human Waste, and chapter 5, Domesticated and Wild Animals. As we worked on -- okay. As we worked on these chapters, the biological soil amendments of animal origin, the requirements of subpart F are the minimum standards for BSAAOs, including agricultural teas that are BSAAOs, and human waste.

Chapter 4, Domesticated and Wild Animals, is

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 80

designed to help you determine the applicability of subpart F to your farms, as well as recommendations applied to related BSAAOs. I got that confused a little bit.

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

This slide sets out an overview of the sections covered in chapter 4 of the draft guidance. As with other presentations, the section numbers and titles are listed on the slide to help you find the content within the draft guidance. As we worked on this chapter, we considered comments from stakeholders that we received during rule development, TAN inquiries, as well as our experiences on farm tours and participation in three soil summits that we held. This presentation will be a brief overview of some of the topics in chapter 4. The sections in this chapter are designed as a series of steps to help you determine the applicability of the requirements of subpart F to your farm, and to provide recommendations and examples related to each of these topics. The draft guidance provides several figures, summarized lists and examples, and we hope you find these useful.

Now, the first step is to determine whether your soil amendment, including an agricultural 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 the definitions in the Produce Safety Rule. Some of these defined terms are also contained on this slide and in the draft guidance.

Section 1 of this chapter provides several examples of BSAAOs, including treated, stabilized compost, compost ingredients or intermediary composting materials that contain materials of animal origin, worm castings, and animal bedding material that includes

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

animal excreta, as well as other examples.

As shown on the slide, the draft guidance provides a figure, figure 4a, as a tool to help with this determination. This figure can be found on page 58 of your draft guidance, and we hope you find it useful.

The next step is determining whether your BSAAO is treated or untreated. The draft guidance reviews the requirements for BSAAO including an agricultural tea to be considered treated. Note the Produce Safety Rule does not require you or your supplier to conduct microbial testing of 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 applicable requirements in the rule: treated BSAAOs contaminated by untreated manure, runoff after treatment and agricultural teas made from raw manure, among other things. The draft guidance also lists options for management of untreated BSAAOs, including using it as an untreated BSAAO to grow covered produce in accordance with rule requirements. Another option is treating or retreating the BSAAO in order to use it as a treated BSAAO.

Section 3 is designed to help you determine the appropriate treatment process and associated microbial standard for your BSAAO. There is flexibility for you to determine a treatment process for your biological soil amendment of animal origin. You can use a physical, chemical or biological process, or a combination of these. If you want to consider a BSAAO to be treated, it must be processed to completion using a treatment process that has been validated to meet the relevant microbial standards as described in the produce rule.

As noted in the draft guidance, FDA does not expect farms to perform validation studies for BSAAOs. However, farms should ensure that the treatment processes they use have been validated to meet the standards of the Produce Safety Rule. We considered

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 82

stakeholder comments from the rule, Technical Assistance Network inquiries, and soil summit discussions as we worked on this section.

Key recommendations for processes to treat BSAAOs include establish procedures to ensure delivery of the scientifically valid controlled process throughout the BSAAO; administer the treatment process in a controlled manner that ensures that treatment parameters established during validation are achieved throughout the entirety of the material. For example, proper blending or turning as necessary, and monitoring parameters such as time, temperature, moisture content, or pH appropriate to the treatment process. Finally, you should ensure that the treatment parameters are achieved in areas where the delivery of the process could be more challenging, such as the edges or the bottom of the pile.

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

First, the application restrictions are based on whether your BSAAO is untreated or treated. There are two different levels of treatment, that is, microbial standards specified in the Produce Safety Rule. The level of treatment stringency impacts the application restrictions. The draft guidance recommends that you consider the application methods that you could use and the likelihood of contact between the BSAAO and the harvestable or harvested portion of the crop both during application and after application of the BSAAO. For example, a broadcast application of a biological soil amendment of animal origin is very likely to contact the crop during application.

This section expands on our current thinking of application for untreated and treated BSAAOs providing several examples. It also provides a figure summarizing the requirements related to the micro

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

standards and application requirements for BSAAOs.

And while we don't have time to go into great detail about this figure, I do want to draw your attention to it. It's figure 4f on page 70 of the draft guidance. It was created as a visual aid to assist with connecting the relevant microbial standards with the application requirements in the Produce Safety Rule. This figure reviews the relevant requirements for treated biological soil amendments of animal origin, including the microbiological standards for the different level of treatment, the application restrictions, and the minimum application intervals.

We also created a figure to review the application requirements and minimum application intervals for biological soil amendments of animal origin. This portion of the figure focuses on the application requirements and minimum application intervals for untreated biological soil amendments.

The entire figure, figure 4b, is located on page 59 of your guidance. Note that FDA reserved the provision represented in the upper right red box of this figure that provides the minimum application requirements, the interval of untreated biological soil amendments of animal origin applied in a manner that does not contact covered produce during application but in which must be minimized with respect to the potential for contact after application.

