UNITED STATES FOOD AND DRUG ADMINISTRATION

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water Requirements Proposed Rule

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P R O C E E D I N G S

MR. KAWCZYNSKI: Welcome to the Agricultural Water Proposed Rule Public Meeting. This is a live broadcast so there will be some breaks as well throughout the day so you can get up and stretch as well with the rest of our presenters.

Periodically, there may be some technical glitches. We always prepare for those. If that does happen, just please bear with us. This meeting, as our previous one, also will be recorded.

Good morning and welcome to the Agricultural Water Proposed Rule Public Meeting. I thank you for joining us today. This is a live virtual event. So if at any time we run into technical glitches, we'll jump in and get that fixed so you're not to miss any of the content throughout the day. We do have a great set of speakers. And with that, I'd like to hand if off to my colleague and host, Cathy McDermott. Cathy, are you all set?

GREETINGS AND LOGISTICS

MS. MCDERMOTT: Thanks, Mike. Good morning, everyone. Welcome to today's FDA's public meeting on the standards for the growing, harvesting, packing, and holding of produce for human consumption agricultural water requirements proposed

rule. As Michael mentioned, my name is Cathy McDermott and I'll be moderating today's public meeting and thank you all for joining us today. The purpose of this public meeting is to discuss the proposed rule on agricultural water which was issued by the FDA Food Safety Modernization Act. These meetings are intended to support the public's evaluation and commenting process on the proposed rule. We hope that you'll find the public meeting useful and that the discussions and presentations facilitate the commenting process. A few quick notes first, though.

The public meeting agenda, speaker biographies and a document entitled "How to Comment," are posted on the FDA website on the "Meetings" page.

This meeting is being transcribed and recorded and will be posted to the public meeting page on FDA's website. The slides will also be posted. The transcript typically takes a little longer and may take a few weeks for us to post. Any questions on the proposed rule can be sent to our mailbox which is agwater@fda.hhs.gov.

It is now my pleasure to begin our meeting by introducing Frank Yiannas, FDA's Deputy Commissioner for the Office of Food Policy and Response, who will provide the welcome for our meeting.

WELCOME

MR. YIANNAS: … working to advance food safety. I believe today's conversation is critical. It's more than critical. It's historic. And I believe it's sorely needed at this moment in history to further protect consumers. Now, before we begin, I know these are challenging times and busy times for everyone and I can't tell you how much I appreciate you taking time to be with us today and for your steadfast commitment to working with FDA to help ensure the safety of agriculture water.

The work reflects our common, or better stated, our shared commitment to strengthening food safety protections for generations to come, not just for us, but for our children and generations yet to come. In fact, I believe so strongly about this that I said this proposed rule, if finalized, will be a gamechanger. That's right, a gamechanger when it comes to the safety of fresh produce. I'll talk more about that in just a minute.

The proposed rule we'll be discussing today will require farms to conduct comprehensive assessments that would help them identify and mitigate hazards in their preharvest water use to grow produce. If finalized, it would replace some of the existing quality and testing requirements of preharvest ag water for produce other than spouts under the Produce Safety Rule.

Now, right at the outset, let me tackle a question that I often receive. That question is this: Frank, why has this taken so long? Listen, I hear your concern and I know it's taken us a long time to reach this point, but I can assure you that it was time that was needed and time well spent. We have worked closely with farmers and other stakeholders to ensure the standards we proposed are the tones that are workable and will improve produce safety. We want to get this right and we have to get this right.

So after many farm visits, listening sessions, and collaborative meetings, we've done what we said we would do. We've offered a path forward that we believe is both practical and feasible for growers and protected -- that's right, protect the public health.

As you will hear, this isn't a one-size-fits-all approach. We have considered a wide variety of water sources, a wide variety of farming operations that exist in the real world, and we've also incorporated lessons learned in outbreak investigations and the latest science. And let me

just say that it's been clear since we started these conversations that no matter whether you're in a government office or I like to say standing in freshly leafy greens, our goal is the same: keep produce safe for the benefits of consumers everywhere.

Today, you're going to be hearing a lot more about this proposed rule from colleagues at FDA as well as from other experts in the public and private sector. You'll be hearing a lot of the what. What's in this proposed rule? What do people like about it? What are the opportunities that exist for improvement and so on. That's the what.

But before I leave you to get onto this important conversation, I'd like to pause and share my thoughts on why, why this proposal is so important. Let's start by looking at the big picture. Water is life. And all of human existence depends on clean and safe water. The idea of safe water dates back to antiquity. Now, in the 21st century, I think everyone knows just how important it is for people in all countries to have access to safe drinking water, but the Produce Safety Rule embodies a recognition that

it's also important that water use in agricultural food production be safe too. Think about it. All of food production relies on water, whether it's seeping water in agriculture, whether it's livestock production or whether it's produce.

When it comes to fresh produce, I don't have to spend a lot of time persuading you that this is critically important because many fruits and vegetables, if contaminated, will not receive a final kill step to eliminate pathogens before they're consumed fresh.

Now listen, we know how important fresh fruit and vegetables are to an overall healthy diet. And for that reason, we -- and I personally want Americans to eat more fresh produce, not less. And we recognize that when you pause to think about just how much fresh produce is consumed daily by Americans, literally millions of servings, the vast majority of those fruits and vegetables are served safely. That said, we also know that when foodborne outbreaks do occur, they are too often, much too often, linked to fresh produce. In fact, according to attribution

studies conducted by the Centers for Disease Control and Prevention, in any given year, roughly 50 percent of all foodborne illnesses are associated with produce. And while produce can be contaminated several different ways, agricultural water can serve as a conduit for the pathogens that have caused produce-related, foodborne outbreaks.

That's why we have produced this rule and why, just why this rule is so important. It's to prevent produce-related illness, increase consumer confidence in fresh produce and to help then to curb a foodborne illness once and for all in this country.

Let me give you a second reason why this rule is so important. We all know this proposed rule is a critical step in our continued implementation of FSMA. It's a critical step as FDA builds on FSMA for continued modernization under the new era of smarter food safety.

As you know, these standards we're revising are part of the Produce Safety Rule. Many have asked just why, why do you want to replace these requirements? Well, it's because we listened to and

learned from concerns expressed by numerous stakeholders, especially farmers, that certain provisions were difficult to understand, translate, and implement in their operations. In particular, the preharvest microbial quality criteria and testing requirements. Why? Because we listened to and learned from consistent feedback that these requirements do not sufficiently account for the wide variety of water sources and methods of applications on farms across the country.

So, we put those requirements on hold until we figured out a different way to go about this and one that works for farmers while still protecting consumers from foodborne illness.

FDA experts participated literally in hundreds of visits and meetings with stakeholders to better understand the implementation challenges that farms faced.

We worked to identify solutions that would be practical and workable across the wide variety of operations while still achieving our public health goals and objectives. We participated in listening

sessions with farmers to learn about their water use practices, how they currently manage water quality, and their perspectives on how to best effectively manage preharvest ag water quality.

In fact, the very idea of an agricultural water assessment was identified during these stakeholders' sessions that included discussions amongst subject matter experts, researchers, educators, industry, and regulators.

We believe this system-based approach is flexible enough to accommodate a variety of water system uses and practices, as well as advancements in agricultural water quality science. We can help farms manage their agricultural water more effectively and help identify potential sources of contamination on adjacent and nearby land that might otherwise go unnoticed and/or unaddressed.

So how are we going to get all of this done if the rule if finalized? How will farmers know how to meet these requirements? The FDA intends to work closely with all stakeholders and I mean all stakeholders, including our state partners to

implement these changes when finalized. We'll work with state regulators, the National Association of State Department of Agricultural, educators, and others, including the Produce Safety Alliance to provide the necessary skills and knowledge through education and training. And consistent with our new era of smarter food safety approach, we are working to develop a smart, user-friendly online tool to help growers evaluate potential risks posed by their water sources and determine potential management options.

We also plan to ensure that foreign producers are also made aware of the ag water requirements and that produce imported from abroad is held to the same food safety standards of those produced domestically.

If finalized, we're confident this proposal will result in fewer outbreaks in the US relating to produce and will further protect public health. Importantly, this proposal demonstrates what we said when we drafted the foundational rules to implement FSMA in the first place. We said then, and we say again now, that food safety is not something that the

FDA can achieve alone, that we need everyone at the table: regulators, industry, consumers, and others, to create the most effective standards. And working together, we must ensure that the best standards are consistently put into practice.

I know there's a lot the government can do and is doing to keep food safe. There's a lot the industry can do and is doing as well. But clearly, there is some much more that we can do together. Thank you for listening.

MS. MCDERMOTT: Thank you for those remarks, Deputy Commissioner Yiannas.

As you may know, the FDA works very closely with the US Department of Agriculture on produce safety. It is now my privilege to introduce Mr. Bruce Summers, administrator of USDA's Agricultural Marketing Service to provide opening remarks. Mr. Summers.

OPENING REMARKS

MR. SUMMERS: Thank you, Cathy. And hello to everyone that's privileged to be here today. The USDA's Agricultural Marketing Service and the Food and

Drug Administration have collaborated over the last ten years on many issues related to the successful implementation of the Food Safety Modernization Act. So it's a real honor for me to help kick off this really important public meeting on the proposed rule for agricultural water standards.

From the outset of this meeting, I want to acknowledge the time and hard work of everyone who hosted and participated in farm visits, who conducted listening sessions and who participated in many, many meetings. All of that work that's culminated in this proposed rule being published in December and has brought us to this meeting today.

I want to thank the FDA for responding to the collective feedback in preparation for the publication of this proposed rule and remind all of you participating today that we need to hear from you again, some more, to ensure a final regulation that will be practical for especially the crop industry and a rule that will advance the food safety for consumers of healthy fruits and vegetables.

In the development of this rule, my

colleagues with the FDA have worked to achieve a delicate balance ensuring public safety through the prevention of foodborne illness while also responding to the growing community's concerns about the feasibility of complying with the proposed order requirements and the complexity surrounding preharvest water use among other unique water usages.

The USDA has worked as our partners conducting food safety outreach to help the produce industry prepare for compliance with the Food Safety Modernization Act.

The 2021 agricultural water proposed rules, consistent with the approach the Agricultural Marketing Service used when we designed our good agricultural practices audit program, which places an emphasis on risk in water usage, the growers who currently utilize the USDA GAP audit programs should this proposed rule becomes final, will be well positioned to comply based on your familiarity with AMS's risk-based approach.

I think it's important also to say and something that's said consistently since FSMA was

passed that, you know, consistent with our approach since the Food Safety Modernization was enacted, AMS will also continue to align our audit program requirements to FDA's regulations.

One of the way AMS helps the produce industry prepare for compliance is through its partnership with FDA and Cornell University by way of the Produce Safety Alliance. These partnership enables us to get funds for educational and training events. Through the Produce Safety Alliance, the AMS enjoys engaging with producers, produce growers, industry members, and extension educators who work in committees, public meetings, focus groups, and webinars. And in preparation for this rule, the water rule, the Produce Safety Alliance began hosting a series of meetings of January and has continued those meetings in February to give organizations working with produce growers a platform to discuss this proposed water rule and the impact it may have on produce growers. With support from USDA and FDA, Produce Safety Alliance will continue to work with growers and educators, provide training on

agricultural water requirements as we move from this proposed rule to a final rule.

And we thank the members of the Produce Safety Alliance for its partnership and its commitment to assist the produce industry in understanding and implementing the regulations.

The USDA's commitment to helping producers achieve success and FSMA compliance extends beyond the work at AMS, really across the entire department. For example, the National Institute of Food and Agricultural and expanding its food safety outreach program. This initiative provides funds for delivery and custom training on FSMA regulations for small to midsize farms, beginning farmers, socially disadvantaged farmers, small processors, and small fresh fruit and produce wholesalers.

Within AMS, we continue to implement the specialty crop block grant program. These grants are allocated to states and territories to enhance the competitiveness of specialty crops grown in the United States. Since 2006 when this program began, USDA has funded nearly 11,000 projects that increased the long-

term success of producers and created new and better markets for specialty crops in the US and abroad.

In recent years, these grants have been used for a multitude of produce safety initiatives such as providing funding for water testing and water research, education on risk management, and produce safety training.

Just this year, the end of January, last month, we announced the availability of 72 million dollars to be awarded for specialty crop block grants this year. AMS will continue to work with our partners throughout the USDA, the FDA, academic institutions and the industry to ensure specialty crop producers are provided the knowledge, the tools, and the resources needed to comply with the agricultural water requirements.

As I said at the beginning, I really appreciate this opportunity to talk to you for just a few minutes today. I want to thank you for the opportunity to provide these opening remarks and thanks to the FDA for doing this very important work and being committed partners to the USDA and the

produce industry at large and for demonstrating the importance of fresh produce.

At AMS, we share the deep commitment with FDA in strengthening the nation's food system and improving food safety, which is why we encourage all stakeholders to submit comments to the proposed rule. Your feedback on this proposed rule is critical to ensuring the outcome is reflective of the unique and diverse spectrum of American agriculture. With that, Cathy, thank you for allowing me to address the group. I hope you all have a great meeting today.

MS. MCDERMOTT: Thank you for those remarks, Mr. Summers. We truly appreciate you being with us today. I now would like to introduce our first speakers on the proposed rule: Samir Assar, Director of the Division of Produce Safety at our Center for Food Safety and Applied Nutrition as well as Kruti Ravaliya, Consumer Safety Officer also with the Division of Produce Safety. They will be providing an overview of the Produce Safety Rule requirements along with stakeholders' feedback that was received. Samir and Kruti, I'll hand off to you know.

OVERVIEW OF THE 2015 PRODUCE SAFETY RULE REQUIREMENTS AND STAKEHOLDER FEEDBACK

DR. ASSAR: Hello, everyone. I'm here to provide an overview before we talk about the 2015 overview for the rule. Again, my name is Samir Assar. I am the Director for the Division of Produce Safety here at FDA. And as such, I lead the team that developed the agricultural water proposed requirements and will be continuing to work on agricultural water approach moving forward.

I'm really proud of them for all of their hard work and time over the years and the team and I know that we couldn't do it without so many of you that are out there that have helped us by informing our thinking along the way. We're really, really excited to be at this point and propose this system-based approach to ag water that is aimed at striking that important balance of achieving our public health goal and minimizing risk from the consumption of produce and at the same time, providing flexibility to account for the diverse farming community.

As you've already heard, this is the most

important and challenging section of the Produce Safety Rule and because of the universal use of water in farming and its role with contributing to outbreaks. It's important for you to know that we are committed to getting our regulatory approach on agricultural water right and as you've heard from Deputy Commissioner Yiannas, we took great lengths in developing this proposed rule through fostering an ag water summit and conducting several farm visits across the diverse agroecological conditions and areas to do our very best and ensure that we are on target with this proposal for ag water.

Even though we are so happy to be at this point of the rulemaking process, after so much heavy engagement during this journey, we know that there is much work that needs to be done. And we look forward to your continued engagement as we move forward with rulemaking and any other supporting efforts such as education training that would be so vital in our approach to fostering compliance and implementation with this proposed systems-based and flexible framework. You play a vital role in this rulemaking

process. So please take advantage of this and many other opportunities to make sure that we get it right together by providing your comments.

Towards this end, I want to put out that although we will consider any comments to the open docket, we find comments that are framed in a certain way that are particularly helpful with our decision making and you may hear this all throughout today's public meeting because it's important.

When you provide your comments, we want you to share your thoughts about specific parts of the rule that you feel are effective and do not want to see changed before final implementation. Please don't assume that just because it's in there, that it will stay in there. So let us know if you feel we got it right; we nailed it. And also give us explanation why. The rationale will be incredibly important.

We would also appreciate any data or real world examples of situations where FSMA requirements might be problematic or where the approach we are proposing is more appropriate. It's vital for us to base our decisions on robust science and specific

scenarios also allow us to understand how the rule requirement would play out in a farm setting.

If you don't like the language or you think something needs to be worded in a different way, please feel free to provide your comments and show us what you feel like the language should look like. And, again, what's important is that you provide your rationale why. I can't underscore that enough that your comments, we will consider any comments that you give us and certainly if you tell us that you like it or you don't, we will consider that, but what is really important to us for decision making is you providing your rationale with as much information as you can provide whether it be scientific information or, again, scenarios that describe how the proposed rule would play out in your farm setting.

With that, I'll hand it over to Kruti to provide the next part of the presentation and overview of the 2015 Produce Safety Rule. Thank you all.

MS. RAVALIYA: Thank you, Samir. I appreciate the opportunity to discuss the 2015 Produce Safety Rule ag water requirements. I'm going to be

discussing both those requirements from the 2015 Produce Safety Rule and then after this presentation, I'll go into presentation on the overview of the new FSMA/framework proposal.

So the requirements from the 2015 Produce Safety Rule for ag water were at a high level. They involved requirements around ensuring the water was safe and of adequate sanitary quality for its intended use. There was also a component around inspecting the water system that's under the farm's control. There were provisions regarding water treatment if a farm chooses to treat the water. There was a tiered approach to testing requirements, so depending on the source of water that was being used, there might have been -- there were different testing frequencies and criteria. And then, again, there were specific microbial water quality criteria for specific uses. There were also corrective measures that were outlined within the requirements if the water exceeded those criteria. And there were also requirements regarding records.