As discussed in section 4, we are deferring action on an application interval for this particular scenario while we pursue certain steps, including a risk assessment and further research. And as a result of this being in reserve, there's no regulatory difference between the application of untreated biological soil amendments that does not contact the crop after application and the application of soil amendments where you need to minimize the contact, although the risk level of those two scenarios is very likely different. What we have said is that we would not object to the use of the National Organic Program standard of 90- or 120-day application interval for

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 84

untreated BSAAOs applied in the manner described in the first row of this figure. We believe adhering to something like a 90- or 120-day application interval would be a prudent step towards minimizing the likelihood of contamination while the risk assessment and further research is being conducted. Again, at this point in time there's not a requirement for an interval in that scenario, but we are working on it.

Note that although FDA has reserved this provision specifically related to application interval, other requirements related to untreated biological soil amendments that are in the Produce Safety Rule continue to apply, things like storage, handling and transport, etc.

Section 5 covers recommendations on determining the requirements for handling, transporting and storing your biological soil amendment. 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 biological soil amendments of animal origin for the potential to contaminate your growing area, water sources and distribution system, other soil amendments, including treated BSAAOs, areas used for covered activities, covered produce and food contact surfaces. Remember that untreated BSAAOs include incomplete or partially treated BSAAOs, and BSAAOs that have become recontaminated after treatment.

The draft guidance expands on recommendations and examples related to BSAAO storage practices and locations, personnel and equipment, and tools involved in handling, transport and storage of BSAAOs.

Finally, section 6 in the guidance, not on this slide, it's on page 72, covers recommendations related to determining what records to keep for your treated BSAAOs, and we look forward to your comments on this section.

Next, chapter 5. In developing chapter 5, we also considered stakeholder comments from the rule, information from other agencies, scientific literature,

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 85

outbreak investigation information, and Technical Assistant Network inquiries. Let's start with a review of background information and some of the rule requirements.

Domesticated and wild animals are sources of pathogens that can transmit foodborne disease by contaminating produce. The Produce Safety Rule requirements are minimum standards to address the potential for biological hazards to be introduced by your own domesticated animals, by domesticated animals nearby, or by wild animals. The requirements of subpart I apply only when covered activities occur outdoors or in a partially enclosed building. They also only apply when, under the circumstances, a reasonable probability exists that animals will contaminate covered produce. We support co-location of animals and plant food production systems in agriculture and do not prohibit animals on covered farms.

For this chapter, there are three main sections listed on the slide. Again, the section numbers and section titles are here to help you navigate through the guidance and find this information. For each topic we describe factors to consider, and we include several examples to illustrate how a farm could evaluate related information. Please keep in mind that even if you have similar circumstances to the examples that are given in the draft guidance, you should still evaluate the conditions on your specific farm and the practices that you follow.

Section 1 of chapter 5 covers determining whether, under the circumstances, there is a reasonable probability that animals will contaminate your covered produce. The draft guidance provides several recommendations. First, that the owner, operator or agent in charge of a covered farm should identify outdoor areas and partially enclosed buildings where covered activities occur during the growing season on the farm. These are the relevant areas that may be

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

subject to subpart I.

Next, you should determine whether under your specific circumstances there is a reasonable probability that animals will contaminate covered produce in the identified outdoor areas and partially enclosed buildings. To do this, the draft guidance recommends that you should evaluate your farm's covered produce conditions and practices. This should also include an evaluation of the types of animals that could contaminate 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 concepts 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 things like land features, land use, and the presence of existing measures or structures on or near your farm that affect whether or not animals or their waste will be present on your farm. Again, more details are provided in the draft guidance.

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

This section also provides examples related to a farm evaluating covered produce conditions and practices to determine whether there is a reasonable probability that animals will contaminate produce. As noted in the *Federal Register* notice, which is in your package, we're asking for comments on a few specific areas. We would like comments on the guidance wherever you have them, but this is one area where we specifically are seeking comments, information and data about factors or conditions that could affect the likelihood of contamination of covered produce by animals. We look forward to your comments on this topic. And, again, I want to emphasize that FDA does not expect, suggest or recommend that farms eliminate

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 87

animals from outdoor growing areas. And we do not require the application of practices that may adversely affect wildlife, such as removal of habitat or wild animals from land adjacent to produce fields. If you determine that there is a reasonable probability that animals will contaminate your covered produce, then you must assess the relevant areas used for a covered activity for evidence of potential contamination as needed during the growing season.

Section 2 covers this assessment, assessing the relevant outdoor areas and partially enclosed buildings on your farm for evidence of potential contamination of covered produce by animals. The Produce Safety Rule provides flexibility in developing your approach to assessment, which could vary depending on the types of animals and other factors that you identified in determining whether or not there was a reasonable probability that animals will contaminate covered produce in each of the relevant areas on your farm. In addition, as I mentioned before, you should periodically reevaluate your assessment and see if it's still appropriate.

This section expands on factors to consider in developing and modifying your assessment approach, some of which are listed on this slide, including personnel responsible for monitoring, timing and frequency of monitoring, details on reporting observation of evidence of animals on your farm and their potential activity. We also include examples of how a farm could assess relevant areas after they have made a determination that there is a reasonable probability that animals will contaminate covered produce.

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

Section 3 covers evaluating significant evidence of potential contamination of covered produce

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 88

by animals to determine whether harvest can occur. If there is significant evidence of potential contamination by animals, you must evaluate whether the covered produce can be harvested in accordance with the requirements of the rule and take measures reasonably necessary during growing to assist you later during harvest when you must identify and not harvest potentially contaminated covered produce that's 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 these concepts. We provide several examples to illustrate approaches for determining whether significant evidence of potential contamination by animals exists, including scenarios involving monitoring observations that likely are significant evidence of potential contamination, and scenarios that are likely not significant evidence of potential contamination. We hope you find these examples helpful.