So for water that was used during the

growing activities of produce for commodities other than sprouts, as I mentioned, there was the testing frequency that was outlined depending on the water source that was being used, so whether it was a ground water source or a surface water source. There were requirements around microbial water quality profile. This profile was composed of data that was collected as part of an initial survey and then it also had data around the annual survey to update that microbial water quality profile annually and then recharacterize that profile under certain conditions.

This framework also enabled farms to understand their water source to better determine how to use that water appropriately.

Additionally, there were criteria that were identified for water that was used during growing activities and those criteria for preharvest agricultural water entailed both the geometric mean that kind of captured the average quality of water and a statistical threshold value that captured how water may vary, how water quality may vary.

And so the geometric mean was 126 or less

CFU of generic E. coli per 100 ml. And the STV was 410 generic E. coli per 100 ml. There were also corrective measures that were in the event of an exceedance. And so growers would have to take those corrective measures as soon as practicable, but no later than the following year.

Those corrective measures included options for accounting for microbial die off between the last irrigation and harvest or a die off or removal between harvest and end of storage. And that removal could also account for things like calculated log reduction associated with washings or other practices in post-harvest.

The corrective measures also included reinspecting the agricultural water system and making additional changes based on inspection results and treating the water if necessary.

So we did a lot of engagement around the requirement for the 2015 Produce Safety Rule. FDA conducted a webinar with over 500 -- 400 participants, excuse me, where the SMEs discussed all the significant provisions within the rule and answered

questions. The SMEs also held public meetings across the country were we engaged with growers across diverse geographic distributions, different commodities and other stakeholders as well.

We also attended farm tours in Alaska, Arizona, California, Colorado, among other states. And through these farm visits with other speaking engagements, FDA gained a better understanding as to how these requirements may or may not be challenging for growers to understand and implement, ultimately resulting in perhaps noncompliance if those requirements are too burdensome to be able to implement.

Within 2016 and 2017, we continued that engagement, as I mentioned, with those farm tours and additional other engagements, which I will get into on our next slide. So as I mentioned, many of the stakeholders provided feedback that the requirement for Subpart E were difficult to understand and implement in their operations and most of that feedback fit into three different categories. The first set was the requirements were inflexible and

took a one-size-fits-all approach. And so the way that the provisions were laid out in the 2015 requirements did not account for the diversity of water sources or how water is used in produce production.

And another category of the feedback was that the requirements were too complicated to understand and implement. So if they were too complicated to implement, then growers would have difficulty with complying. An example of the complicated provisions include the geometric mean and the statistical threshold value criteria for preharvest water.

And lastly, the last category of feedback included that the challenges around implementation were that some growers had many different water sources to capture information around to make management decisions and if the grower has so many different water sources and sampling, inspection, you know, a lot of those were too difficult to be able to comply with those water sources.

So in 2017, the FDA announced an intention

to consider ways to simplify those requirements. We engaged with a variety of stakeholders and as I mentioned before, we had two sort of larger engagements and the first was the meeting with the Pew Charitable Trust and the Robert Wood Johnson Foundation in the collaborative forum that we held with them. And then also the Produce Safety Rule Agricultural Water Summit. And those were on top of the educational farm visits that we did and the eliciting sessions that we held.

We also announced a compliance date extension in 2017 and finalized that in 2019 in order to accommodate additional time to conduct this reassessment.

So the collaborative forum for the Robert Wood Johnson Foundation and the Pew Charitable Trust involved a meeting with key stakeholders and during these conversations, we identified several alternatives to the finalized requirements for the 2015 Produce Safety Rule.

And so those alternatives were first, to perhaps retaining the preharvest testing requirement

and issuing a companion guidance. So that would mean maintaining the framework as it was published in 2015 and then issuing substantial guidance to help growers how best to comply.

Another option would be to replace the preharvest testing requirement for the qualitative standards and then issue a companion guidance associated with that.

A third option would be to adopt an industry standard for the short term while conducting a risk assessment to identify for preanalytes and/or numerical thresholds for microbial water quality.

And then lastly would be -- excuse me -- performing a risk assessment was the option and then identifying appropriate numerical requirements outside of a risk assessment would be the other option.

The last option would be conducting a risk assessment to better identify appropriate thresholds and organisms.

Additionally, stakeholders raised considering whether or not qualitative standards and data sharing would be useful for additional guidance

and considering whether or not we should further pursue those issues either through rulemaking or guidance.

At the Produce Safety Rule's Water Summit, FDA joined about 250 other stakeholders to discuss implementation challenges and those summit participants identified complex factors that are associated with agricultural water and challenges to implementation, so identifying that water quality source can be pretty variable depending on whether you've got a groundwater source or a surface water source. And then even within categories of water sources, the surface water variability can vary from region to region.

There is no one set number that can be assigned to water quality, surface water quality sources across the country. Then applying water to the crop, how that water is applied, whether it's applied overhead or whether it's applied through a furrow irrigation. And then identifying commodity characteristics that would influence whether or not the crop may be vulnerable to any type of

contamination.

And then lastly, of course, taking into account whether or not there are regional challenges that will need to be addressed when identifying how best to comply.

The summit participants also identified agricultural water assessments as an important characteristic of continuing to manage water quality and identify appropriate means of applying water to crops.

And so the conversation around that assessments ranged from how best to visually observe water or whether or not there are actions that can be taken to manage that water at certain times. It was a very robust discussion around assessing water quality.

Participants also recognized that regardless of how the water in Subpart E would be reassessed, if there's going to be the need for additional educational tools to assist in compliance.

At the same time, several produce-related outbreaks happened. And investigations based on those outbreaks identified that preharvest agricultural

water would be a contributing factor in the introduction and spread of contamination to produce.

Those issues were related to how water is involved in activities that are conducted on adjacent and nearby lands. And it also really just highlighted the decades of scientific research that we have on preharvest agricultural water as a contributing factor to the spread and source of contamination on produce.

And so taking into account all of the information that we had available during that time, we developed the framework that I'm going present on next. Mike, would you advance to the next presentation?

PROPOSED RULEMAKING REQUIREMENTS

MS. RAVALIYA: So keeping in mind everything that I just talked about in the previous presentation regarding the challenges that stakeholders felt with complying with the 2015 Subpart E for agricultural water, we really took a lot of that information to heart in order to develop this new framework. This new framework provides both flexibility while still being protective of public health we believe. And it

allows for sort of a customizable assessment based on the various characteristics and sort of features of a particular growing operation in a particular part of the country or in the world and really allowed for introduction and use of unique features that can still help us understand and capture the risks that are associated with the use of agricultural water.

So for this presentation, I'm going to go over the proposal at a high level. And then we're going to go into the more specifics around the agricultural water assessments, the outcomes that you can expect, and then based on potential outcomes, the corrective mitigation measures, and then lastly, go over the regulatory impact analysis.

Okay. So as I mentioned, this framework takes into account many of those stakeholder concerns. So, again, those concerns were the complexity with the practical implementation challenges for preharvest agricultural water testing requirements. So this framework replaces those preharvest microbial quality criteria and testing requirements with a system-based preharvest agricultural water assessment.

We've added a couple of definitions to this framework, namely the agricultural water assessment and an agricultural water system to provide better clarity on how we discussed the assessments and systems.

Agricultural water assessments at a high level would be conducted once annually and whenever a significant change occurs. Based on those assessments, the grower would make determinations on outcomes and based on those outcomes, a grower would be required to identify whether a corrective measure or a mitigation measure would need to be applied.

There's also a category of expedited mitigation measures that would be required if it's finalized as written, for hazards that are related to specific activities that are associated with adjacent nearby lands.

So components of the agricultural water assessment range from understanding the source of the water, how the water is used, crop characteristics, other environmental characteristics to consider and then also encompasses any essential testing that a

grower might do to identify how water may or may not present as a hazard to the operation.

Specifically, for the agricultural water system, it's important to identify the location and nature of the water source, so whether it's a surface water source of a groundwater source, the type of distribution system, whether it's being distributed through a closed plumbing line, an open canal, and the degree to which the system is protected. So is there -- are there opportunities to have burns on that surface water source? Are there -- is the plumbing intact and then considering as much as the grower can about what the water actually looks like before it's being applied to the crop. Then considering what the agricultural water practices are: how is the water being applied? Is there a time interval between the last direct application and harvest? Are there any other characteristics about how that water is applied that may influence whether or not there is additional risk involved in how the water is being used?

Growers also need to consider whether or not there are crop characteristics that maybe make the

crop vulnerable to additional contamination or internalization of hazards. And so we know that there is some science out there about particular crops, but there may not be information for every crop that's being grown.

So this is one example of how the assessments can be flexible to accommodate the science that is there and then science that will be coming in the future.

The assessments also captures information around environmental conditions, so understanding whether or not there are events of heavy rain or whether or not there are any type of extreme weather events. It also takes into account whether or not here are cold temperatures, high temperatures and whether or not there is any level of UV exposure. And so just taking into account what are all the factors that could contribute to potential contamination through water that's being used in the farm.

And we have this also last category: other relevant factors. And so this category captures information around how testing could be used to form

additional features of the assessment. So the requirements that we finalized in 2015 represent, they still represent our best, the best available science to support public health protection through the use of water in produce production practices. However, we recognize that are additional uses for testing that are not limited to the time of harvest. So this gives us the opportunity to incorporate testing outside of that time frame and for other purposes. So it's possible to use testing to identify how water quality may change after a heavy rain. It's also possible to use testing to identify water quality for water sources that not used around the time harvest, if you use one water source for transplants and another water source after the transplant has established itself, then you get more information about your water. So this slide captures both what we had as the best available science at the time and beyond.

So if finalized as written, the preharvest agricultural water assessment would need to be written and have supervisory review of those assessments and then based on the information captured in the

assessment, a determination would be required. And that determination of the outcome would also capture whether or not a corrective measure or a mitigation measure needs to be applied.

This assessment also captures information on adjacent and nearby land uses. As I mentioned in the previous presentation, there were a few produce-related outbreaks that were associated with water in the recent years during the time of the reassessment up to today. And taking into account the outbreak investigation summaries that we have, we identified that water that is used in produce production, may also have some relationship to the adjacent nearby land uses. And so this assessment takes into account that potential relationship. Growers would need to consider whether or not there is land use nearby and adjacent to that produce production that involves animal activity or application of biological soil amendments of animal origin, or if there's the presence of untreated or improperly treated human waste.

Farms will also be required to consider the

nature of the water system and how close it is to the adjacent and nearby land uses that are near the water system, as well as the topography of the surrounding land, whether there's high hills or whether there's any way to prevent runoff into that river or other surface water source, and consider whether or not any containment or fencing would be appropriate or is appropriate and being used for that animal operation adjacent to the water source that you're using.

Other opportunities to reduce the risk of influence of runoff include earthen diversion berms, ditches, and other barriers.

So, as I mentioned, the information that's captured in the assessment would go into this assessment. And then once you've got your assessment information, you consider how that assessment could contribute to contamination within that produce production operation.

So first, we're going to start on that blue box in the top left corner here. The assessment is the consideration of various factors. So that's the source and distribution system, the type of crop

that's being grown, the environmental features, and any other information, including testing results. So if you determine based on that information in the assessment that your water is not safe or not of adequate sanitary quality for its intended use, that first middle white box on the left. If you determine that that water is not safe, so you answer yes. You go down to the red box on the left and you immediately discontinue use of that water You must apply a corrective measure resuming use of that water source. If you determine that your water is not safe or its adequate sanitary quality for its intended use, so you determine that your water is, in fact, safe, and is, in fact, adequate for its intended use, then you would continue to the right, the second white box where you identify whether or not there are any conditions that may introduce hazards into or onto the crop or food contact surfaces.

If you answer that there are no conditions that may introduce hazards, then your next action would be the green box on the bottom where you would continue to regularly inspect and maintain your water

source and distribution system.

If, in fact, you do identify that there are conditions that could introduce hazards, you would continue to the third white box on the right. And then you would consider whether or not those hazards that have been identified are related to specific and certain uses of adjacent and nearby land. If you determine that there are specific uses that are related to adjacent and nearby lands, so that would be a biological soil amendments of animal origin, the untreated or improperly treated human waste, then you would determine whether or not a mitigation, you would determine which mitigation needs to be applied, and apply that promptly within the same growing season.

If there are no conditions that are related to the specific adjacent or nearby land uses, then you would continue on and determine whether or not you wanted to collect additional information through microbial water quality testing or whether you want to right away apply a mitigation measure. If you determine that you want to -- that's the yellow box on the right -- if you determine that you want to apply a

mitigation measure, you don't need any additional information on the potential hazards that you've identified, then you would apply that mitigation measure as soon as practicable but no later than the following year. Instead, if you determine that you want to collect additional information to better inform your assessment, then perhaps you would consider testing that water to identify any additional information. And that would be the box on the right, the yellow box on the right where it says "test."

If you determine or after testing that water, you would then go all the way up to the top left corner, back to the blue box, you would follow that dotted arrow back all the way to that top left blue box and you would consider the information within your assessment alongside the data that you've collected through water quality testing and go through this decision tree once again to determine how best to apply a mitigation measure if necessary based on the hazards that are identified.

And so this flow chart is also going to be explained in the next slide where I've got sort of a

summary of what we just discussed here. I know this is can be kind of confusing to look at, but ultimately what this flow chart aims to do is to walk a grower through what needs to happen based on the information that's been collected for this assessment.

So the blue box is going to start you where you've already collected all of your information and now you're making your decision based on the outcome of the assessment.

So as I mentioned previously, here is the big chart of the summary of the outcomes that could potentially happen based on what you've identified in the assessment. So if you determine that your water is not safe or not of adequate sanitary quality for its intended use -- this is the top left blue box -- then you must immediately discontinue the use of that agricultural water source and take a corrective measure before resuming water for preharvest activities.

The second box down, if you determine that there is one or more reasonably foreseeable hazards that are specific to those adjacent and nearby land

uses that were identified before, so those would be the uses around animal activity, biological soil amendments of animal origin, or untreated or improperly treated human waste, then you would need to apply mitigation measures promptly and no later than the same growing season.

The third box down on the left: If you identify a known or reasonably foreseeable hazard that is not related to those adjacent and nearby land uses, so not related specifically and directly to animal activity, biological soil amendments of animal origin, or untreated or improperly treated human waste, then you have two options. The first option is to implement a mitigation measure as soon as possible and no later than the following year, or, as we discussed with the yellow bases, you may test that water as part of your assessment and then based on the test results and the assessment results, you would then implement a mitigation measure based on what you have identified. So if testing provides you a little bit more information, you may be able to more specifically apply a mitigation measure based on the assessment

outcome and the testing results.

Lastly, in the bottom left blue box: if there are no known or reasonably foreseeable hazards for which a mitigation is necessary, then you must continue to inspect and adequately maintain your water system at least once per year.

So going back to the requirement for testing as an option for the assessment, so farms that are conducting testing would still have to follow some requirements. So the samples must be collected immediately prior to or during the growing season and must be representative of the water that's being used. The water must be tested for generic E. coli or another scientifically valid indicator organism, index organism, or another analyte. The sampling frequency and microbial quality criteria would have to be appropriate to assist in determining alongside other factors whether mitigation is necessary. And farms could choose the sampling framework and the criteria that were identified in the 2015 Produce Safety Rule, among others.

Some feedback that we received from

stakeholders already are around the corrective and the mitigation measures. And so identifying where corrective measures are more appropriate and where mitigation measures are more appropriate is definitely something that we've heard feedback on.

So a corrective measure is on that is applied in response to water not being safe or not of adequate sanitary quality for its intended use. So it's specific use is a corrective measure. A mitigation measure would be applied in response to the finding of hazard that are associated with animal activities, biological soil amendments of animal origin, or improperly treated human waste that is specifically related to adjacent or nearby land. And, if there are conditions that are identified that are not related to those categories above, then mitigation measures are also applicable in those situations.

So a breakdown of the corrective and mitigation measures, so farms that are applying corrective measures specifically have the flexibility to choose from reinspecting the water system and making necessary changes based on that inspection and

treating the water.

Farms that are applying mitigation measures would be able to choose from, again, making the necessary changes such as repairs or increasing the time interval prior to harvest, a minimum of four days unless is otherwise supported by additional science; increasing the time interval between the harvest and end of storage and/or conducting other activities such as commercial washing; changing the water application method; treating the water; or taking alternative measures. And the EPA is also working, or has actually developed a protocol that FDA developed regarding the registration of chemical treatment for preharvest agricultural water.

And so now there is that opportunity for chemical companies to develop preharvest agricultural water treatments where previously, they may not have been widely available and specifically related to public health targets.

So additional clarifications around this subpart, we have reorganized this subpart in its entirety to more clearly delineated which provisions

apply based on how the water is being used. However, this doesn’t, this doesn't alter the requirements for sprouts, water that's being used for harvest, packing, and holding, or for treatment.

There are some exemptions that have been identified in this framework. If finalized, covered farms would be exempt from conducting the preharvest agricultural water assessment if they can demonstrate that their preharvest agricultural water meets certain requirements that would apply for harvest and post-harvest water such as the microbial quality criteria for testing and testing requirements for untreated groundwater. If that water is received from a public water system that meets the requirements that are established in the rule for the Safe Drinking Water Act and providing the certificates of compliance demonstrating that the water meets those requirements, or if that water is treated in accordance with the standards that have been identified in the Produce Safety Rule.