This concludes our review of chapter 5, Domesticated and Wild Animals. Thank you for your attention for these two chapters. There will be time for questions a little bit later this afternoon. We look forward to your comments on these sections of the draft guidance, and thank you again for your attention.

MS. NAIR: Alright. I've got the last talk of the afternoon. Hopefully, you all won't fall asleep. Stay with me. Alright. Again, I'm Amber Nair from the Division of Produce Safety, Fresh Produce Branch, and I will present overviews of two chapters in this presentation. These will be brief overviews of each chapter highlighting selected recommendations. We will not have time to cover all of the content of these chapters.

First, chapter 6 provides our current thinking and recommendations related to the requirements of subpart K. This subpart is applicable to growing,

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 89

harvesting, packing and holding activities, including the transition points between those phases. Then chapter 7 provides draft guidance related to equipment, tools, buildings and sanitation associated with the requirements of subpart L. In both of these chapters we recommend evaluating your relevant procedures, processes and practices periodically to consider the breadth of your practices, including any infrequent or unusual practices, as well as any changes that have occurred and how this relates to the requirements of the Produce Safety Rule.

We included numerous examples to illustrate how a farm could use the principles and recommendations discussed in both of these chapters. We hope you find these 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 evaluations based on your farm's specific conditions and practices.

This slide provides an overview of the sections in chapter 6, and we will only discuss a few of these today, which are highlighted in bold. The section numbers and titles are listed on this slide and are provided on later slides to provide a sense of where the information is located. Each of these sections directly relate to a specific requirement in the Produce Safety Rule. As we worked on this chapter, we were aware of stakeholder comments to the rule, as well as TAN inquiries.

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

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

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 90

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

Let's start with section 1, Separation of Covered and Excluded Produce. At the beginning of this section, the draft guidance reviews the Produce Safety Rule requirements to help you determine the applicability of 21 CFR 112.111. The draft guidance recommends that you evaluate your farm's activities and produce to determine whether you grow, harvest, pack or hold both covered and excluded produce and how you handle any excluded produce. It is recommended to visually assess farm activities during this evaluation.

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

You should identify the locations where activities for covered and excluded produce occur. Further, you should identify shared equipment and tools and personnel that are involved 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 of stakeholder comments on the rule and expanded on several concepts. As a reminder, immediately prior to and during harvest activities, you must take all measures reasonably necessary to identify and not harvest covered produce that is reasonably

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

likely to be contaminated with a known or reasonably foreseeable hazard, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta. At a minimum, your efforts must include a visual assessment of the growing area and all covered produce to be harvested regardless of the harvest method. These are flexible requirements to allow appropriate steps based on your farm's conditions and practices.

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

With respect to the required visual assessment, the draft guidance recommends that it should involve designated personnel visually examining the entire designated harvest area, including areas that will be mechanically harvested. These visual assessments are most effective when performed as close in time before beginning harvest as practicable, or during harvest.

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

Continuing on with section 3, Handling Harvested Covered Produce. The draft guidance recommends the owner, operator or agent in charge of the 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 is a great deal of flexibility in the

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 92

relevant requirement to tailor practices that are appropriate for your operation. The draft guidance recommends that the owner, operator or agent in charge of a covered farm should establish procedures to ensure that harvesting, packing and holding protects against contamination of covered produce.

Practices to consider include avoiding contact between the cut surfaces of covered produce and soil, reducing damage to harvested covered produce to the extent practical, and packing and holding covered produce in a manner that minimizes the potential for contamination. There is additional information on these topics in the draft guidance.

It's important to note that this topic is likely to involve personnel who handle covered produce or food contact surfaces or who are engaged in the supervision thereof. The draft guidance in this section reviews training requirements and provides recommendations related to these personnel and handling harvested covered produce.

Now, let's review some of the draft guidance content in section 6 on food packing materials. First, I'd like to point out how we addressed some overlap in content for chapters 6 and 7 of the draft guidance related to this topic.

Food packing materials, including food-packaging materials, are subject to requirements provided in subpart K and subpart L. To minimize the redundancy on topics, we provide draft guidance on the aspects of 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 nonporous materials can facilitate contamination if they are damaged or their surfaces are not intact. At the beginning of this section, the draft guidance lists recommended steps to help the owner, operator or agent in charge of a covered farm determine whether a food

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 93

packing material is adequate for its intended use, and the steps are listed on the 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 your food packing materials are unlikely to support the growth or transfer of bacteria, taking into consideration your handling, maintenance and storage practices, and determine whether reusable materials can be cleaned, considering your handling, maintenance and storage practices. In this section, other recommendations and examples are provided relating to single use and reusable materials.

Continuing on with section 6 on food packing materials, the draft guidance expands on evaluating your practices and food packing materials. The draft guidance recommends that the owner, operator or agent in charge of a covered farm should periodically evaluate your practices, including handling, maintenance and storage of food packing materials. This evaluation is important to account for changes that could occur over time, including the use of certain food packing materials for your practices. The draft guidance lists factors to consider, many of which are included on this slide, such as the type of material, for example, plastic, wood, foam or cardboard; the nature of the material, for example, whether it's smooth, coarse, absorbent, porous or nonporous; the durability of the material, how the material is constructed; the existing conditions of the material, whether it's intact, scored, cracked or damaged; and maintenance practices, for example, repairing or placing worn or damaged components; and also handling practices and storage practices, such as how the material is received and prepared for use, among others.