You will hear later on this morning about a tool that FDA is developing regarding walking growers

and other stakeholders through the assessment and so that's called the Ag Water Builder Tool. The FDA has been working really hard at developing this tool to provide an example of thinking on how we would anticipate growers walk through an assessment and identify how hazards and conditions that may contribute to contamination associated with water. So look forward to that coming in shortly. And Chelsea and Michelle will speak to that later on this morning.

We recognize that compliance dates are of interest to many of our stakeholders and we want to insure you that FDA has recognized that the compliance dates for large farms began on January 26th for Subpart E for produce other than sprouts. And again, this is a very high priority for FDA. In the proposed rule that was issued, that was released last fall, we focused on the standards themselves and did not propose new compliance dates. But as previously announced, we're exercising enforcement discretion with the agricultural water requirements for all Subpart E provisions that are applicable to fresh produce while we work diligently to address the

compliance dates.

The regulatory impact analysis. The preliminary economic analysis considers various considerations and benefits that are associated with the proposed rule compared with the current preharvest agricultural water testing provisions in the 2015 Produce Safety Rule. We estimate that the benefits of the proposed rule would result from illnesses averted as a result of the proposed provisions that are relevant to illnesses averted as the result of current provisions. Additionally, we discussed the qualitative benefits of the proposed rule stemming from increased flexibility for covered farms to comprehensively evaluate their agricultural water systems and as discussed earlier today, these changes to preharvest agricultural water systems are being proposed to address possible implementation challenges of the current preharvest agricultural water testing requirements in the 2015 Produce Safety Rule.

We estimate the cost of the proposed rule that may result from various sources and those costs include those that result from reading the rule,

conducting the preharvest agricultural water assessment, conducting mitigation measures when necessary based on outcomes of the preharvest agricultural water assessments and associated record keeping.

This slide provides a summary of the estimated costs and benefits of the proposed rule in comparison to the current preharvest agricultural water testing provisions that were outlined in the 2015 requirements. And the highlighted in yellow cells demonstrate that our primary estimates show both positive benefits of the rule relative to current testing provisions and positive costs of the rule relative to current testing provisions.

The FDA is really looking for engagement from stakeholders. As Samir mentioned earlier, comments to the docket are, of course, very welcomed. And comments to the docket that provide additional information around scenarios or parts of the framework that are good or bad, but specific around why the commenter is supportive or not supportive of particular components of the framework. Understanding

specifics are really helpful to us to be able to take those comments and to do something useful with them. If we get a lot of "I like this," but not a lot of additional information on it, we don't know how best to finalize the framework that makes sense for everybody, all the people who have submitted comments.

So, really, we're looking to get a lot of hopefully specific information around the challenges and lack of challenge in complying with the way that the framework is presented. And so being able to get those comments, those specific comments are really very helpful in finalizing the rule.

And so thank you so much for the opportunity to discuss this morning and I look forward to comments. Thank you.

MS. MCDERMOTT: Great. Thank you so much, Samir, for your remarks. And thank you, Kruti, for that great presentation. We will now be taking a break and I'm handing it over to Mike.

MR. KAWCZYNSKI: Looking at the time, we are going to take a 20-minute break. So with that, look forward to joining us back at around 10:25.

(Off record)

MS. MCDERMOTT: Thank you everyone for coming back from the break and joining us again. I'd now like to introduce our second set of FDA presenters: Michelle Smith is a Senior Policy Analyst in the Division of Produce Safety in our Center for Food Safety and Applied Nutrition, as well as Chelsea Davidson, a policy analyst in our Office of Food Policy and Response. They will address the Agricultural Water Assessment Builder. I'm handing it off to you both now.

AGRICULTURAL WATER ASSESSMENT BUILDER

DR. SMITH: Thank you, Cathy, and thank you everybody for attending today. As you've heard previously just a little while before the break, the FDA has been working really hard on an ag water assessment builder tool. And so what we'd like to do now is I'll start with a brief overview of why FDA has been working on this tool and a little bit about our current thinking surrounding the tool. I'll pass the presentation to Chelsea to share more detail about the development of this tool and to give you a preview of

what the tool looks like now. At the end, I'll talk about next steps that we're thinking about right now.

So for background, as you've heard, after the final Produce Safety Rule issued in 2015, stakeholders shared a lot of feedback that some of the requirements, specifically those surrounding testing for preharvest agricultural water were difficult to understand and implement across the wide variety of water sources, water uses, and practices in the produce industry. So these concerns, as well as possible approaches to addressing them has been the focus of numerous outreach activities over the last few years, including the 2018 Produce Safety Alliance Ag Water Summit. Now this is where attendees identified agricultural water assessment as a promising approach, but at the same time, they really stressed that education, training, and other tools would be needed to help farms conduct the assessment in appropriate and consistent ways.

And so FDA began working on an ag water assessment tool and in doing this work at a really high level, we wanted to develop a tool that was user-

friendly and designed to help users understand the proposed requirements. So this tool incorporates information from the proposed rule and from the qualitive assessment of risk conducted for the 2015 Produce Safety Rule.

The use of this tool is optional. It will not be required and I'm going to jump back -- okay. It will not be required. It's also not meant to be a standalone tool. We see it as part of the picture where it might supplement, but not replace, other technical assistance, education, training, and experience. And likewise, technical assistance, education, and training could supplement use of this tool.

Now some of the guiding principles, as we worked on developing the tool. We wanted this tool to help users or to allow users to input dynamic information about their own individual farms into the tool. The user's data is for their own use. It will not be shared with FDA. We wanted users to be able to access this tool regardless of their computer's operating system and across all common browsers. We

also wanted this tool to be something that could be used either on a computer or a mobile device such as a phone or a tablet. The tool allows users to safe their progress and return later either to finish it or to do a reassessment. Users can also save the information they inputted as a PDF for their own records.

Now, as this point, I'll turn things over to Chelsea and she'll say a little bit more about the development process for the tool and share a preview of what it looks like now. So Chelsea.

MS. DAVIDSON: Thanks, Michelle, and thank you, everyone, for joining us today. We're very excited to share a bit more information. We just want to ensure that everyone externally is very excited to get an idea of what the tool would look like once it is available.

Even though it's not quite ready for public release yet, we did want to get an idea of the process that we used for development and also, as Michelle had mentioned, kind of a sneak peek of what the tool would look like.

So in terms of development, we did take a stage-wise approach to doing this. So the first stage was really focused on the development of the information flow. So much of this was just figuring out what types of questions we would be asking, how the different sections would be grouped and would flow from one to the next. It was also a matter of identifying areas where we could provide some extra information just to give some additional context to the questions being asked.

So this would include information from the proposed rule itself, if there was any relevant background information from the 2015 Produce Safety Rule, and also from our qualitative assessment of risk which served as a basis for much of the produce safety standards.

So the next stage of development was largely focused on IT development and we broke this down into three different steps. So the first one was focused on the factors that you would consider as part of your assessment. As Kruti mentioned earlier today, this would be things like looking at your water system,

your water source, crop characteristics, environmental conditions, the types of information you would consider in doing that evaluation.

The second stage of IT development is focused on looking at your determinations for outcome and what other measures would be necessary to implement. In between these first two portions of IT development, this really makes up the bulk of the builder. And then the third part of that was focused on the reassessment of functionality. So if you do want to come back to your builder at a later time, makes some edits, there's a significant change with your system that you would want to account for, having this functionality would allow you to bring the information back in so you don't need to necessarily start from scratch with the builder.

And then the third stage is testing. So the first part of this was focused on internal testing. This was done by a group of agricultural water subject matter experts and also IT subject matter experts. This was focused mainly on mainly double checking for factual accuracy, drought, and also ensuring that the

technical components of the builder are working, just making sure the questions are directed in the right path, we are not accidentally skipping over any relevant sections and things like that.

The second part of testing is a group of limited external audience. And this was predominately so we could begin to get some internal feedback from them that we could incorporate.

I 'm sorry, just give me a quick second. My cat is trying to break in. Sorry about that. I am back now.

So with this limited external testing, where we're at now is really taking into account that feedback. That feedback provided us with -- and figuring out not only what information and changes we can incorporate in the short term, that we can incorporate into Version 1.0 of public release that we hope to release shortly, but also keeping in mind longer-term what kinds of changes we might incorporate to really maximize the user experience of this tool.

So I had already mentioned that there are a few kinds of main sections of this builder, the first

being the factors that you would consider as part of your assessment. So that the slide that we are on now just shows a high level overview of what that kind of question flow looks like.

This section begins with general scoping questions such as do you use preharvest agricultural water? Whether any of the proposed exemptions would apply. Depending on how you answered these questions, the assessment may or may not be required if the proposed rule is finalized. If you carry on with the rest of the assessment, you then go through a series of questions focused on the factors themselves. So the first one being water system components, so looking at your water source, your distribution system, and whether they are protected from potential sources of hazards.

The next series of questions would be focused on the habits themselves, so looking at animal impacts and activity, biological soil amendments, human waste, other water users, or is there any other potential sources of hazards? This would also include considering whether they are associated with adjacent

or nearby lands.

And then within that series of questions, there is also just some really helpful questions that you should be asking yourself in determining the actual likelihood of those habits being introduced. So things like proximity to water sources, whether runoff has a potential to occur, for animals, whether they have direct access so things like that just to kind of get everyone thinking about what the level of risk posed actually is.

So from there, the questions go on to crop characteristics. So, for example, if there is any unique characteristics of the crop that would allow for the attachment or entrapment of pathogens. That then goes on to water use practices, including both feed method and timing of application. And then environmental conditions which, of course, have the potential to impact not only the quality of the water itself, but also if there were hazards introduced to the covered produce what the risks might be imposed by them.

And the last part of this section is for

other relevant factors this is really just intended to be a catchall for anything you might not have addressed elsewhere.

So from there, you would consider all of that information. I am going to move onto the next section of the builder. This is focused on the determination of outcomes and measures that you may or may not be required to implement.

So this slide aligns very closely with what Kruti had discussed earlier. You would begin by thinking through whether or not those conditions would be that your water is not safe or not adequate sanitary quality. If that's not the case, you would then go onto whether there are any conditions associated with adjacent nearby lands. And, this of course, is focused specifically on animal impacts, biological soil amendments, and untreated or partially treated human race waste. If that's not the case, then you would consider whether other conditions present that might need to be addressed. And if there are, then you would have the option to either coast straight to mitigation measures or test your water and

consider those results as part of your assessment. And then go through the whole decision-making process again to determine whether measures would be necessary to implement.

And then I mentioned that we wanted to give kind of a sneak peek to what the builder actually looks like. So this is the landing page of the builder currently. It just provides some high-level information on what the builder is, what it isn't, provides the legal disclaimer. There are a few key features that I did want to point out.

In the upper right-hand corner, you'll see that it is supported by bothered browsers, so Chrome, Edge, Firefox, a lot of the main ones. As Michelle mentioned earlier, you can access this builder through both MAC and Windows devices. You can also use this on mobile devices as well as tablets. So there won't be a specific application that you need to download to use, but you are able to access this through the browser on those devices.

In the upper left-hand corner, you'll see a button on each pace that is for navigation and I will

show you what that looks like in a bit. Basically, this just helps you to monitor your progress, see where you are, what you completed, what you still have yet to do. It also allows you to skip back if you want to look at any questions or how you responded before.

And the last thing I will point out this slide, you'll see sprinkled throughout the builder there's this little icon. It's small blue eye with a circle around it. And when you see that, it means there is more information available to you. So this could be in the form of just useful definitions, if there are any helpful resources, or any language from, you know, the preamble or the 2015 final rule, or a qualitative assessment that could help you get a bit more context to the question being asked.

So like I said, on the left-hand side of this page, this is just an example of what the navigation chain that will pop up if you click on that navigation button at the top of the screen. So as you go through, you will see that the color of the different sections changes as you complete them. So

in this case, looks like you completed about half of the factor section. You can also use this to click on one of the sections to go back, look through any questions that you had already been asked, see how you answered them so you don't necessarily need to toggle back through every single question that you had done up until that point.

On the right-hand side is an example of the more information pop-up that you will get if you click that little blue eye icon. So in this case, it just has some definitions, some resources, and then for much of the extra information that we provide throughout, it does contain language from the proposed rule just to give you a little more flavor to the types of questions that we are asking and also what types of things you would think about going through the builder and answering those questions.

I wanted to give you a quick idea of some of the questions and ways to respond that you will see throughout the builder. So on this page, you will see at the very top there will be instructions or the actual question being asked. For this one, in

particular, for proposed exemptions, you would first respond by selecting one of the choices from the drop-down menu that aligns with the proposed exemptions. And then for many of the questions throughout the builder, we do have open comment field that you were able to put in a bit more of the narrative response so you can explain why you answer to question in a certain way or why you think it is appropriate or not, just give a bit more operation specific information.

The bottom of each page, you will see there are page controls which allows you to not only toggle back through each individual question, but also once you've completed the question that you are on, it allows you to move forward.

So this is the last type of response we have in the builder. There are a few of these sprinkled throughout the builder. And in this case, it's a series of questions and then you have the option to select either yes, no, or not applicable depending on your specific circumstances. And then if I was able to scroll down on this page, you'll see there's also an option again to put in a bit more of that narrative

response where you can provide a bit more clarity on what you responded certain ways, why some things may not be applicable, if you're not doing something, why you don't take it's necessary, just to really round out your assessment.

And the last thing I will point out before passing it back to Michelle, you'll see the bottom of each page there is also a button for saving. If you click that, you get this pop up what test two options first saving.. The first one is save for import. This tied in with what Michelle had mentioned earlier about how we didn't want to user information or data to be saved within the browser itself. So if you are partway through an assessment and think you want to come back to it at a later time or if you have completed an assessment, but you want to have that information on hand to make any edits or updates down the line, you would click the save for import button. It would save what's called a JSON file to your local device. When you are ready to resume, you could upload that file to the browser and it will pick it right back up for you left off, so you don't need to

start from scratch.

And the other save option is the save for viewing, just a second button on the screen. This basically saves a PDF file of all the information that you put into the builder up until then that you can save to your local device. So this is not editable. This is not something that you can upload to the builder at a later time, but it is a helpful resource to have on hand for your records if you do want to come back and look at it and see what you had inputted, maybe track changes over time, things like that. So with that, I will pass it back over to Michelle. Thank you.

DR. SMITH: All right. As Chelsea mentioned, we just finished external testing with a small group of people who gave us really appreciated, substantive feedback. And we are currently working with developers to determine which of those suggestions could be incorporated in a timely way and which we may need to say for later.

And so I would like to make the point that we have gotten a lot of really valuable feedback so

far. We're not going to be able to put everything in the initial version that we release soon, but we are keeping a list of things that we can do at a point in time when we have more time. And once this tool is available, we really welcome feedback on the tool from all of you as well as ideas for how it could be shared with states and other stakeholders.

And similar to what Samir said about comments on the proposal, the more detail you can provide in your comments on the tool to help us understand what you're looking for or what you think might increase its usefulness and value, please share them. Keep in mind that the tool we're hoping to release soon is Version 1.0.

Longer-term, if the rule is finalized, we expect to update the builder based on final rule requirements and based on all of the feedback that we received such as usability and how understandable the information provided by the tool is. I also would like to let people know that we have heard stakeholders' desires to have a tool available in a format that does not require Internet access or

technology, such as a paper format. There is also a desire to have this tool available in languages other than English. So those are things that we will keep in mind and consider doing as the time is right. So thank you very much for your interest in the tool and we are excited about sharing it soon and hearing whatever kind of feedback you would like to share with us. So thank you.

MS. MCDERMOTT: Great. Thank you so much for that presentation Michelle and Chelsea. It was very interesting. So, our next presentation, we will hear from Diane Ducharme, Consumer Safety Officer with the Division of Produce Safety who will speak to training, education, and outreach around the proposed rule. Diane.

TRAINING, EDUCATION, AND OUTREACH

DR. DUCHARME: Thank you, Cathy. Good morning, good afternoon. Thank you for being with us today on this Friday and the second public meeting for the proposed agricultural water rule. I am Diane Ducharme, I am with the FDA and the Center for Food Safety and Applied Nutrition in the Division of

Produce Safety and Acting Team Lead for the Produce Safety Network.

So little bit about the Produce Safety Network, we are a regionally located team and specifically designated to support our farmers, our regulators and other key stakeholders for implementing the Produce Safety Rule. We provide the support through providing regulatory and technical assistance. We answer questions and conduct outreach education and training. And so it's with that I am here today to speak with you a little bit, bringing all those previous conversations together into that training and education efforts as we work through this proposed rule, moving it towards that final rule and that the implementation.

So we start with the specifics of the training, education, and outreach are not fully outlined. As I talked about, we are dealing with a proposed rule. But the FDA has many lessons that we learned through the development of the proposed Produce Safety Rule published in 2013 through the supplemental notice of the proposed rule in 2014 and

then to the final release in 2015.

We intend on applying those lessons learned and building upon them as we develop our training, education, and outreach plans for this final rule. From previous processes, taking us to that final rule, FDA has forged those communication pathways with the establishment of meeting platforms, identification of contacts, getting to know the personnel, building those relationships with the state partners and more importantly, extending those communication efforts to our farmers in the farming community, the produce associations both domestically and internationally.

We recognize that effective and frequent communication that provides that ability to explain FDA's current thinking and to obtain the feedback as we are doing today in this public meeting are essential for educating each other. But right now, we are working on raising awareness around the proposed water rule.