The draft guidance also provides examples to illustrate how a farm could evaluate food packing materials and their use. Taking into consideration the factors described in the draft guidance, we hope you

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 94

find these examples a useful tool. We look forward to your comments on this section. This concludes our review of chapter 6.

Chapter 7 of the draft guidance includes four sections, Equipment and Tools, Building, Other Sanitation Measures, and Records. The section numbers and titles are listed on this slide and are provided on later slides to provide a sense of where the information is located. In this presentation there is a slide featuring each of the three sections in bold that highlights the topics covered within each section to emphasize the extensive amount of information contained in this chapter.

As we worked on this chapter, we considered stakeholder comments from the rule, 10 inquiries, experiences from our educational farm tours, outbreak investigations, and engagement with our educational partners. The topics in this chapter are important concepts for consideration. Based on our inspections of sprout operations, the most frequent citations relate to the requirements of subpart L, particularly requirements for equipment, tools and buildings. So, the content of this chapter may be useful to farms, including sprout operations, to assist with implementation of the requirements.

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

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

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 95

Starting with the first recommended step, it's important to identify the equipment and tools subject to the requirements of subpart L. You should visually assess your covered activities in your growing, harvesting, packing and holding areas to identify the equipment and tools that are intended to or likely to contact your covered produce. The draft guidance provides some examples to illustrate how your practices could affect whether contact is intended to or likely to occur. I like to highlight that in the *Federal Register* Notice of Availability for the draft guidance, we believe additional information would assist us, and we seek specific comments, including information and data on the following: When acquiring equipment and tools, how do you engage with equipment and tool suppliers about the size, design and construction of your buildings so that they can accommodate the equipment and tools?

Moving on to step 2, let's discuss some of the recommendations related to design, construction, workmanship, installation and maintenance for equipment and tools, which is covered in section 1. The draft guidance recommends evaluating the materials used to make your equipment and tools, and the impact of the materials and their construction on adequately cleaning and properly maintaining them. You should also evaluate the design, construction and workmanship of equipment and tools. The draft guidance recommends considering several factors, including those listed on this slide. We recommend that you use equipment and tools made from nonporous materials to the extent practical.

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

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 96

maintained should be repaired or replaced.

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

The draft guidance recommends that the owner, operator or agent in charge of a covered farm should establish and communicate the following: procedures for inspecting equipment and tools, including food-packing materials; frequency of these inspections, the personnel involved, conditions that should be reported to you; a supervisor or responsible party to determine appropriate steps to protect covered produce; and expected practices when personnel observe unclean, damaged or worn equipment and tools, including food-packing materials.

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

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

There is a subsection in section 1 focused on providing examples that use the principles and recommendations discussed earlier in the chapter to illustrate how a farm could visually assess and evaluate their equipment and tools, conditions and practices based on the requirements. In some of these

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 97

examples the evaluations led to changes in equipment or tools, practices or procedures, and in others the evaluations do not lead to a change in equipment or tools, practices or procedures on the farm.

These examples help illustrate our current thinking related to the evaluation of food-packing materials, including harvest containers, and equipment and tools that use wood, foam and carpet. And there are other topics.

We hope you find the examples in section 1 helpful and look forward to your comments.

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

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 should evaluate equipment and tools by identifying food contact surfaces and nonfood contact surfaces of equipment and tools, and determining the cleaning practices and, as necessary and appropriate, sanitizing practices for each type of equipment and tool, and the frequency at which you will perform these practices.

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

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

Next, there is a subsection that expands on the frequency of cleaning and, when necessary and

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 98

appropriate, sanitizing. This section also provides more recommendations, examples and factors to consider.

This is another topic where we seek specific comments, information and data as noted in the *Federal Register* Notice of Availability with a question: What information or data can you provide about cleaning, sanitizing and maintenance practices and procedures for equipment and tools that have wood, foam or other porous or absorbent materials? We look forward to your comments on this question. For your reference, the *Federal Register* Notice of Availability with this and other questions noted this afternoon is available in your packet of materials.

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

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

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

In the section on preventing contamination,

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 99

including floors, walls and ceilings, the draft guidance also recommends evaluating your buildings and their components, including visual assessments.

Let's move on to the recommendations on pest control. This section of the draft guidance provides several recommendations and some are highlighted on this slide. The draft guidance recommends that the owner, operator or agent in charge of a covered farm should minimize pest attractants in 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 develop pest-monitoring activities and the draft guidance lists several factors to consider when establishing a 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, and we will discuss some of the content for handwashing facilities in more detail.

Here we have an overview of some of the recommendations related to handwashing facilities. The draft guidance recommends that the owner, operator or agent in charge of a covered farm should consider personnel and visitor activities in growing, harvesting, packing and holding areas to help determine the number and locations of handwashing facilities to accommodate typical numbers of people accessing these facilities. The draft guidance discusses recommendations for accessibility of use, such as near entrances to packing or other work areas, as well as access for servicing, maintenance or disposal activities.

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 100

The location of handwashing facilities and associated waste disposal is also important to prevent contamination. The owner, operator or agent in charge of a covered farm should establish monitoring, servicing and cleaning and sanitizing procedures and schedules for handwashing facilities. These activities should be performed at a frequency that ensures that they remain sanitary. The draft guidance expands on recommendations for solid and liquid waste disposal systems including considerations for portable handwashing facilities. Your personnel responsible for maintaining handwashing facilities should understand your procedures, and your supervisors or responsible parties should be directed to ensure that these activities are conducted and make corrections as needed. As a reminder, handwashing facilities must be furnished with soap, running water and adequate drying devices. You may not use antiseptic hand rubs as a substitute for soap. The draft guidance discusses that hand sanitizers could be used as an additional measure after handwashing with soap.

This concludes our overview of chapters 6 and 7. We are glad to have the opportunity to discuss these with you today. We look forward to your comments on these chapters of the draft guidance including our request for specific comments, information and data on the questions mentioned earlier in the *Federal Register* Notice of Availability. Thank you.

MS. BARRETT: I'm going to ask our additional FDA subject matter experts if you could come up. We have another opportunity for some questions, and we'll have the entire group of subject matter experts here. We just went through a lot of content, some key issues, and we welcome anybody who has a question. Again, the process being we've actually changed out our microphones, so we have sort of a podium there that will be comfortable when you ask a question, and just give your name and affiliation, and if you want to direct it to a specific person, you can feel free to do that. Any questions?

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 101

MS. STANGER: Hello. Toni Stanger, Indigenous Food and Agriculture Initiative, University of Arkansas. And I just have a comment that I'd like to add, and that is for chapter 6 and 7 -- or actually, no, 4 and 5 on animals, and that is that we would really appreciate if the FDA would include guidance or language or a footnote letting people know that in certain circumstances or instances when they are engaging in agricultural practices located within Indian community or traditional aboriginal territory, or an area that is governed by a tribal jurisdiction and entity that they include the fact that there are certain animals that have spiritual significance, and in order to move them, they might need to access a culture keeper or contact the tribe, and usually a tribe you'll find online. Almost every tribe in the country has a website, and they'll have a contact person, maybe its range, maybe it's an agricultural office person. Even if you just call and talk to the secretary. But in some areas, if you are a non-Indian and you are leasing the land, there are tribal laws that prohibit you from eradicating the animal or moving the animal, and that could cause significant delay in your own crop practices. For instance, there was an issue in Arizona where an individual killed an animal and it caused a week delay and harvesting because a spiritual practice, a ceremony, had to be conducted before they could start harvesting again.

MS. BARRETT: Thank you. Thank you for raising awareness around that. Other questions or comments?

MR. ASSAR: If I can, while I think Stuart is making his way, which might take a little while.

MS. BARRETT: Okay, sure.

MR. ASSAR: I just wanted to comment on the last comment that was made, and I greatly appreciate that. We weren't aware of that issue, at least I wasn't aware of that issue, so I appreciate being informed of it. And obviously we don't require the removing of animals at all, and we do make special note

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 102

of that in the rule as well as in the guidance that we don't -- we're not authorizing the removing or taking of animals. And the primary reason for taking that approach in the rule is because of the environmental impacts, the environmental concerns that we've heard with respect to certain practices that have resulted from, you know, efforts that have been focused on food safety but have had collateral effects, if you will. So, we're sensitive to that and we want to avoid that. I mean, we're focused on food safety, but we also need to account for the impacts that the food safety requirements and the guidance could eventuate into, so we appreciate that and we'll certainly take that into consideration. Appreciate it.

MS. BARRETT: Thank you, Samir. Question or comment?

MR. REITZ: Stuart Reitz with Oregon State University, and I have one sort of specific question and then just a general comment or suggestion, if I could. So, the specific one, and it gets to my earlier point about the shoulds and musts, and this might get to Michelle's presentation on subpart I with the wildlife. And in section 1 it says that you should determine the reasonable probability of contamination occurring. And then I think on the following page in the guidance it says if you do that and determine that there is a reasonable probability of contamination, then you must assess areas for that contamination. So, again, as an educator I'm kind of struggling to resolve, first it's suggested that you look for contamination but it's not required, and so the only requirement comes after that. Am I missing something in there, or how do we help growers understand, again, what it is they need to do?

MS. SMITH: First, thank you for your comment. I have not yet memorized our guidance, but I will go back and look at that language. Sometimes we have a series of steps where one step is required depending on the outcome of the previous step. So, we may have recommendations that you follow that are different ways

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 103

to do things, and if you're following one of those recommendations and you see something that triggers a requirement, it might be that that's why the should came first followed by the must. But having said that, I really do appreciate the confusion that the must versus the shoulds may be having, and anywhere that you think it could be handled better or differently, please let us know, because we want people to be able to understand what the requirements are, what our expectations are, and what best practices are, and to not get them muddled, because then it's not as effective.

MR. REITZ: Okay.

SPEAKER: So, thank you.