Stakeholder engagement began shortly after the proposed rule was published in the Federal Register with outreach to key external audiences

representing our federal, state, our partners, consumer groups, trade groups, and others. Additional engagements continue to be scheduled as we receive those requests.

FDA has also initiated communication with our partners on the expectation and what has changed in light of this proposed ag water rule as it pertains to the implementation of the Produce Safety Rule. Specifically, FDA continues to encourage farms to use good agricultural practices to maintain and protect the quality of the water sources. Importantly, while we work through the proposed rule for the ag water, produce remains subject to other provisions of the Produce Safety Rule as applicable and to the adulteration provisions of the Federal Food, Drug and Cosmetic Act.

So the FDA recognizes the important role that state and educators play. We look forward towards the development of the final rule and the incorporation into the produce safety implementation for national consistency.

This process includes working with

stakeholders to hear the concerns about the proposal and incorporating those into the final framework, much like what Michelle just mentioned with the tool. And as Kruti mentioned, we know you are also interested in hearing more about the compliance date. She noted that the compliance date for large farms began on January 26, 2022, so this year. That was last month, for that Subpart E provisions for covered produce other than sprouts.

So I ensure you that this is a high priority for the FTA as well as Kruti mentioned, a proposed rule we released last fall focused on the standards themselves and did not propose a new compliance date. However, we are exercising enforcement discretion for the agricultural water requirements for covered produce for all Subpart E provisions applicable to the produce while we work diligently to address these compliance dates.

If the proposal is finalized as written, the agency intends to work closely with our state regulators, National Association of State Departments of Agriculture, or NASDA, educators and others

including the Produce Safety Alliance as mentioned earlier. This is to provide that necessary training and updates through implementation of these changes to the agricultural water requirements.

So I wanted to share a couple of examples of the integration and collaboration already taking place on the proposed rule. Several slides have been added to the required food safety training within the standardized Produce Safety Alliance curriculum as well as FDA's produce inspections for regulators training or FD 226. And the slides provide content that addresses the proposed ag water rule, specifically, FDA's decision to exercise that enforcement discretion while working on the compliance dates for ag water, also how the growers can comply, utilizing -- pardon me -- how growers can utilize good agricultural practices currently to maintain and protect the quality of water sources.

And finally, that there no changes to current implementation of the Produce Safety Rule until this proposed ag water rule is to a final rule and is published.

Also it's important to note that our partners are already working as well. The Produce Safety Alliance is holding weekly office hours extended to the researchers and extension educators to collaborate, to understand more about what are those questions that we need to offer. Maybe improve some overall clarity to what is currently proposed, help transform the comments that FDA receives, and then also revisiting how growers can submit their comments so their voices can be heard.

Further, working with our NASDA partners that represent some of the states produce safety programs, there are five virtual regional meetings that are organized through the month of March, coming up, to address some of the -- parts of the proposed ag water rule requirements, just much like what was done today through the public meetings.

So as you can see, we are actively working on the development of the framework for the training, education and outreach, and welcome your support and ideas as this evolves. FDA recognizes that we stand on the Food Safety Modernization Act. And as we stand

on that, we know that we can better protect public health using a system of collaborations that explicitly recognizes the need to work together in an integrated way to achieve our public health goals. The strength of these cooperative efforts can support the integration of this ag water rule if finalized into a nationally consistent Produce Safety Rule.

Looking forward, we understand that providing the continuum of technical support as we work towards the final rule and implementation while engaging with our stakeholders and colleagues is essential. We, as you can say, are gathering steam, defining processes that take into consideration the aspects of this consistent messaging, that the proposed rule requirement intention is to be workable across produce farms of all sizes, both domestically and internationally, and recognize the wide variety of water systems, their uses and practices that are in play.

And finally the proposed rule is designed to also be adaptable to future advancements in the ag water arena around the science and technology. We

recognize that to fully realize the benefits of the proposed ag water assessments, farms must understand and translate the requirements of their own operation. Working with our partners, the education, training materials, and online tools will be critical to help ensure that farms can conduct that robust water assessment evaluation we envision within the proposed rule.

So there are -- there is a lot of information covered today. I wanted to highlight a couple of resources that are on the website. There are fact sheets that provide an understanding of the contents of the proposed ag water rule as outlined by Kruti earlier. So highlighting two that are on the website, there's the agricultural water proposed rule and this gives you the preharvest ag water requirements, the factors to consider, corrective and mitigation measures, reassessment, records and extensions. So all of those areas that Kruti talked about.

There is also an expanded table on additional factors that might be considered from the

farm. And these include your water system practices, your crop considerations or characteristics, any environmental conditions and other relevant factors within your farming system. Of course the main page is also there. You could Google any of these, but the proposed ag water rule is up on the FDA's website and then the links to those fact sheets are with that main website.

Finally, the FDA focused first on developing the proposed rule and that this then lays the groundwork for the online ag water assessment builder tool that Michelle and Chelsea mentioned and reviewed. We anticipate launching a pilot of that proposed online tool in the coming months.

So I would be remiss if I didn't mention the Produce Safety Network. They remain available for technical assistance. You can certainly use the website the bottom of the screen or just Google Produce Safety Network and you will find a map such as this. There will also be a directory and you can find what state you're in, find who you need to talk to as far as the PSN representative. There is email as well

as phone numbers. So that should be a quick connection.

So I want to make sure that I encourage you to provide your comments with clarity of what you would like to see so that it is incorporated into the federal docket. The federal docket number you have heard many times but I'm going to say it again FDA-2021-N-0471. And that can be found on regulations.gov. And then if you should have any clarifying questions about the contents of the produce ag water rule or if you want the FDA to speak at one of your engagements, you can submit your request to the email and agwater@fda.hhs.gov. We will make sure it gets to the appropriate personnel.

So with that, I would like to thank you for your time and pass it back to Cathy.

MS. MCDERMOTT: All right. Thanks so much for your presentation, Diane. Now we will be moving to questions. For this portion, I will be posing questions to our subject matter experts that were submitted as part of the registration process. Each question is opened for any and all of our panelists to

answer. The panel will consist of all of our subject matter experts that presented this morning as well as Charlotte Christian, Director of Policy Initiatives with our Office of Food Policy and Response.

QUESTIONS

MS. MCDERMOTT: How does the regulatory process work and when can we suspect a final rule?

DR. SMITH: Cathy, this is Michelle, I can take that one. Federal rulemaking generally follows the notice of comment procedure where an agency publishes the proposed rule, explaining our current thinking and the agency's proposed approach. The proposal has a finder docket number published in the Federal Register. And the public has a specified amount of time to review and provide comment on the proposal and that's where the ag water notice of proposed rulemaking is within the rulemaking process. FDA will read all comments submitted in a timely manner and consider all relevant substantive issues raised in the comments in developing a final rule.

And it's difficult to predict how long it will take to get to a final rule, especially at this

stage of the process. And it will depend in part on the extent and the type of feedback we receive. But what we're able to, FDA will transparently keep all stakeholders in the loop as to where we are and would share an expected timeframe on the proposal and the publication of a final regulation when we have some information to share. And with that, I'll turn back to you. Thank you.

MS. MCDERMOTT: Great, thank you, Michelle. Our next question: Will stakeholders implement these new requirements as soon as possible?

DR. ASSAR: Thanks, Cathy, I will go ahead and take that one. This is Samir. It's really important to note that this is a proposal and not a final rule. The farms are not expected to comply with the proposed approach. Some of these provisions may change and none of them are enforceable at this time. It's really important for folks to understand that. We certainly look forward to continued engagement on the proposal to determine an appropriate course for the final rulemaking and meanwhile, we encourage farms to follow good agricultural practices to ensure that

water is suitable for its intended use and that farms are also responsible for ensuring that the food that they produce is not adulterated under the Food, Drug, and Cosmetics Act.

MS. MCDERMOTT: Great, thanks, Samir. Our next question: Can you describe a plan for implementation of the regulation when it is finalized?

DR. DUCHARME: Cathy, I'll take that. This is Diane. We recognize that education, outreach, and training and the online tool will be critical to help farms to be able to conduct that robust water assessment evaluation that we envision with this proposed rule. So the online tool that the FDA is developing can provide that valuable assistance in helping those growers evaluate those potential risks associated with their agricultural water sources and determining the management options. We also recognize that FDA and state partners must have that necessary training and tools to verify compliance. And specifically working with our FDA safe produce safety implementation cooperative agreement program, the states that have developed the produce safety program,

we knew all of that will be training and educating and the ability to extend that to the farms and the farming communities and other regulators. We are committed to early engagement, close partnerships with our state regulators, our National Association of State Department of Agriculture or NASDA, our educators and others including the Produce Safety Alliance in the development of training plans for both the industry and regulators on the preharvest agricultural water assessment that assures the consistency for the inspectional approach. We are also committed to continuing to educate before and while we regulate. Thank you, Cathy.

MS. MCDERMOTT: Thank you, Diane. My next question is what will compliance and enforcement for the rule look like?

DR. ASSAR: I will take that one, Cathy. We get this question a lot. And really just kind of building off of what Diane said earlier in her response, we are going to be working closely with the state regulatory partners in implementing the produce safety rule through the programs that she talked

about. Some states will take the lead for conducting routine farm inspections in their state. And if finalized as proposed, the FDA and the states would assess a farm's compliance by reviewing records and observing practices and conditions on site and specifically they would review the written agricultural water assessment to determine if the farm evaluated all of the required elements of the assessment including consideration towards agricultural water sources, distribution systems and practices, as well as any adjacent or nearby land uses for hazard identification purposes as you heard from us earlier today.

The inspection would include a review of test results, if any, and we know that this can be used for assessment and whether the assessment and the supervisory review occurred in a timely manner and if finalized as proposed, the FDA and the state would also review the farms written determination on any measures to implement based on the results of the assessment together with these findings from inspections and maintenance of agricultural water

systems under the farm's control.

MS. MCDERMOTT: All right. Thank you, Samir. Our next question: How do you see the agricultural water builder tool being used by growers and other stakeholders?

DR. SMITH: And Cathy, this is Michelle, I can start this one off. The tool in development represent FDA's current thinking around how a grower might conduct an assessment for ag water, reflecting the current thinking that's in the proposed rule right now. The tool is intended to help users understand the proposed requirement for ag water assessments and get more information on the factors they should consider and input data about their own operation and water systems. And I'll pass to Chelsea in case she has anything to add.

MS. DAVIDSON: Yes, thanks, Michelle. And I will start up I sank my cat is now in cat jail and as much as she loved ag water, she won't be interrupting. I do want to emphasize that that this initial release is really intended to be just that. We're envisioning this as kind of a longer-term project with updates

down the line, which, of course, would include updating the builder for a final rule if it is finalized as proposed. Once it is available, we, of course, welcome any feedback from any stakeholders on what works, what doesn't, if there's anything else that could really be adapted or updated to really enhance the user experience as much as possible. I know the feedback that we received from that small group of external users so far has been incredibly helpful not only in identifying things that we can change in the short-term head of Version 1.0, but also some longer-term items that given additional time we could really take the time to reformulate the builder to make it as useful as possible. I'm sure we'll continue to get feedback along those lines. So we're really looking forward to that type of input.

MS. MCDERMOTT: All right. Thank you Michelle and Chelsea. Our next question: Will my information be shared with FDA if I use the online tool when it becomes available?

MS. DAVIDSON: Sure. This is Chelsea. Yeah, as Michelle mentored in her presentation, none

of the information or data that is put into the builder will be saved by our shared with FDA. So if there is summation that you want to have on hand for future reference or to work on the builder at a later time, we do recommend that you save that to your local device so that you don't lose it and have to start from scratch when you go to work with the builder again.

MS. MCDERMOTT: Thanks, Chelsea. Our next question: Why is the FDA shifting away from requiring all growers to test their water?

DR. ASSAR: Yes, Cathy, I will go ahead take this one. It it's really important that we are clear about what the proposed requirements are relative to the 2015 requirements. The FDA considers testing to be one tool in the toolbox of approaches to managing water quality in this proposed set of requirements. We recognize that in 2015, the Produce Safety Rule, growers were required to conduct testing around the time of harvest, develop a water quality profile to better inform them of potential hazards that could be introduced to produce or food contact surfaces by

their water. As you heard, many farms found these requirements complex and challenging to implement. We recognize that these factors, never mind successful implementation, then the desired public health improvements are not likely to result.

So we sought an alternative means to achieving improved public health protection in this area with this proposed regulation. And while the proposed approach to not establish a broad testing requirement for all preharvest agricultural water, it does include a testing option for serving covered farms that elect to test their water to help inform their agricultural water assessments. This testing option really again is aimed at incorporating flexibility for growers with respect to how and when they might test their water to help inform their agricultural water assessment.

For example, if we incorporated -- we incorporated flexibility to collect samples at any time prior to or during the growing season and to use analyze sampling frequencies and microbial criteria beyond the mode specified in the 2015 rule. This is

another example of how we are accounting for emerging research and science around this area of agricultural water and specifically around agricultural water testing.

MS. MCDERMOTT: Great. Thank you, Samir. Our next question: What are FDA's expectations for growers to mitigate hazards on adjacent lands when the grower may have little knowledge are even less control of hazards on nearby and adjacent land?

DR. SMITH: And this is Michelle. I can take this one. It's well-recognized that hazards on a farm and hazards outside the borders of the farm do have the potential to impact on produce safety. So while the activities that occur on adjacent and nearby land may not be under the farm's control, the potential hazards that could result from these activities are still important for the farm to consider when determining the safe use of agricultural water. And we understand that there are challenges but because these activities do have the potential to serve as a risk for farm's produce, those farms really should consider the likelihood of hazard introduction

to the water system from adjacent or nearby land uses when they are making decisions around the safe use of their water. And this is also an area, it's not new. It was covered in the 1998 GAPS guidance, but it's getting renewed attention in the form of a number of different kinds of programs including the Good Neighbor Program, to try and facilitate conversations between produce farms and adjoining neighbors that may be involved in other types of operations like animal operations so that everyone can have a conversation and try to work in a collaborative way. So that's something to continue to look for resources to help people in this area. Thanks.

MS. MCDERMOTT: Thanks, Michelle. So our next question: We have been testing our agricultural water for five years to better know our water. Can we continue to test our water and use this data along with risk assessments?

MS. RAVALIYA: That's, Cathy. I'll take this question. So, that's great. Water quality testing can provide a lot of information for growers to be able to make better management decisions. As I

mentioned earlier in the presentation, water quality testing can be used in conjunction with the assessment based on the way that this framework has been proposed. If it is finalized as written, testing can still be a really, really important feature of how to identify and manage risks that are presented by the water source and distribution system based on all the information that you are collecting. As Samir mentioned, testing is one tool within the toolbox that we've presented within this framework. And so, you know, having this historical data to help you understand a number of factors whether you have variability in your water source, whether you have certain spikes that may be attributed to particular environmental conditions, you know, there's a lot of information that you can get from testing. And within the framework that's been presented, there is flexibility to accommodate different analytes in different numerical thresholds to identify whether or not water may be, may be safe to use in certain instances along with all the other information through the assessment.

MS. MCDERMOTT: All right. Thank you, Kruti. Our next question: If I use drip irrigation or produce where the water doesn't contact the harvestable portion, what I still have to do an assessment?

DR. SMITH: Okay. I could take this one, Cathy. So the short answer is that growers who are using water that does not meet the definition of agricultural water, which is likely to or intended to directly contact the harvestable portion of the crop, are not required to comply with the ag water requirements in Subpart E including not needing to do the ag water assessments if the proposal is finalized. Now, it's important to remember that there may be other preharvest uses of agricultural water, not just irrigation. For example, water use to make up crop protection sprays, applied to tree fruit just before harvest would be considered ag water because the water is intended to contact the covered produce. But irrigation water that is neither intended to nor likely to contact covered produce such as water used for drip irrigation of tree crops and other crops that

grow high above the ground and are not likely to touch the ground is not agricultural water and therefore, would not be subject to Subpart E. Thank you.

MS. MCDERMOTT: Thank you, Michelle. Our next question: How often would I need to conduct a reassessment?

MS. RAVALIYA: I'll take that question, Cathy. So a reassessment as we mentioned earlier the presentation would have to be done at least once annually or whenever a significant change occurs that would affect the outcome of a previously conducted assessment. Example of a significant change could be switching from an untreated groundwater source to a surface water source and understanding the risks that may be posed from changing those water sources. Groundwater is less impacted more often than surface water to external runoff and therefore, doesn't necessarily bring with it as many potential contaminants or microbial variability. Whereas with surface water, there is more opportunity for it to be subjected to runoff and potential changes microbial quality. So considering what significant changes may

occur with your use and source of distribution system, that's how you can determine whether a reassessment needs to be done based upon certain changes.

And again, that would only apply if the proposal is finalized as written. And we welcome comments on situations that may help us better understand significant changes or not significant changes. So please submit those comments to the docket you have consideration on them.

MS. MCDERMOTT: Okay. Thank you, Kruti. Our next question: FDA has proposed to include crop characteristics as one of the factors for a grower to consider their assessment of risks associated with water and its use. However, the science on crop characteristics and the potential for adhesion or internalization may not be available for many crops. What should a grower do to fulfill that part of the assessment if there is no data on the crop being grown?

MS. RAVALIYA: Thanks, Cathy. I will take this one as well. The assessment framework that we proposed represents the FDA's best thinking on how to

take a systems-based approach in identifying hazards that are specifically related to agricultural water in growing produce. And so, we know, we recognize that there's many factors that can contribute hazards and can contribute risks and recognizing that crop characteristic is one of those factors is important in making sure that we have a comprehensive systems-based assessment.