MR. REITZ: Alright. Thank you. And I do want to thank the FDA for all of the work in the guidance. I really appreciate the examples that you have in there. That really helps to clarify a number of things. But just sort of my general comment, when you do get to a final version of the guidance, I would love to see it as a user-friendly document. So, 150-page plain text PDF is -- it's really cumbersome to use, and if there was any way you could hyperlink parts of the guidance back to the actual rule sections, just to make it, again, something that people can easily navigate through, that would be, to me, a tremendous asset.

MR. ASSAR: We definitely appreciate that and it is a challenge to provide the level of detail that we did provide with the guidance and at the same time have it be in a format that can be easily kind of referenced and read and so forth. So, the factsheets that we've put out there will certainly help in that regard. However, your idea of hyperlinking to actual, you know, sections of the rule, or just kind of sections across the guidance I think is certainly a good one that we can consider moving forward. Do you have any thoughts about factsheets?

MS. KILLINGER: Yeah, I think it's been helpful to hear today that the at-a-glance overviews

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 104

are helpful to provide those key summaries, and I think that is an area where we could consider doing some sort of hyperlinking. And I appreciate your suggestion that we also try to match up, if you will, or kind of crosslink within the guidance. We'd really like to hear that in an official comment to the docket so that we can take that into consideration, because I think, I agree, it would be helpful to have that kind of information to kind of navigate across the topics within the guidance. And certainly we do have an incredible diversity of farms that we're trying to take into consideration, and there's a lot of information that we're trying to provide in the guidance, and any suggestions that you have on how to make it easier to navigate the guidance would be appreciated. Thank you.

MR. ASSAR: And ideally we want more examples, and so that would build a bigger document.

MR. REITZ: Yeah.

MR. ASSAR: Again, there's a need to make sure that the document is reader- and user-friendly as well, so we do need to come up with some way of making it more reader- and user-friendly moving forward.

MR. REITZ: Thank you.

MS. BARRETT: Thank you. Other questions?

MS. CARNES: This is just for clarity. I know Michelle and --

MS. BARRETT: Actually, again, if you could say your name --

MS. CARNES: Oh, sorry. Candy Carnes with Oregon Berry Packing.

MS. BARRETT: Okay.

MS. CARNES: And there were a couple areas where Amber and Michelle, you both pointed out specifically that the FDA is looking for comments on. Is there a place that lists those, or do you have to search through the --

MS. SMITH: Okay, in your package is a copy of the *Federal Register* Notice of Availability for the draft guidance. It's in this package, and there's a section in there requesting comments. We are looking

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 105

for comments on anything in the guidance that you have a comment on. If you like it, tell us, because if everyone likes it and they're silent and one person says it's awful, that may be all we hear. But there are some things even going into this that we knew we had additional questions, and so we called them out in particular. There are a couple different three-column *Federal Register* notice pages in your package. One of them is the Notice of Availability or the guidance.

MS. NAIR: And if you go to the background section of that *Federal Register* notice, that's where you can find those specific questions.

MS. CARNES: There are the two in there.

MS. SMITH: Okay. What you're looking for is the page that is dated Monday, October 22, 2018. It says Proposed Rule, and the page number, you flip that over to the second page, that's page number 53197, the first of the three columns, Supplementary Information Background. That's where we announce the availability of the guidance and talk about what it covers, and that it's based on our current thinking. We seek specific comments, information and data on the following; in that second column, we list those out.

MS. CARNES: Okay, thank you.

MS. BARRETT: Thank you for pointing that out and for walking folks through that.

MS. SMITH: Because if you couldn't find it, then a couple of other people probably couldn't either.

MS. BARRETT: And it is good to see it all in one place. Other questions?

MR. GERLACH: I'll give it another shot one more time. Bill Gerlach, World Variety Produce. I assume that FDA is talking to the sustainability people, because I recently was at a conference with the vineyard people and one of their metrics for sustainability is providing nesting sites and habitat for wild animals, and it seems to me there's sort of a dichotomy here, kind of a contradiction, because there would be encroachment. So, can you elaborate on that a little bit?

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 106

MR. ASSAR: Yeah, and we are in close contact and we have a great connection with the National Sustainable Agricultural Coalition. I would say we meet with them on a fairly regular basis. And so, yeah, obviously there's a recognized need to line the sustainable practices with food safety practices, and there's certainly opportunity to do that. And so I would say our work in that regard scopes, you know, among other stakeholders that have a vested interest in sustainability, including some of our partner agencies, USDA and the Natural Resources Conservation Service. They have an interest in fostering practices that are environmentally friendly as well. So, we want to stay in tune with them and in line with them as we move forward with our food safety policy development.

MS. BARRETT: Thank you. Other questions? Okay. We do have -- we are going to move on now to our public comment session. We have two organizations who had registered to give public comment this afternoon: California Citrus Mutual and United Fresh Produce Association. Do we have a California Citrus Mutual individual here?

SPEAKER: [Microphone inaccessible.]

MS. BARRETT: You're going to hold your comment? Okay. Alright, yep. Well, then, I will go with United Fresh Produce Association. And, again, if you'll state your name and affiliation once more.

DR. GRIEP: Good afternoon. I'm Dr. Emily Griep, manager of food safety for United Fresh Produce Association, and I first want to thank you again for holding the public meetings on the draft guidance in support of the Produce Safety Rule. United Fresh is the National Trade Association for the fresh produce supply chain representing over 1,200 members, including growers, shippers, fresh cut processors, wholesalers, distributors, retailers, food service operators, industry suppliers, and allied associations. We've offered many comments during the rule development process and appreciate that FDA continues to engage with industry regarding challenges and implementing the

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

rule.