So just as important as understanding the water source and distribution system, it's also important to recognize that water that is being applied to crops that have different surface features could behave differently in how the risk accumulates throughout the operation. So if you have produce that has a smooth surface compared to produce that has a less smooth surface, so taking into perhaps a tomato in comparison to a cantaloupe -- and if you've heard me speak other meetings, I always give the tomato and cantaloupe example -- but those two, the surfaces of both those commodities is different and recognizing that those differences can play a role in how pathogens are trapped or potential for adhesions onto

the surfaces of the commodities is a necessary piece of information. If there is no information on how -- on what type of crop characteristics are specific for certain commodities, then that leaves the door open for evolving science to accommodate lack of knowledge at this point. So being able to provide a flexible and ever growing framework that can continue to accommodate new science is also part of what we are trying to achieve with this proposal.

MS. MCDERMOTT: Thank you, Kruti. All right last question: How does this proposed rule effect small growers, for example, less than 25K?

MS. RAVALIYA: I will take this one too. All exemptions and exclusions for farms in the final Produce Safety Rule continue to apply and that includes the exemption for farms that have average value of produce sold during the previous three year period of $25,000 or less and that accounts for inflation. Thank you.

MS. MCDERMOTT: Thank you. Great questions. We want to thank everybody that submitted during our registration process and hope everyone appreciated

those answers and those that submitted got additional clarity around those question. Thank you all subject matter experts for those great answers as well. We will now be taking a lunch break and I'll hand it over to Mike.

MR. KAWCZYNSKI: All right. Thank you. Let's see. We are going to take -- it looks like we are going to take a 35-minute break and reconvene around -- let's just see where we are for time -- we are going to reconvene at 12:00. So that being said, we will see you all at 12:00. I will set the timer for it. Thank you.

(Off record)

MS. MCDERMOTT: Hi everyone and thank you for joining us again. I hope everyone had a good lunch break. I would now like to introduce our next panel with our state regulatory colleagues moderated by FDA's Barbara Cassens, Director of the Office of Partnership in our Office of Regulatory Affairs. Barbara, handing off to you now.

REGULATORY PARTNERS PERSPECTIVES ON THE AGRICULTURAL WATER PROPOSED RULE

MS. CASSENS: Hey, thank you, Cathy, and I'm really pleased to be the moderator for this panel and to talk with our state regulatory partners. We have two people joining us today, Richard De Los Santos, the Director of the Office of Produce Safety and Livestock Export for the Texas Department of Agriculture. Welcome, Richard. And Abbey Willard, the Agricultural Development Division Director at the Vermont Agency of Agriculture, Food and Markets. Welcome Abbey. Two of my good colleagues here. So folks, how this is going to work is I'm going to ask you, have you both answer the same questions. I'm going to alternate them back and forth and just, you know, give us your thoughts because the state's perspective on ag water and the proposed rule is really vital to us and we want to get a good clear perspective on that.

So I'm going start first of all, so Abbey starts with A. Richard, I'm going start with Abbey on this question and then we'll go to you.

But just thinking in your role at the state, why is ag water safety important and important to food safety as a whole?

MS. WILLARD: Thanks Barbara. Hi everyone. Hopefully you can see and hear us okay with the challenges and questions of being in a virtual public engagement process. So the role from the Vermont Agency of Agriculture that I think is important to just start by acknowledging as a way of answering your question, Barbara, that as a state agency, we spend time managing relationships between the general public and our producers. We support our ag industry to feel appreciated and valued by their community and work to demonstrate the value that agricultural land managers have on our landscape, the sense of community that they provide and the importance of the economic viability that they contribute. And we do this also while ensuring that regulations are clear, understandable and implementable and all the while ensuring that conditions where producers can be compliant and innovative while also safely feeding consumers, which is their primary objective.

So when we've look through and read -- it's been really helpful to have the staff from the Vermont Produce Program really dig into the proposed ag water

rule -- our first observation was that post-harvest requirements in Subpart E will generally remain unchanged. So that feels good and clarifying for our staff and looking forward to starting engaging with producers on that subject when it's authorized for us to do so when the rule becomes final.

So then what we looked at was we did a quick audit of the water sources in Vermont that were used by the produce operations that are captured in our farm inventory and captured in our portal of our covered farm. And what we observed was that 50 percent of those covered farms in our inventory are not significantly likely to be impacted by this rule. And that's because they're apple orchards, they engage in indoor production, or their crops are irrigated with a protected source coming from wells or municipal water. And so they don't typically apply water directly to a crop close to harvest or the water that they're using, as I mentioned, is protected and already being tested.

But the remaining 50 percent are heavily impacted by this proposed rule and they apply

preharvest water to produce near harvest from unprotected sources, typically surface water and sometimes even multiple sources of water. About 12 percent of those farms use a pond resource, 50 percent use river water source and 50 percent use a stream and again, that percentage is greater than 100 percent because some farms are using more than one source.

And so many of those farms that we know that will be irrigating from rivers or streams from surface water, it's very likely that they will identify at least one condition, sort of using language from the proposed rule, that is reasonably likely to introduce a known or foreseeable hazard. And it's likely related to some sort of animal activity, or impacted by adjacent or nearby land uses. Being that Vermont is primarily a dairy agricultural state, we can expect that there will be livestock or grazing practices or manure application on lands that are adjacent to produce fields and therefore the possibility of a potential risk.

We've also started to think about, and this is one of my last point, is that farmers will likely

be looking for the most realistic and the easiest option for water sources and water uses. And that's due to we're seeing such a change in precipitation and temperatures being more unpredictable with shifting climates. And so, you know, we can talk about some of the mitigation strategies that we anticipate that farms will be likely looking to utilize, but that will probably be looking at some of the preharvest microbial quality -- excuse me, quality criteria and testing as well as looking at the four-day wait period between irrigation and crop harvest.

And so in these ways, water is pretty critical and ag water, in particular, to the production and viability of the produce industry.

MS. CASSENS: Thank you, Abbey, good thoughts. Richard anything you'd like to add to those comments and then you get to go first on the next question.

MR. DE LOS SANTOS: Okay, thanks. Along with Abbey, sure, there are many reasons why ag water, is important to food safety in Texas. Fruits and vegetables represent over $630 million in the state's

economy and Texas produce growers supply Department of Defense, schools, direct to consumers, farmers markets, retailers, restaurants and more. So all these entities are our sources for selling our produce.

The Texas Department of agriculture wants all farmers to succeed and we understand to succeed, the farm has to develop consumer trust. By consistently providing safe food, a farm can develop consumer trust and grow and succeed. We also understand that agricultural water has been identified as the cause for past outbreaks, although, knock on wood, Texas has not been identified as a cause for past outbreaks and we want to keep it that way.

Texas has many different water sources like many other states, which allows for many opportunities for contamination. Texas has groundwater, wells, surface water with lots of rivers and lakes and open canal systems and, of course, municipal water.

All these water sources if not monitored correctly or not assessed correctly can become a source of an outbreak.

Texas also has a variety of climates that require different water needs. We have desert-like conditions and we have tropical conditions. Agriculture is the diverse industry and Texas is diverse state. We have a year-round growing season and grow a wide variety of produce. We have a different, very different farms from different farm sizes and these farms have different water sources.

All these scenarios play a very important role in produce safety and we had to be prepared for all of these scenarios and that's why ag water and its assessment and management is very important to food safety.

MS. CASSENS: Both of you, excellent points there. Richard, the next question I'm going ask you, and this is sort of a bit of a crystal ball question, but what is your initial impression of the proposed rule? And, Richard, we'll start with you and go to Abbey.

MR. DE LOS SANTOS: Okay. To us, the proposed rule focuses on understanding and knowing your water system. It puts the control back in the

hands of the grower. You know, we know we all know that Produce Safety Rule is about knowing your production system and identifying risks and mitigating those risks before they become a public health issue. When you know your water system, you can identify potential threats and address them before they can cause issues when even the unexpected happens. If adopted, it's important for growers to take the time to evaluate and conduct an assessment on their water systems and make the necessary changes, improvements, and modifications the water systems, but most importantly, understand why these changes need to be made, not just check it off as something that needs to be done.

A common phrase that everybody uses across the country, across the world, is know your water. If you understand the reason behind the changes and improvements and modifications of your water systems and how it relates to the water quality on your farm and produce safety, you can be in a better position to mitigate these risks due to water, especially if something were to happen. It's an adaptive standard.

So you can adjust your water sources and your water needs and it gives you the option to extend out into (inaudible) if a grower up can provide testing treatment, a four-day withholding time. So with all these different options within the proposed rule and with the appropriate accountability, these schemes can work and this can be an asset to the farms to be able to really understand their water systems.

MS. CASSENS: Excellent. Abbey, anything to add to Richard's comments?

MS. WILLARD: Yeah, I do have a few thoughts. I mean, I think first off, as we've read through the proposed rule, there's great appreciation that FDA listens to the feedback over the last five or six years about making Subpart E easier to implement while also remaining protective of public health.

So it feels like the proposed rule is moving in a good direction. It's more flexible than the singular approach of the water testing requirement in the old rule. It provides examples of some recent outbreaks related to water use that are helpful and provides some insightful background into FDA thinking.

And the rule gives growers more options, additional control and the ability to preemptively prepare for situations. But with that increased flexibility comes some added complexity and lots of room for circumstantial interpretation, a bit of what Richard addressed earlier.

So I wanted to just share a few thoughts that we've had that are sort of some background conditions that have been valuable for us in beginning to understand and just sort of sort through the proposed rule. And really thanks to my staff who have kind of assembled many, many of these ideas.

So the first is that, at least in the state of Vermont, and I suspect across the country, we acknowledge that livestock operations, development and produce operations can and must exist on the same landscape within our communities. And that these activities will continue to occur in close proximity for many reasons but mostly based upon the fact that our best agricultural soils are in our valleys along waterways and both livestock and produce operations need to access water. And that's often a surface

water source, at least in our state. And that's where our existing community and farm infrastructure lies and it's already built up in these areas.

We also acknowledge that the produce growers and industry is busy. And as Richard said, it's really important to be thinking about water source risks and mitigation strategies as a result of their responsibility for providing a safe food product.

The risk mitigation and evaluation of likely hazards does require knowledge of our water and the watershed and the conditions that may introduce known hazards into the system. And as Richard said, it is the responsibility of the grower to understand their ag water sources and embrace the use and management once the water is on the farm.

But we do foresee some challenges for growers to accurately identify the likelihood and the severity of conditions that could introduce the hazard and then to successfully mitigate all the risk factors influencing their ag water sources.

So two things that have been really helpful for me in sort of trying to dissect and better

understand the proposed rule are two acknowledgments. The first acknowledgement that there's two aspects of ag water, there's source and use. And so the source being where the water comes from, in many cases, maybe outside of the growers' control and they'll need to understand the potential risk of that source and that could require some upstream or some watershed assessment.

Use, on the other hand, is how the water is treated once it reaches the pump or the pipe and is within the control and influence of the grower. The use of the water will require a plan for how to use it, is it safe to apply during harvestable portions of the crop, and when to maintain control and safety. So just really thinking about ag water as both the source and the use.

And then acknowledging that there's two steps in this ag water assessment process and the first step being the conducting of the assessment and identification of the potential hazards that may exist and/or influencing that water source -- that ag water source. And then the second piece, which is the

evaluation of that assessment to determine which steps, if any, are needed to mitigate the potential hazards identified in the assessment.

And again, I feel like it's helpful to recognize that there's sort of these two components to how the ag water assessments are going to be implemented and then, you know, as regulatory agencies have the responsibility to enforce and engage compliance around. Those are our first kind of first step reactions.

MS. CASSENS: Both of you, excellent, excellent comments. You know I sit out here in California and I have to admit as District Director for San Francisco District, at the time I had way too much experience maybe with outbreaks related to possible water issues and just trying to get our arms around that. And then you look across the country and having traveled with Mike Taylor back in 2010, 2011, agriculture across the country is quite different. And when we're talking about things that fall under the Produce Rule, you're looking at like all sorts of sources for water and I appreciate greatly -- I'm an

old farm girl from Iowa way in the beginning, so I understand that and I think you're thinking is very good.

It sounds to me you're telling me that the rule is flexible, at least we've made it flexible, and if I got that wrong, please correct me. But I want to turn something to training right now because we all know training so crucial and get an idea from both of you. What hurdles or challenges do you foresee with, not just training our growers, but also training our inspectors? So if you can touch on both of those and, Abbey, I think I'm going to start with you and then we'll go to Richard.

MS. WILLARD: Sure. So I think some of the challenges from the grower's perspective will be the complexity in identifying the potential hazards and determining whether a hazard is reasonably likely to contaminate the produce that that grower is responsible for. And I think specifically those ag water assessments on surface water sources are going to be more complex. I think it's going to require this knowledge of upstream or adjacent hazards and as

I mentioned, being outside of the growers control likely. And we have some ideas on some of the technical assistance or ag water assessment hazard mapping assistance that may be helpful and maybe even potentially supported through the cooperative agreements that exist with grantees.

I think it's going to be time consuming to conduct the ag water assessment, which is challenging for an industry that's already very busy, especially in the Northeast where they have a shortened window of a growing season and where all those activities of preparation, production, marketing, and sales happens during a few months of the year.

And then the implementation of that evaluation stage to determine which mitigation steps are best to utilize in the circumstance given the conditions that the water source is experiencing.

And I think it'll be interesting to see the online training tool that FDA is proposing to be developed or something similar that could be user friendly. I worry that it's going to be difficult to have one option of a tool for such a diverse industry

and with so many unexpected circumstances that could arise and I'm sure we'll touch on some of those at some point in this panel, and really thinking about the opportunity to educate the industry through some ongoing training, whether that's through the Produce Safety Alliance partnership, some updated curriculum on ag water assessment requirements and scenarios.

So those are some of the hurdles I think that growers are likely to experience. From the regulator and inspector side, there's three points that I thought I would make. One was is generally determining how all the grower conditions are being considered when implementing the mitigation steps. So there's just a lot of nuance and detail that's happening in the thinking of the farm and on the ground that will be challenging, I think, for the inspection staff to have awareness of. And because the ag water assessments are so subjective, I think it's going to make assessing compliance difficult. And then lastly, just offer that there's a need for guidance to accompany a final rule that will better define some of the ambiguous terms in the proposed

bill language -- or proposed rule language and offer some suitable examples of how to assess and best advise growers if they look to implement it.

MS. CASSENS: I mean I'm going to add just a follow-up question, so, Richard, you may want to jot it down in your memory because I'll ask you to address it to, but is there value for training growers and inspectors together on some of these components? And have we considered that or have you considered that?

MS. WILLARD: That's a great question, Barbara. I think there's a component of that that does make sense especially because of the dynamic nature of the assessment and the evaluation of what mitigation strategies and plans to put in place. I can imagine that there would be value in the regulating inspection staff hearing and engaging with the growers on some of the circumstances and conditions that they will be addressing and vice versa for the growers to know the type of backup or plan documentation that an inspector may be looking for.

So I feel like because this is such a, this is a whole new component to the Produce Safety Rule

and it really feels like on some level, a whole new regulatory component, that there will be significant questions and uncertainty and probably confusion at times. And so having both the growers and the inspection and program staff on the same page attending some of the same conversations I think could be really valuable.

MS. CASSENS: Richard, your thoughts on training both the growers and the regulators?

MR. DE LOS SANTOS: Okay, okay. I think the biggest thing that growers are initially going to have with training growers is training them on where do they start? And where do you where start conducting your assessment? Will you follow your water to conduct your assessment? If you're using a well, it's easy -- but if you're using well water, it's easy. But if a large part of the irrigation system comes from a canal that is miles, miles long or comes directly from the river that is hundreds of miles long, where do you begin? What is the grower responsible for? So training them for that aspect of it is very important.

Abbey mentioned upstream and the source versus use. That's going to be, again, a difficult training scenario for them and it will be time consuming uh to do that. And do these growers have the time to do that?

Something else is, you know, I've been on the farm for years, I've been in agriculture for over 40 years and I've seen a lot of things and growers have a lot of unexpected things that happened on their farms. So how do you train these growers for these unexpected circumstances? How do you train growers to account for leaks that turn non-ag water into ag water? You know I've been on farms where in the middle of watermelon field, you see the drip irrigation lying there busted and spraying water all over, all over the watermelons. Now, how do you train a grower to prepare for that? I've seen the same thing in citrus fields where irrigation breaks and sprays water onto the trees so that now becomes ag water that they weren't accounting for.

So those things need to be addressed and train those growers to look into those things, even

though it is not something that they think about all the time.

Another is a lot of growers are used to third-party audits. A lot of growers are used to check off. And if they check off these 10 things, they're going to pass their assessment. Assessing your water and training the grower to do that is not going to be able to be a check off. It's going to have to be something that the grower really has to understand.

And another thing, as mentioned a little earlier, is finding the time for the training. Growers -- we've all been on farms. They're, they're so busy. There's not enough hours in the days for these growers to get all their work done. Now, we're asking them to take some time to train with them for an assessment when they could have done something when they know their water is safe. So those are the things and we're just adding one more task that may be overwhelming to the grower.

The inspectors, it's much the -- even though the rule I think is flexible, I do think that these

growers are going to have to think -- use critical thinking on the complex subject while conducting these assessments. And to make sure that, you know, we need to meet the needs of the standard, inspectors are going to have to understand many different water systems not and how they interact with each commodity. And I mentioned earlier, there's so many different farms out there that use different types of irrigation systems for an inspector to be trained and really understand how these different systems work to be able to assess that that grow correctly and make sure the grower is doing it the right way, is going require a lot of time, a lot of training. And in states as big as Texas, when you have so many different types of farms and water systems out there, it's going to be a complex task for these inspectors to really learn that. This are annual reviews, but if a grower has a water system that supplies multiple commodities growing across multiple growing seasons an inspector will really need to understand how they all interact. And does that assessment address all the challenges that farm is going to be experiencing dealing with

that water system?

So you asked earlier about if growers and inspectors should train together? I always believe in in face-to-face and these opportunities for them to mingle and interact and ask the questions, go over the FDA tool they're working on and things like that to help understand at a high level what is expected from the assessments, I do believe that the grower will be able to understanding more one-on-one on their farm, walking through that assessment with the inspector, to be able to ask those questions that pertain to his farm and to his system helps him understand it better. So it's a little bit of both, a little bit of being together in a conference environment and then again, you know, one-on-one, that's where we've had the most success is being one-on-one with the grower on their farm where they're most comfortable and where they can see it face-to-face.

MS. CASSENS: Great, great comments on that and I totally agree from what I've experienced in the field as well is we learn from each other. And when we're dealing with it one-on-one the conversations are

very rich and we need to keep those rich. So I'm going ask you my final question here. Richard, I think I'm starting with you. That's right. So this is going to be one of these things. If you could change one component of the proposed rule as it is now, what would it be and why?

MR. DE LOS SANTOS: Good question. I do believe the way the rule is, proposed rule is written, it's going to be beneficial for growers and it's going to be beneficial for the consumers and those that consume the produce, because that's our end goal to keep the consumer safe.

If there was one thing that I change, it would probably be the area of annual, especially down in the area where you have growers growing so many different commodities in different times of the year. If was twice a year or sometimes even three times a year conducting these assessments, these water assessments on your system, I think it would be very beneficial especially when you have different commodities, one growing during the summertime when it's hot and has its needs there and then others --

leafy greens growing in the wintertime down here in south Texas where the needs of that are much different than the watermelons growing in the summer. So I think a grower to really understand his water system and how it's being used on his farm, it's going to have to be done a couple of times a year.

MS. CASSENS: Take it off mute here, Barbara. Abbey, would you like to add to that?

MS. WILLARD: Yeah, I thought for a moment that my internet was unstable because I could see that your lips were moving. I just couldn't hear you, Barbara. I think there are some components of the proposed rule that remain a bit unclear and I'd love to, you know, if I had the ability to update or change, it would be to better explain or provide support for how farms -- so how farms would identify those potential hazards and how a farm would determine whether a hazard is reasonably liked -- likely to contaminate produce. And, you know, as we've said, the assessment process and the mitigation decision making is going to be difficult and sometimes very time consuming and feel unrealistic for certain

growers based upon the knowledge that they may or may not have of adjacent land uses and water sources that that they don't have complete kind of protected control over.

So I have a, you know, I and our program has a worry of the expectation that growers will be able to sufficiently perform an ag water assessment. They're not typically food safety specialists that are trained in hazard identification and they may simply fail to identify some of the potential hazards while performing the ag water assessment because of a lack of expertise or time. And so, you know, a solution that we've started to talk about and think about would be the technical assistance that could be made available to farms on how to evaluate the assessment and identify what mitigation steps are needed to address and ameliorate any of those potential hazards and that could be, you know, an on-farm readiness review like free compliance assistance visit and capacity within state programs to recognize that farms are going to need some GIS mapping, you know.

So we did a quick little experiment and had

one of our inspection staff look at five produce farms and looked at the potential hazards that may exist, knowing that they -- knowing where their irrigation pump pipe was and that it's quite an exercise to be able to look at an aerial photo, look at the upstream land uses, identify where there's agricultural land, which agricultural land has livestock, where there's municipal development and possible wastewater treatment facilities, important components of conducting an ag water assessment at least for a surface water source. And it takes an expertise and access to resources and capacity that I'm not sure that most growers are going to have the capability to do.

And so I think there's a real opportunity to identify and explore some of those technical assistance options that we can make available to growers.

MS. CASSENS: And what I'm hearing from both of you, it's going to take resources, as we already know, human resources, financial resources to roll this out and implement it appropriately.

Any last comments before we turn this back to Cathy? Any last thoughts?

MR. DE LOS SANTOS: No, none for me, thank you. I thank you for the opportunity to speak.

MS. WILLARD: Yeah, I guess the last thing I'd say is I think just this general acknowledgement that we all recognize that it's producers, consumers, and communities that have this shared responsibility for safe food and water. And this is a great step in the direction of engaging farms in that conversation through ag water. So, thanks.

MS. CASSENS: Awesome. Abbey and Richard, you've been phenomenal in sharing your wisdom, your knowledge, your experience and I thank you very much for joining this panel. Cathy, back to you.

MS. MCDERMOTT: Thank you. Thank you Abbey and Richard. Your perspective as our state regulatory partners is very important. We really thank you for participating today. And thank you, Barbara, for moderating. Now I'd like to introduce our second panel of stakeholders which will be moderated by Samir Assar, our Director of Division of Produce Safety.

DR. ASSAR: Hello everyone. And I'll wait for the rest of our panelists to be on camera. And I'll just start off by saying that was a wonderful panel that Barbara Cassens moderated. It was great to hear about both Abbey and Richard's perspectives. They touched on some very important things that we are definitely aware of and have been aware of throughout this kind of the development of the proposed rule and we're going to hear probably more about this from the next panel. And it really is my pleasure to be able to moderate another panel for the second public meeting with our external stakeholders.

And I've had the, I've had the pleasure of working with some of the panelists here and I know how, you know, they are, they are very passionate about food safety. They believe in in food safety and so it will be really interesting to hear from their perspective. I have with me Jennifer McEntire, who is the Chief of Food safety and Regulatory Affairs at the International Fresh Produce Association. Hey,

Jennifer. I have Hilary Thesmar and she is the Vice President of the Food Safety Programs at the Food Industry Association. Hello, Hilary. And I have Roger Noonan, who is the President of the New England Farmers Union. I also have Michael Hansen, who is a Senior Scientist with the Consumers Union. So hello Roger and hello, Michael. Thank you for joining us.

MR. NOONAN: Hello.

DR. HANSEN: Thank you.

DR. ASSAR: I really, yeah, I do appreciate the time that you're taking with us and, you know, I gave you some brief introductions about the organizations that you represent and your work, but I would encourage the public meeting participants to go to the speaker bios that are, that are linked to the FDA public meeting webpage is what it's called. So please go there to find out more about your panelists. I'm going to go ahead and kick off by asking some questions and, Jennifer, I'm going to put you on the on the spot first. IFPA, International Fresh Produce Association touts itself as being one of the most diverse international associations serving the entire

fresh produce and floral supply chain and integrating world facing* advocacy and industry facing* support. And so I'd like to hear from you. Why is agriculture water important for food safety?

DR. MCENTIRE: Well, first Samir, thanks so much for having me. I appreciate the opportunity. Yes. So the International Fresh Produce Association does represent the entirety of the global fresh produce supply chain. So we represent the growers who would be directly impacted by this rule, as well as their commercial customers, fresh cut processors, distributors out through retail and food service. So every part of the fresh produce supply chain I think has a invested interest in produce safety.

It starts with the growers. That's where this rule would be focused. And so this is definitely an area of key interest for our association to support the industry and to support produce safety. Produce requires water to grow. Water can be a vehicle of pathogens. We know this. And so it's critical that this component of the rule is solid, useful, beneficial to public health. We also -- we would

really urge FD to finalize it quickly.

So this has been outstanding for many years. It is an important component of the rule. And so we do hope that with the public comments that the agency gets and hearing the consensus around the direction that this proposed rule is taking, that it will be possible to finalize this and we recognize that industry and academia need to step up and continue building the knowledge base for these assessments, implement mitigations, start the education process.

So water is important and just because the rule isn't final right now doesn't mean we shouldn't do anything, but we are looking forward to seeing this rule become finalized.

DR. ASSAR: Great, well, thank you very much, Jennifer. It sounds like you appreciate that we finally have the proposal out and you're looking forward to when we finalize this proposal. And I know that there's a lot that is contingent around that with you and your membership. So we appreciate those comments and absolutely agree that academia and industry is going to have to play an important role as

we move forward with ag water standards as you really have over time. So greatly appreciate those comments. I'll go to you next, Hillary. The same question and you represent retailers who sell to consumers to producers to supply the food as well as a wide variety of companies providing critical services to advance a safer, healthier, and more efficient consumer food safety supply chain. So you represent the retailers. Let me hear your perspective about, you know, why ag water is important for food safety?

DR. THESMAR: Thank you so much and thanks for the opportunity to be here and engage in this important conversation. When consumers shop at our stores, consumers expect the food that they buy is safe. We know this through decades of asking them about food safety and they have an expectation of safety. We also know that consumption of fresh fruits and vegetables and fruits and vegetables of all types are essential for a healthy diet. And from the dietary guidelines, we know that half of our plates should be produce. So the importance of this sector of the food industry is critical and we have to

provide safe products for our customers.

We do know it has been acknowledged that ag water can be a vector for pathogens to contaminate produce. And we've learned a lot since this was originally published and held back a little bit. So we we've learned a lot and we should take those learnings to move forward. We should pay attention to what we've learned in the last, I'll say five or six years. And water is critical. Produce isn't growing without water as was said earlier. So we know that it's really, it's probably one of the most important things to make sure that the produce is safe. And we encourage the FDA to clarify the scope of this rule and the application as we see increases in indoor farming, alternative production environments, we need to make sure that's considered in scope too because water is necessary for all production environments.

DR. ASSAR: Thank you so much, Hillary. I appreciate your comments and you hit on a lot of really good points. You know obviously the goal is for you to basically minimize the risk associated with produce. So make the produce safe. And so we are

absolutely committed to doing that and definitely want to hear more from you and other potential commenters on how to best do that.

And, so I appreciate you mentioning that. And, yeah, the water is, indeed, very critical there are, you know, inherent challenges with agricultural water today. So we've got to account for all of that. And we've got to build an approach that is going to not only, you know, work tomorrow or once the rule becomes final, but also be able to adapt over time to address changes that are happening with respect to this precious resource. So, thank you for that comment, Hilary. And Roger, I'm going turn it over to you. I've had the pleasure of working with you for a number of years. And represent grassroot organizations that work to protect the social and economic well-being of family farmers. So I'd really like to hear from you about why you think ag water is important for food safety?

MR. NOONAN: Well, I think the other speakers have done a good job. I mean we can't grow produce without water. And as many small farmers are

also diversified operations, they may have livestock operations or, you know, other operations besides produce associated with their farms. And so it's critical that they understand the importance of assessing that water system. I don't want to get ahead of the question here, but the water is critical. I live in an area where we're overly abundant in water, including surface water, but other folks are not as blessed with the water we have in the Northeast. I think, you know, what we've gone through here and what nearly a 10-year journey with FSMA is that we've really raised a lot of awareness about that fundamental principle of assuring that the water is of an adequate quality for its intended use. And I think you guys have done a good job of bringing us to a holistic approach in assessing that.

There's certainly lots of details to be worked out here, but I'm confident that, you know, with folks that I've heard on both of these sessions so far, there's a good groundswell of support from our regulators and our research community and our educators and trainers to get this right.

DR. ASSAR: Thank you Roger. You definitely stated a fact at the opening. As far as I know, you can't grow produce without water. So it's true about how critical that water resource is and you are very fortunate that you're living in a region where you don't deal with, you know, water limitations let's say. So that that is really good. And I definitely appreciate your good feed -- your positive feedback about our approach. And also noting, as I think we all will today, we recognize that details need to be sorted out over time and, and so we greatly appreciate that. We will get a chance to talk about that more though. So Michael Hansen, the same question will apply to you and you represent Consumer Reports as an independent, nonprofit member organization empowering and informing consumers and helping policymakers prioritize the rights and interests of consumers in order to shape a truly consumer-driven marketplace. So I'll turn it over to you and let me know why you think ag water is so important for food safety.

DR. HANSEN: Well, as others have said, you know, to grow produce and grow crops and other things,

you need water. And there has been a problem with outbreaks of foodborne illness that have been linked to produce and particularly from a water source. I think two major risks would be the interagency food safety collaboration and that's CDC, FDA, and USDA. You look at their figures and salmonella causes the most illness. And if you look at that data, about 40 percent of all the salmonella illnesses are linked to -- basically to the farm, not so much to animals, but to the plant-based operations. This gets also more important with particularly out west and elsewhere, there have been these outbreaks with E. coli 015787 and again, if you look at the data over, you know, 55 percent of those outbreaks, they're linked to row crops, to seeded, you know, basically to leafy greens. So clearly pathogens can get into the water and those - that risk that has been identified needs to be dealt with because we want to increase consumer confidence in the food supply because we all need to eat more fresh fruits and vegetables. They should be half of our diet, and yet we're not eating as much. And whenever there are these outbreaks, people will

stay away from -- like if there's an outbreak of bagged salads, they'll stay away from that for a while. So we need this to get consumer confidence back. And so I think this rule is a first step toward that, but ag water is clearly, since it can carry pathogens, it needs to be looked at more carefully.

DR. ASSAR: Yes, absolutely, Michael. I definitely appreciate that and the safety of the water, again, really addressing the risk associated with the use of water. You know we're aiming to minimize that risk as much as possible for the reasons that you described. There's certainly public health benefits that will be realized through this proposed rule if it becomes finalized, but we also are very careful that we want to, you know, keep the access, keep availability of this incredibly healthy and nutritious commodity that, that we all should be eating, you know more of. So, definitely, you know a very key point there. And it also speaks to the balancing act that we need to play with respect to rulemaking. How do you how do you address the risk in such a way where you are minimizing the risks

efficiently without overly burdening the community and therefore hindering access to fresh fruits and vegetables, which are important for nutritious diet. Thank you for those perspectives. And I'll go ahead and go on to the next phase. And some of you already have talked about this, but please feel free to expand, elaborate if you would like. And, Michael since you did a good job here with the last response, like all the other panelists have, what are your overall thoughts on the proposed rule?

DR. HANSEN: Well, we have sort of mixed thoughts in this because in the original rule there was a testing component for microbial testing. That's not in there. And so while that's a drawback, we also understand that part of the pushback to this rule was because one size doesn't fit all and there was really a myriad of systems out there. So we're glad that you're taking an overall systems approach and that you will require an agricultural water assessment, but we still think that even though there's multiple different kinds of operations out there that taking a holistic ag water assessment, that a key part of that

is going to have to be at some point testing, right? Because even if you're doing mitigation measures, you have to be able to show that they work and to do that you have to test to actually look for the pathogen.

So what the problem with the initial rule was it had this simple test for ag water, just test for generic E. coli and sometimes that's not what the problem is. So some people might think, oh, there's a simple test I can do and it's a test and check off. Well that's not the proper approach. The proper approach should be to look at the system as a whole and figure out what kind of problems there might be there and then test for those things. So I think this rule does give us increased flexibility, but I think there should be more sort of emphasis on the need for testing at some stage because the initial rules required that and now everything is just being put off to the farmer right and saying you can make all the decisions yourself.

But while it's good that you have an ag water assessment in there, I think that the agency should be saying that a good assessment will have

testing, microbial testing as part of a tool for that. But I'm glad that it's actually taking a larger approach, a more systematic approach and is flexible because as science evolves, as we're able to test things more readily and easily, the risks might change. And just one quick example. Last month there was a recall that had to do with produce grown in a hydroponic system. And they actually used that generic E. coli water test. Right? So they did a simple test. Thinks there was no problem. And it turns out that there were two different species of salmonella that contaminated that produce, that caused for the recall. Now if they had done a holistic assessment, they might have realized that there could be risk for other things and look for that rather than just do you have a simple test there and check off and that's not a good thing. You need to look at it from a more holistic perspective. So I'm glad the rule does that and that it allows for evolution to happen in how we approach these things. Hello?

DR. ASSAR: We could hear you.

DR. HANSEN: But I can't hear Samir.

MR. KAWCZYNSKI: Samir, Let's just make sure you're not muted at the moment. Hold on one second we'll just give Samir a second here. No problem. He's reconnecting his audience. So like I said, there's got to be at least be one little technical glitch or also it wouldn't be a live virtual meeting. So he's coming in now. There you go, how you doing.

DR. ASSAR: Hey can you hear me?

MR. KAWCZYNSKI: Yes, we can. Take it away.

DR. ASSAR: Boy, how frustrating. It just kind of, it just kind of died on me, the signal. And then, yeah, for some reason it wouldn't pick up on the -- it transferred to the computer. So thanks for figuring that out so quickly, Michael. We're back online again. Hey, thank you for the comments, Michael, I greatly appreciate the fact that you pointed out that we do appreciate that we're taking a bigger picture, a holistic approach, a systems-based approach, which is exactly what we were, you know, aiming to do obviously. And we definitely recognize that when you, when you focus on one thing, you only

focus on one thing and you really do need to take a bigger picture look at the system in order to truly understand the risks and what to do about this risks.