First, again, congratulations on getting the draft guidance published. We recognize that it is no easy task. We appreciate the plain English tone of the guidance but feel that it's length may deter some growers from actually reading it. We find that there is a fair amount of redundancy in the draft guidance, particularly around training requirements.

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

The situation most concerning to our members is what's referred to as bush tomatoes, which are more common on the West Coast and are not staked, as tomatoes often are, on the East Coast. United Fresh considers and recently stated in our updated guidelines for the tomato industry that this type of production practice does not constitute dropped produce, since the tomatoes ordinarily and expectedly grow in a way that they may touch the ground. However, since the FDA preamble and draft guidance use tomatoes as an example of something that would be dropped produce, it has caused confusion that we hope FDA will address.

United Fresh advocated for a rule that offers growers flexibility in meeting regulatory requirements, but we fear that some of the examples FDA has selected suggests that some practices could be appropriate when in fact research funded by the Center for Produce Safety and others demonstrates risk. For example, example 7m discusses the use of foam pads and states that they could be permissible if cleanable. Foam pads are extremely difficult to clean and we discourage our

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 108

members from using them -- using foam due to *Listeria* concerns. We suggest FDA reconsider using this type of example, which is subject to misinterpretation and could trigger food safety concerns.

United Fresh will submit more detailed comments to the docket and is happy to provide additional information at any time. Thank you again for the opportunity to offer comment on this important draft guidance.

MS. BARRETT: Thank you very much for your comments. We do have time; is there anyone else who would like to make a statement? Alright. Well, then, we are going to end a bit early today and we'll have Samir Assar give us some closing comments. Thank you.

MR. ASSAR: Yes, thank you again for being here and for being on the webcast. We greatly appreciate your time. We hope you found it worth your time and you've learned a lot about the Produce Safety Rule guidance, the compliance implementation guidance. And, really, I just wanted to kind of recap today's discussion and kind of emphasize some of the things that were brought to us in this meeting.

And just really kind of to recap, we started out with opening remarks, and Director Taylor talked about how education, including OFRR work, is incredibly important and really bringing or fostering compliance with the Produce Safety Rule, and we appreciate the efforts that they -- that Oregon has done in that regard.

Jim talked about kind of the four-step continuum of awareness, promoting understanding, implementing and verifying implementation as being a kind of, again, a continuum process for fostering compliance with the Produce Safety Rule.

We heard several comments and questions, actually a lot of comments from the panel. A lot of interesting things were said during the panel discussion. There was certainly a sharing of roles and responsibilities with respect to produce safety, and we appreciate the panelists doing that. We had heard from

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 109

all of them about how they serve as connectors to resources that are available to growers, the community that they serve, and those resources include certainly education materials, including PSA curriculum materials, but also guidance. And this guidance will be useful, it sounds like to the community that they work with to foster compliance with the Produce Safety Rule.

We had heard from Sue about -- Sue Davis during the panel discussion about how it is important to her community that we consider to take maybe a commodity or at least account for in future guidance development efforts, consider developing commodity-specific guidances that are tailored to needs out there that are, again, specific to commodities that are grown not only in the Pacific Northwest, but elsewhere. That is certainly something that we will consider doing, and Jim had mentioned that we -- this is part of our process. We certainly welcome the opportunity for -- to be involved in industry and stakeholder developed, led developed guidance work. We'd be more than happy to provide technical assistance to those efforts. We have in the past played that role as providing technical assistance and then in a few cases we've actually adopted those guidance. So, that is certainly an opportunity for us to move forward with to address the various produce safety needs that are out there.

And then Ines talked about how her research priorities have shifted over time based on produce safety needs, and at first there was a lot of work done on water and then certain outbreaks occurred with respect to packing facilities, and there was a need to kind of shift and really look at packing facilities. And, really, again, this research is incredibly important as we move forward with guidance development. The research that's being done, the studies, the science that is done really serve as building blocks for the policymaking that we do. So, it's very important for that work to continue, and obviously we will continue to keep our eyes open as those findings

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 110

come about and make sure that that information is built into our latest thinking.

She also said -- made a very resounding statement about -- that growers need to do more than -- to do more than just say what they do but actually do what they say, and I thought that was very important. And I think we're all kind of guilty of that a little bit, but I think it's very important to really put your words into action, and obviously in doing that, that would make a big public health difference.

There are also questions about the farm definition and how we're moving forward with addressing the farm definition. And we definitely recognize the complexities, the confusion about the farm definition and who -- again, who would be responsible for complying with the preventive controls regulation versus the Produce Safety Rule. And, again, this is something that we're working on addressing and hopefully we'll be able to provide some more information on that shortly. Definitely recognize that it's a question that's out there that is really putting the industry and certain industry segments in an uncomfortable position, not knowing what they're subject to. And so we want to provide that clarification as much as possible moving forward.

Also, questions about hops and other kind of commodities that are in that same related territory of where there is a commercial treatment or there may be a commercial treatment applied, how does that fit with FDA's regulatory approach moving forward? It's a very important issue. The commissioner has made a statement with respect to certain similarly situated commodities, and we're working on it. We're working to address those issues and hopefully, again, we'll be able to provide some more thinking about that to resolve the issue. And, certainly, whatever we come up with in terms of a decision on our approach, we would, again, need to put out guidance to kind of reflect or kind of convey how that approach would fit into complying and implementing the Produce Safety Rule.