You also point out your thoughts about the importance of testing and the role with testing and you feel, it sounds like you feel like it needs to include, you know, a stronger testing regimen recognizing that there's also a need to foster flexibility. So we'd love to hear, you know, any of your thoughts and your comments and I'm not just speaking to you. Obviously, I'm speaking to our public at large here. You know what is the testing that we should be applying? You know what should that look like? What, you know, what are the testing options for us to consider moving forward? We certainly considered one, you know, as we finalized the last rule, the 2015 Rule. So, you know, what is your thinking on another framework that would work and accomplish what you mentioned, Michael, that systems based approach, but building in testing? I'm going to turn it over to Hilary next. Yeah, I just want to hear from you essentially your thoughts, and you kind

of touched on them as well in your opening, what are your thoughts on the proposed rule?

DR. THESMAR: Thank you, Samir. So a lot of thoughts and we're gathering our comments to submit to the docket. So those will go in in April. There's a lot of nuances in the rule that I think we need some some clarity and additional information about. And I'll mention going back to the definition of ag water, what water are we talking about because it's not all water used in food production or produce production. The one thing that caught me in the rule that I think deserves some additional conversation, I heard it mention a couple of times today, is the provision about the investigation or the inspection of the water system and the extent that that water is within the control of the grower. I think that needs some clarity and additional conversation around because it could be considered a loophole that we don't want to be a loophole.

We think it's great that FDA is reaching out to stakeholders and broad stakeholders. So the direct growers of produce who this will impact but then also

the industry that is dependent on that produce, and, you know, even all the way to retailers and consumers. So please continue the outreach and engagement. And we heard loud and clear that it will be kind of that same approach of educate before you regulate and we think that's appropriate. You're going to need a broad outreach program to educate everyone who needs to know about this.

The rule overall, given that it's a systems-based approach and it's flexible, recognizes the variety and the threats of the produce industry. Not all produce is the same. Not all regions that grow produce are the same. And this rule does allow for that flexibility, so that's a very positive move in the right direction.

The guidance is going to be extremely important for growers of different commodities so that they can identify the appropriate hazards and make sure they're not overlooked. And that's a risk. We would have to be mindful of that.

And we also have to consider that ag water is in other farm activities beyond irrigation. It

could be used for pesticide application, for fertilizer, cleaning and sanitizing of the harvest equipment and apply it to food contact surfaces. So this is bigger than just the water we put back in the soil. And I will stop there.

DR. ASSAR: Thank you. Well, definitely appreciate all of those comments, Hillary. Very, very well thought out and again, very helpful to hear more about, you know, through your comments to the docket. And I know others share your thoughts too.

You may have seen me struggling in the background a little bit. I did experience that same issue. I was able to recover again. So just flagging that this might be a thing for my session here. So please bear with us. Alrighty, Roger, you're on deck for the same question. What do you think? What do you think about the role? You, again, had some very positive remarks to say at the opening. Give us your full perspective.

MR. NOONAN: So yeah, sure. I'll give you the bad stuff. Well, I think you've, you know, you've got a systems-based approach, but the system is not

exclusively in the purview of FDA. There are other factors, right, beyond me and produce growing and the regulations I need to comply with. You know we've got, you know, we've got, you know, like animal agriculture. We've got municipal development. Now municipal development, you know, if I'm farming in a suburban or peri-urban area, that would be one of my concerns. If I'm farming in a rural area, you know, my concerns is definitely going be more about animals. And as grower of livestock, a past grower of livestock, I knew that I could go to NRCS and I could learn all kinds of things about managing the water going off of my farm, but I don't, there's not really a lot of resources for me out there on managing water coming on to my farm. So I have, you know, serving as a soil and water conservation district official and cooperating with NRCS, I certainly learned a lot of stuff that's very transferable to the water that I'm using and understanding that. But you know, is that what the average farmer's knowledge bases? You know, I'm certainly not, you know, a food safety scientist like Jennifer and others that we rely on in the

business, but I think it's important to understand that, you know, if we're looking at reasonably foreseeable hazards, reasonably foreseeable to who? And I think that's, to me that's the question. I mean I can go down a whole list of reasonably foreseeable hazards, but is it reasonably foreseeable to a prudent person? What level of knowledge that the farm have? Is that based on my, you know, I mean, how do I really assess that? That said, you know, for those folks that rely on surface water, I'm glad I'm not one of them because you know what surface water is. There are innumerable hazards in surface water. So therefore you may end up with a tendency to want to treat it chemically and that has its own set of risks, some that we know about from the material data safety sheet that goes with those chemicals and the EPA label all the way to the unknown impacts on soil health of long term effects there. So that's my perspective.

But the flexibility you put in this rule to sort of address and tease those things out, like that four-day withholding, to me that's, you know, I don't want to call that a panacea, but I think that's really

critical for small farmers, all farmers, but particularly smaller farmers that may use a variety of water sources. And as we continue this, I think folks will learn more about their water systems.

And I'll tell you, Samir, based on the previous proposal, we had growers already conducting increased testing. They learned a lot about the variability of their water source over time from doing that increased testing. Now, whether or not those metrics are the ones that are going to help stem the next outbreak, they learned about temperature variation, the depth of flow rates and the impacts of, you know, flooding in the hills on their water source. And those, you know, I think that was a good thing. I would, you know, encourage you to keep the door open for that new testing protocol. It's affordable. You know people can afford to implement and I'm sure technology will bring us something pretty soon, maybe not my career span. I agree that is the hope that that magic technology comes out so that we can, again, address the concerns from a safety standpoint and minimize the burden to the growing community. And

definitely appreciate your comments about, you know, the kind of the issues associated with assessing, you know, adjacent nearby land issues as well as, you know, doing hazard identification. Absolutely get your point. You know some growers may be well equipped and knowledgeable in this area, probably very few. But, you know, there are others that just don't know how to do that in an effective way. So you know that really does speak to the importance of technical assistance and training and why that needs to be a part of our regulatory approach moving forward. It's really a dependency.

DR. ASSAR: Last, but certainly not least for this question, Jennifer McEntire, if you could give us your overall thoughts about the proposed rule. I'm definitely anxious to hear.

DR. MCENTIRE: Sure. I agree with what the other panelists have mentioned and, you know, to take it back to the high level, I think compared to the rule that's currently on the books, the 2015 rule, that this is a tremendous improvement. So yes, there are details to be worked out there. I think between

today and the session last week, the public meeting last week, there seems to be remarkable consensus. Everybody seems supportive of this approach of being more holistic, more comprehensive, looking at it as a system, recognizing that testing is a tool, but testing is not an answer. And I think that that is where this approach is just much more capable of taking new information into account as we develop more knowledge as a community and as an individual growers acquire more knowledge to be able to put it to use.

So the old rule is kind of maybe stuck in the past a little bit. The flexibility here, I think is something that, will it take education? Will it take time? Yes, but it's absolutely the right thing to do. It is the right path to go down, even though it will be challenging.

DR. ASSAR: Thank you. Absolutely understand and recognize how challenging it is. It sounds like you definitely appreciate the flexibility and again, are citing the, you know, the need for time to develop the training and to do the training that's needed to fully implement this rule so that everybody

can understand what the expectations are for basically complying with the rule and implementing the rule for food safety. So I appreciate that, Jennifer.

I'm going to come right back to you. What are the lessons learned from over the recent years from implementing other subparts of the Produce Safety Rule that would be relevant to agricultural water? What are your thoughts on that?

DR. MCENTIRE: I think the biggest lesson is around education that education is not one and done, that education is ongoing. It's a process that change won't happen overnight, but saying that something is too hard for growers, I think it's quite insulting to growers. So I have full confidence that with the support with the evolution that this is a continuous improvement kind of process and that we all, growers, the associations, extension agents, those in academia, regulators, we all can play a role in building the system and improving public health. So I think that the biggest learning is in that education piece.

Compared to the other parts of the Produce Safety Rule for which we have had the education

support for implementation, I think that this proposal for ag water is more revolutionary then the other parts of the rule. The other parts of the rules are, you know, kind of codifying gaps. This is taking a different approach and so for as much as we've learned about the need to provide that support, education and training for other parts of the rule, I think that this one will require additional effort, substantially greater effort. But again, at the end of the day, it is the way that we need to move forward. It's the way that the rest of the food industry has moved forward and I recognize there are questions within the produce space now about what is a reasonably foreseeable hazard? How do you judge that? Other parts of the food system have encountered these same types of questions, but over time have kind of calibrated, come to that common understanding of where thresholds are, what triggers are. And so I'm very optimistic that the produce industry will follow along that same path and be able to improve public health and provide safe products.

DR. ASSAR: Thank you so much. You said a

lot of kind things about the proposed rule. You said that it was kind of more modern or more of a modern approach to ag water compared to the 2015 final rule. You even said revolutionary; I'll remember that one. So appreciate those that positive feedback. You also really underscored the importance of with this flexible framework, and you believe it's the right, you know, balance, it sounds like, with this flexible framework, you cite the need for a community-based effort to, you know, make it kind of all fully realized and fully effective. And you cited again, also, I think that it will take some time for all of us to work in the way that it should work in order to again, make it as, you know, effective as possible. So definitely appreciate the comments. And Hilary, I'm going ask you the same exact question. Lessons learned over years of implementing other subparts of the Produce Safety Rule that would be relevant to ag water? Yeah, we really need to know what has worked and what hasn't worked with respect to implementing the Produce Safety Rule and what we should learn from that with agricultural water proposed requirements.

DR. THESMAR: It's a great question. So we've done a lot of work in produce safety. We've worked with the produce industry. We've gone to farms. Our members have reached out to their suppliers and have a lot of requirements in place that are produce safety based and above and beyond Produce Safety Rule based. And the reality is that hazards are overlooked and it might be from a very, very small contingency of the industry and they might be the outliers, but hazards have made it through. And we see this in the public health data. And it's a general perception on farms whose water is assumed to be safe. And I think we have to move past that. Sharing of data and sharing of lessons learned and root cause analysis is absolutely critical to advancing the safety of produce. We have to talk more. We have to share our failures. We have to be open to moving forward and we have to make it acceptable to not harvest the crop if the safety of the water is in question. And that's a tough one and that's going to be a huge shift, but we have to say, you know, it's not worth the risk, it's not worth the

risk of making someone sick if we harvest this crop. It's not worth the money I'm going to get for the crop. It's going to be more expensive if I do harvest it and something's wrong with it. So there's a lot that needs to happen.

The other thing that I think is absolutely critical is research. Research is so important and we have to continue investing in research and we have to use the research to move forward.

So the prevention control strategies, even just the basic plant science research that's ongoing is critical. So our knowledge will continue to advance and we need to be open to those changes in order to improve the safety and protect public health.

So the stakeholders are broad and I'm adding academics and research to this list because of the critical information that they can help us answer these questions, solve these problems, make the product safer.

DR. ASSAR: Thank you so much. You said a lot of really great things in there. You made a good reference to the importance of ag water safety and

implementing, you know, food safety, produce safety, with the recognition that there's certainly a public health cost associated with not, you know, being safe, but there's also an economic cost associated with that, with not taking the measures. It sounds like you're saying that it will be more costly for food safety or farms to not implement produce safety regulations or standards versus if they do. So appreciate those comments and also the need for research and the recognition that, you know, our knowledge base changes over time and we need to account for that in a framework. You know, yes, we based the current thinking on, you know, science. It's a science-based proposal, but we know at the same time that, you know, we're not shutting the door. We need to keep, keep the door open for more, more science to roll in and inform, you know, other things that will help provide clarity and detail about how to really implement and comply with the Produce Safety Rules such that it is effective and not overly burdensome to the community. So thank you for that. Roger, same question to you. Definitely, you know,

you've been on this for it seems like forever. So you definitely have some experience here about lessons learned from implementing other subparts of the Produce Safety Rule that would be relevant to us with respect to agricultural water.

MR. NOONAN: Well, yes, Samir, and I still remember meeting you in Connecticut at that first regional NASDA meeting. You know the primary issue there was water, I mean, that was the big issue and what we saw was, you know, driving people to, you know, maybe drill more wells to sort of avoid. You know, I mean businesses tend to want to take the low cost approach to things. So that's just, you know, that's just the way our system works. And I think there's some part here that will still put some pressure on, you know, folks to change water sources where they can. But I'd say the lessons learned mostly as far as, you know, we've gone through with local food safety collaborative, the tribal cooperative agreement, of course, Produce Safety Alliance, the state cooperative agreements, you could take representatives from each of those groups and

some growers put them in a room, ask them questions about the rule and you will still get different interpretations. And then you'll still get some folks, especially in the grower community, that still lack some fundamental understanding despite, you know, the extensive resources that have been deployed. So that educating while and before regulating, is still, I think, an important mantra. But, you know, I think what we've done here over the 10 years is the people we have reached, we are developing a culture of food safety and this approach, to me, speaks more to developing that culture of food safety, understanding your water source. I mean, heck you can start with Google maps right? Take a look at the neighborhood. You know who's upstream of you? Most of the farmers we're working with and local food safety, collaboratives and farmers in general are smaller scale farmers. They're direct marketing, maybe highly diversified. They may also be organic. And, of course, in organic farms, it's a holistic approach. You know, you're taking a look at the practices on the neighboring lands to mitigate pesticide and other

drift issues. We've got a lot of work to do. I would, you know, I look forward to the next, you know, few years as we, you know, as the rule, you know, becomes final. We have guidance out there and you know that I mean this is a big one. I think we're going have a lot of, you know -- hearing it called HACCP on the farm is kind of, you know, scary to a lot of farmers. It's not, you know, it doesn't state that in the rule, but when you're going through the details, you can, you can kind of wonder if this isn't really where we're sort of headed as far as a regular regulatory framework. And I do have other things to say about some of the challenges later too.

DR. ASSAR: Alright, well, I'll look forward to that one, but I appreciate, I appreciate your comments so far. And again, I think what you did was underscored the need to continue to educate before and while we regulate approach as we have with the Produce Safety Rule as a whole, so greatly appreciate that feedback. You also said that, you know, which was probably the most important thing here is, you know, just taking on food safety, a good solid positive food

safety culture and I couldn't agree with you more on that. It's tough, it's tough to regulate food safety culture, but yeah, it sure would make everyone's lives a lot easier if there was more adoption of a solid food safety culture. So I appreciate that. There are those little things that can be done that can kind of build into a food safety culture that makes a difference.

Michael, you're next. What are your thoughts?

DR. HANSEN: I sort of agree with what a number of the other folks have said. I do think what we've learned in the last 10 years is you do need to take this more holistic or whole systems approach. I think the root cause analysis is actually key so that trying to figure out why something is happening and that usually will end up, I think, leading to more testing. But, also, one thing I do think is important that it's happening more is reaching out to all stakeholders to -- that is farms of all different sizes, not just for example, LGMA. They already have the ag water testing components But many of the small

farms or other folks are not part of that and I like that there is reach out to all the stakeholders, to tribes, to every single level. And I think that coming up with clear guidance documents, will help with all this. And I also think since it has been pushed, trying to have this food safety culture, have it permeate more, I think is a good idea. And I would sort of agree with Roger that it sort of looks like conceptually what is happening is you are basically saying that there now needs to be a sort of HACCP system on farms and all that is, is taking a holistic approach, right? And trying to identify where there might be problems and then figuring out how to deal with those problems. So I think the fact that the, what we've learned in the last few years is even though it's been said for decades, they are this sort of HACCP approach or taking a systems-based approach is finally filtering down to smaller and smaller levels, which is, I think, ultimately a good idea and that's reflected in the rule itself.

DR. ASSAR: Yeah, appreciate this comment. That is absolutely the intent. I'm running into

another issue. Can everybody hear me? Okay, thank you. I, yeah, the holistic approach, looking at it from the big picture, and, you know, and that approach not only -- I mean obviously we're focused on the regulated community, you know, primarily with respect to education training efforts and so forth. However, um, there's also a need, and I would say we've also invested a lot of resources into education and training to the community that may not be regulated by the Produce Safety Rule because they're exempt. It's important for everybody to implement food safety standards and practice, you know, good food safety culture and all of that, no matter, you know, size. So moving forward, our regulatory approach will continue to be that way. We will cover who we can cover. And then we will foster education training, continue to do that for growers that are not covered so that they are also implementing good food safety practices. Appreciate those comments.

I will go ahead and go on to the next question. Hilary, I'm going start with you this time. Based on what you've seen of preharvest agricultural

water use on farms, what do you expect to make (inaudible)to be? Yeah, I'd like to hear. I know you're representing the retail perspective, but I'm sure you have some exposure here as well.

DR. THESMAR: Thanks, Samir. So the first challenge is identifying what agricultural water is and what it's not. The definition in our analysis allows for some level of interpretation. So it's a pretty tight definition and I have it right here in front of me. I'm not going to read the whole thing, but the language that concerns us is, and this is in the Produce Safety Rule, so it's not even part of the proposed language, but water is intended to or is likely to contact covered produce or food contact surfaces and it goes on. So I think who's in, who's out is going to be a huge challenge. Other challenges I think are going to be communication. And this has been mentioned multiple times that communication between the growers and you know, either further processors or distributors, but then also throughout the entire supply chain and then with our other stakeholders, it's going to be critical. We're just

going to have to talk more and make more information known and solve this problem together.