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 111

There were questions about that there would be a need to do -- I'm sorry -- that there is a need to actually do lead trainer certifications, or translated lead training to the community, and that's, again, something that is on our radar. Definitely understand the need to translate material, curriculum material, PSA curriculum material, and other material to basically build the ability for, you know, non-English-speaking community to understand what the requirements are in the rule and really get some good quality training around the Produce Safety Rule.

And there were questions about the musts and the shoulds, really, a comment about there needs to be more clarification with respect to what is a must, what is required by the Produce Safety Rule, and what are the recommendations that are listed as shoulds in the guidance? Really provide -- we were asked to provide more clarification on that. And also, going along with that comment, I think Stuart also commented on that, that it is appreciated it that there are examples within the guidance, and at the same time the examples do basically make for a lengthier document, and there is a need to basically provide a more, kind of user-friendly format so that growers can easily refer to the guidance, look at what is applicable to their situation and really understand, again, what our current thinking is on that. And that's something we will consider. As I've mentioned, we've developed an at-a-glance set of documents, but we're open to other ideas in terms of how to simplify and really, again, allow for the guidance to be more user-reader friendly.

And, finally, the comments that we just heard with respect to questions and confusion maybe around the dropped produce issue, and certainly we want to hear your comments regarding that. We did use tomato as an example. We understand that there is a need for some clarity, and we'd be happy to provide that clarity, and please provide us with your thinking about how those commodities should kind of fit within the regulatory regime or with the regulatory approach that

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 112

we provided in the rule.

And so otherwise, again, I think that pretty much wraps up what we've heard today. Those are a lot of the high points. I guess I'll open it up to the panel, if there is anything else that you'd like to share in terms of comments or feedback? Okay.

Again, we really do appreciate you coming out here and providing us your thinking. It's going to make a big difference in the way that we are thinking moving forward with the Produce Safety Rule compliance and implementation guidance, and I guess I'll hand it off to you. I'm sorry, Michelle, do you have something?

MS. SMITH: Okay, just two things real fast. What we do can only be as good as the information that we have to work with, so we're counting on you. I heard a lot of people ask questions and give comments and say that they appreciated how hard FDA staff had worked, and being on the inside, I can see how hard we work. A lot of times that's invisible to the outside and they think we're not doing anything. But what I really want to do is throughout all these presentations today we cited the number of things that we took into consideration in developing the guidance, some of it being information that we got during the rulemaking process itself that was better handled in guidance, comments from stakeholders, folks that let us on their farms and in friendly farm visits so that we would see the diversity of operations. Once again, we're looking for your comments to help make this guidance as good as it can be. If there's some scenario where it may be true in one situation but not true in another situation, let us be aware of that so that we can kind of parse things out into different categories, if that's appropriate. So, please let us know.

When folks talk about commodity-specific practices, I think commodity-specific guidance, this would end up being 3,000 pages long. But having said that, there may be ways that are appropriate in examples to highlight some of the commodity

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 113

differences, and not just commodities but regional differences and differences between different kinds of practices. So, I thank everybody in advance for helping us do our jobs.

MS. NAIR: And I'd like to expand on some of those concepts and some things that you all have said today, and we've heard that there were several positive responses related to the summaries that were provided in the sections, in the chapters, and that's really helpful to hear. But I also heard in several comments that you'd like to see more of those summaries provided, and we are certainly trying to balance, as Samir said, having a long document with also having a helpful document. So, we'd love to hear specifics on what topics you'd really like to see more specifics or more summaries and more examples. So, we'd just encourage you to please be specific in your comments on the areas where you'd like to see expansion and we will absolutely consider how to make the document a little bit more user-friendly so we can accommodate those areas that you'd like us to expand on, yet try to make the document as easy to use as possible. So, the more specific you can be in your comments the more helpful it will be to us, and we look forward to receiving your comments. Thank you for being here today.

MS. SMITH: And you might even consider, if you think there are ways that can be streamlined to let us know, keeping in mind that not all of our stakeholder communities have access to the technology or have interest in hyperlinks. But to the extent that something can be presented more simply or with less redundancy, feel free to point that out.

MS. BARRETT: Well, it does sounds like there's lots of opportunity for providing input and, again, appreciate your time today. I just want to remind folks, if you didn't get that parking discount to please grab one at the registration. I want to thank you for your time. I know you took a day out to be here. I hope it was helpful, and we look forward to working with you as we get to finalizing this document.

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18

Page 114

Thank you. Have a great evening.

(Whereupon, the public meeting was concluded.)

**Standards for the Growing, Harvesting, Packing and Holding of Produce for
Human Consumption: Draft Guidance for Industry 11/27/18**

Page 115

CERTIFICATE OF TRANSCRIBER

I, SANDRA TELLER, do hereby certify that this transcript was prepared from audio to the best of my ability.

I am neither counsel for, related to, nor employed by any of the parties to this action, nor financially or otherwise interested in the outcome of this action.

December 5, 2018

DATE

SANDRA TELLER

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption: Draft Guidance for Industry 11/27/18