Another one is inspections and this has been mentioned also and we're just not sure how, what this looks like and how it's going to be done. We're huge proponents of risk-based inspections and, and FDA has a history with risk-based inspections. And we would like to see the FDA and the state agencies go in that direction with this rule. But, you know, it's going be hard to, to evaluate the water assessment. There's a lot of subjectivity. So training is critical. We think that training should be open to all stakeholders at the same time to help with that communication piece. So there's, there's a lot of hurdles ahead but we're optimistic that we will have a final rule implemented in the upcoming years.

DR. ASSAR: Wonderful. And we agree we are looking forward to the finalization of this, of this, you know, of this chapter. And so we definitely appreciate all of your help for being here. And it looks like unfortunately through technological glitches and so forth and, and just, you know, really

a robust conversation around the other questions, it looks like we're about out of time. We only have a few minutes left for this session. I wish, I wish we really had more. I know others are chomping at the bit to provide their perspective. So please do provide your perspective and certainly my panelists to the docket. I'll say it again. And I know there will be other opportunities for you also to share your thoughts as well as you have in the past. So I greatly appreciate this opportunity. And I guess I'll just open it up for if there's anyone on the panel, because we do have an extra three or four minutes here, do you have any, you know, anything that you really want to get out there about the agricultural water requirements? Any last parting shots that will be on the public record from any of you? Appreciate that. All right, Michael. Michael had his hand up first. Sorry, Jennifer. Go ahead. Oh, he might be stuck, Michael.

DR. HANSEN: Okay, now it's been turned on. Yes. Actually just one quick thing that I'd like to say is just go back to testing. I do think that the

definition of what makes a good ag water assessment should include testing. And I also think that those testing results, they should be made available to the federal, to the FDA, for example, via inspection. And we also think that inspections can be either virtual or in person. So that means access to any testing data should be able to be done via virtual inspection, if that's what's done, or with the physical inspection.

DR. ASSAR: I appreciate that last comment and again, appreciate all of you for taking the time. I know everyone on this panel is very busy. I appreciate everyone for really participating in this in this session live and I know it'll be watched on YouTube as well. So, thank you all for joining this. Hopefully it was useful and valuable to you. I'm going to turn it back on over to Cathy at this point. So thank you panel.

MS. MCDERMOTT: Well, thank you everyone. Thank you to all our panelists. We truly appreciate you participating in today's public meeting. And thank you to Samir and Barbara again for moderating

the two panel sessions. Great discussions. We will now be taking a 15-minute break and I'll hand it over to Mike.

MR. KAWCZYNSKI: All right with that, since it looks like we are at 1:30, it will take us over to -- actually looks like we will come back at around 1:50, so a 20-minute break. Here we go.

(Off record)

OPEN PUBLIC COMMENTS

MS. MCDERMOTT: Well now we go to our public comment section where we will listen to stakeholder reaction and perspective on the proposed rule on agricultural water. I want to welcome our public comment presenters. Thank you for taking the time to prepare remarks and offer public comment.

This afternoon we have a number of folks ready to give common, please ensure that your situated so that you're ready when you name is called.

I will call each individual by name. They will have three minutes to present their remarks. Be respectful of the time. If you go over three minutes, you will be asked to wrap up and submit your full

comments to the docket. And joining us during that segment will be the FDA subject matter experts who presented today.

At this time we will be starting the public comment process. Our first public comment is Gretchen Wall with the International Fresh Produce Association. Gretchen.

MS. WALL: Good afternoon. My name is Gretchen Wall. I'm the Director of Food Safety and Quality for the International Fresh Produce Association, which represents company from everything that the global produce supply chain. I really appreciate the opportunity to provide comment public comment which builds upon the remarks made by Dr. Emily Griep on behalf of IFPA during the February 14th public meeting.

We commend FDA for moving away from a one-size-fits-all approach to the inclusion of agricultural water assessment, which imparts a more holistic mechanism to identify food safety hazards on farms and in packinghouses. The knowledge of how to conduct a risk assessment is needed to determine the

real impact or severity of the hazard. This will be a fundamental shift in the thinking for the industry.

IFPA is prepared to assist industry by working with our members, commodity-specific associations, extension partners, and other stakeholders to develop resources necessary to guide hazard identification and risk assessment. This includes leveraging existing resources developed by our association, as well as developing new resources such as case studies which can help illustrate the thought processes necessary to conduct the assessment and draft written determinations as required in the proposal.

Similarly, we encourage FDA to continue working with produce organizations and educational institutions to make effective, accurate, science-based resources and educational opportunity available. IFPA recognizes the need to craft flexible language which will allow many different types of produce growers who utilize a diversity of agricultural water sources and application methods, to continue the safe use of water for growing produce crop.

Extending the time between application of ag water and harvest is one way to reduce risk with assumption of reduction of pathogens if they're present over time. FDA's proposed use of four-day minimum preharvest time interval, especially without requiring corresponding data for appropriate decision-making, asserts a level public health protection that's unlikely could be achieved in all areas given the diversity of environmental conditions across the United States. The use of a preharvest application interval as a mitigation measure may be appropriate in certain circumstances, but only with the support from a robust risk assessment and relevant supporting scientific data, much of which currently does not exist for all commodities or environmental conditions.

We commend FDA for working collaboratively with EPA toward developing a protocol for reviewing antimicrobial pesticide products for treatment of agricultural water use. The use of treatment as a mitigation measure to ensure that agricultural water is consistently safe and of adequate sanitary quality for its intended use will require approved products to

be accessible to growers, along with supporting research for their effective application and monitoring.

Currently, growers don't have access to required registered products to meet the microbial criterion proposed, nor has the industry fully addressed the logistical challenges of consistent application of water treatment. IFPA supports the multi-hurdle approach to mitigation and cautions the FDA against asserting that water treatment or any mitigation currently available is a silver bullet especially without access to approved products and supporting science.

IFPA will submit more detail comments to the docket and we appreciate the time today to share our thought on the proposed ag water rule.

MS. MCDERMOTT: Thank you. Our next public comment is Priscilla Rodriguez with the Western Agricultural Processors Association of California.

MS. RODRIGUES: Good morning or afternoon. My name is Priscilla Rodriguez and I am the Director of Regulatory Affairs for the Western Agricultural

Processors Association. We represent tree nut haulers and processors of walnuts, pistachios, pecans, and almonds in California. Thank you for the opportunity to provide public comment today on the proposed changes to the agricultural requirement in the Produce Safety Rule.

Our members handle their products in a responsible manner and have, for many years, used the guidance and tools provided by the FDA as a basis for its practices. We support the new risk-based approach in the proposed agricultural water requirement that would replace the preharvest microbial quality criteria and testing requirements with agricultural water assessments. This approach would offer the necessary flexibility for farms to evaluate a range of factors for individual farm-specific cases using a systems-based approach, unlike the one-size-fits-all approach. This approach is reflective of the vast difference in farm practices based on commodities, water practices, water availability and regions. Allowing the farm to evaluate their water systems and practices to determine the best mitigation measures to

ensure a safe environment will work to help farmers address any hazards based off of their current situation on the farm.

This is a reasonable approach and allows for understanding, less confusion, and less burdensome on the ag industry.

Finally, while this is a significant move forward for the proposed ag water requirement, we encourage the FDA to continue to work with stakeholders as we move towards implementation and focus on providing training and support for farms.

In closing, we would want to reiterate our appreciation of FDA's commitment to listening and working with stakeholders. I appreciate the opportunity to provide comment and we will be providing additional detailed written comments about some concerns in areas that may need clarity and some suggestion. Thank you.

MS. MCDERMOTT: Thank you. Our next public commenter is Gina Nicholson Kramer with the Center for Foodborne Illness Research and Prevention at the Ohio State University.

MS. KRAMER: Good afternoon. As you heard, my name is Gina Nicholson Kramer and I'm the Associate Director of Partnerships in Learning at the Center for Foodborne Illness Research and Prevention at the Ohio State University.

Our goal is to translate science and data coming from research to make change to prevent foodborne disease.

First, I'd like to thank FDA for providing stakeholders a platform to openly comment on the proposed rule change to Subpart E of the Produce Safety Rule related to agricultural water. The Center for Foodborne Illness is asking for an extension on this comment period. Due to the complexity of this topic, we will be submitting written comments to the proposed rule change. The Center for Foodborne Illness recognizes that implementation, there are implementation challenges for small growers to test agricultural water as outlined in the original rule. However, the Center requests the FDA reconsider requiring the testing of agricultural water. Testing agricultural water is the best way to assure safe

growing conditions for crops and to limit the contamination of water with biological and chemical contaminants that impact human health.

Regarding the proposed rule, the Center for Foodborne Illness is concerned that completing an accurate risk assessment will be equally challenging for small farms as testing. Proper on-farm risk assessments are a key step in assuring produce safety, especially given the number of outbreaks associated with contaminated agricultural water.

Small farms will need resources and support to navigate the agricultural water assessment. We believe that outreach partnerships and resources are key steps in training small farmers on how to assess the risks on their farms using both water testing and water assessment. Small farms need support and guidance from FDA to complete risk-based agricultural water testing and risk-based water assessments. Thank you for your time and we look forward to further discussions about the Produce Safety Rule.

MS. MCDERMOTT: Thank you. Our next public comment or is Katie Peterschmidt with Parker Farm.

MS. PETERSCHMIDT: Hello and thank you very much for this opportunity. In general, we agree that ag water is too complex for a singular approach. My comments primarily address open source irrigation water because of uncertainties around terms such as risk, safe, and adequate sanitary quality within the regulation, leaving farmers potentially exposed to expensive or time-consuming efforts depending on interpretations of what is reasonably necessary.

Nothing is 100 percent risk-free. I agree with FDA's exemptions for low-risk water. However what does the FDA consider to be medium or high-risk water? The complexity of weighing multiple aspects of an assessment to formulate a conclusion on risk is overwhelming. Just looking at crop characteristics, we are not finding readily available or translatable scientific data for the edible portion of all of our covered crops.

Also, why is establishing the risk of a 200-mile long river's water quality the responsibility of farmers? The following are some difficulties we find within the proposed mitigation measures under 112.45.

Measure 2: Spray irrigation and harvesting often occur daily for the viability of the crop not allowing for the proposed minimum four-day interval. This leads us back to water testing and using that MWQP calculator by UC Davis to analyze if a one-day interval is justified.

Measure 3: How does the farmer find and translate science on microbial die off and storage considering specific crop characteristics and their necessary postharvest activities such as dump tank, spray bar, hydrocooling and slush ice injection?

No. 4: We estimate about $1000 per acre for filtration and pipe when changing to a drip irrigation system, plus many other monetary and operational considerations.

No. 5: Overhead spray irrigation pumps an average of 1000 gallons per minute per pivot. A 1000-acre farm attempting to treat overhead spray irrigation would spend six to seven figures on chemicals alone per year.

Finding science that can justify alternative mitigation measures sounds more daunting and extensive

than the scientific justification involved in HACCP programs. Does the FDA foresee that farmers will need weeks-long training in order to ID risk and determine when to pull the trigger on a mitigation measure?

In conclusion, farmers desire to do the right thing in order to provide fresh, high-quality and safe food to our customers. My take away from the Ag Water Summit of 2018, was that farmers wanted assurance that the EPA study on directly ingesting recreational water was reasonably applicable to establish a threshold for all types of irrigation water. If farmers are to conduct expensive or time-consuming changes to their operations, it should be based upon science that is readily available, easily translatable and directly applicable to its intended use.

Thank you very much for your time and consideration. We appreciate FDA's willingness to listen to farmers.

MS. MCDERMOTT: Thank you. And our last public commenter is Paula Fisher from the state of Florida.

MS. FISHER: Good afternoon. I'm Paula Fisher. I 've been consulting for food safety on farms since 2007. And while I am Florida-based, I'm a strategic partner with farms and food safety across the country.

After reading through the proposed language and multiple conversations with farmers, the research community and regulators, I agree that the proposed approach for risk-based versus a checklist regulation is the right to shift for the agency to take, but it is disappointing that since FDA took comments in 2018 at the PSA Water Summit, that this as far as the Agency has come in understanding ag water.

The EPA standard for recreational water use is still the best data available. There is very little data specifically for agricultural use. As we have seen over the years, the EPA standard has struggled in agriculture because of the recalls we have experienced.

The proposed changes to this rule give very little, if any, guidance to farmers and how to access water beyond listing possible factors. It puts the

whole of the burden of the overall lack of understanding of ag water on a farmer and while the word "stakeholders" is used multiple times in the language, there is no proposed partnership or information for the farmer when it comes to data or responsibility.

On the 14th of February and again today, Deputy Director Frank Yiannas, Dr. Samir Assar, and Dr. Susan Mayne resounded their views on the vital importance that ag water plays in food safety. I am thankful for that understanding and agree with Dr. Mayne that this is not something we should skip ahead on.

The acknowledgment of the shift to a risk-based approach doesn't make this rule automatically better. I beseech the FDA to take another back and to focus on understanding of ag water before they regulate it. Educate while you regulate is not possible if the agency does not understand what it is regulating to. Please take the time, engage with the scientific community and get this right. I have several questions for today and the rest I'm going to

submit to the docket.

Has the FDA communicated with the EPA on the data that was collected for recreational purposes being used as that the standard for raw produce and vegetables? Has the EPA -- does the EPA have conflicts or responses with this unintended use of their EPA? Why has the EPA been able to develop data standards for water and the FDA not?

Based on the lack of guidance in the proposed rule, FDA is attempting to regulate agriculture to an element the Agency does not yet understand. How has the FDA and other regulatory agencies been successful with this approach in the past? How will the inspectors that are conducting these inspects be trained to a regulation based on so much speculation instead of knowledge?

I look forward to the answer of these questions, the continued discussion and appreciate the opportunity to speak with you today. Thank you.

MS. MCDERMOTT: Thank you. And thank you to all of your comments today and for submitting them. We look forward to your full comments being submitted

to the docket. Thank you, as well, to our subject matter experts. And at this time I would like to offer our subject matter experts the floor if they like to provide any additional thoughts for today.

DR. ASSAR: Thanks, Cathy, and I'm going to spend two or three minutes, again, just appreciating the commenters and what they explained to us in terms of their thinking on the proposed requirements. And so it does sound like in general that there's an appreciation for the flexibility that this approach takes, but there's also, at the same time, recognition that there needs to be tools, education, technical assistance to make it -- to actually have it be implementable in a way that, again, is effective to public health as well as minimally burdensome to the grower, so appreciate all that.

And with respect to the science and engaging with the scientific community. I can absolutely say that leading to the development of this proposed rule, we engaged heavily with the scientific community, including EPA, but we can be made aware of other information that we need to consider in

finalizing the rule. And so we would greatly appreciate any information that you can provide to really bolster the science that we've already utilized to develop this proposed thinking. And, again, the aim is to strike that balance of flexibility where you are able to account for the diversity of operations not only in the United States, but also outside of United States offering for import into the United States. So it is a tricky challenge for the Agency to take that on, to draw that line. And, you know, we need your help to get that right. So thank you for those comments and I will turn it over to any of my other colleagues for commenting.

DR. SMITH: Okay. This is Michelle if I can pilot on top of Samir here. I think that I heard was with general support for the new approach with the heavy emphasis that the devil would be in the details. And some of the comments included really substantive information on what details they think we need the most help on or need to expand to give more help both the growers and regulators. And I totally appreciate that. I'm hoping that we hear a lot more.

I also would like to say that what we do with a regulation is take it so for. And then there additional information that may be really helpful possibly not across the board, but to different kinds of individual situations, operations, et cetera. And that's what guidance is for. And so we have the opportunity to put out guidance on top of the rule to further explain things, to give help to people if they need it. And then as implementation starts and other issues come to light, we can put out fact sheets and do other things.

Another really important part of the big picture, as Diane mentioned, we have education outreach and training infrastructure that we've already put in place for the Produce Safety Rule more generally. And we don't know that things will look like yet for ag water when they are final, but I think will be tapping into a lot of those relationships and continued interaction with scientists, regulators, farming community, consumers moving forward. This is one piece of the puzzle. Even when the rule is finished, we are not done by any way, shape or mean.

Thank you.

MS. DAVIDSON: This is Chelsea, if I can chime in really quickly. I mean from what I have heard from all panels and the commenters today is that everyone truly does recognize the importance of preharvest ag water when it comes to public health and ensuring produce safety, but also that there are certain challenges when establishing a regulatory framework for it. That's something that we been working with you all over the last two years on and even now, we're very much looking for your feedback on what aspects of the proposed rule work, areas where there might be some room for improvement, whether that be to the proposed requirements themselves, or even beyond that such as establishing guidance and education outreach activity and things like that.

I'll just echo what Frank said in his opening remarks today. We really do believe it is a gamechanger for food safety, not just in terms of some of the outbreaks that we have seen over the last few years, but also going back decades which has established preharvest ag water as both a source and

route of contamination. I think I'll wrap up by saying that we are really excited to continue to hear feedback from you through meetings like this, as well as comments you submit to the docket so we can develop a rule that is feasible to implement, but also does, importantly, achieve those public health protections.

MS. RAVALIYA: And I'd just like to echo what Chelsea has said that, you know, this is absolutely something that we can consider like a gamechanger. We're looking at a completely different way of approaching assessing risk, looking at it as more of a preventative perspective rather than a reactive perspective. And I think because this is sort of the first iteration of this novel level of thinking, you know, it's going to take some back and forth and it's going to take some development to really think about how best to make this approach applicable across the board while still protecting public health and taking into account available science and evolving science. Again, any way that stakeholders can get information to us that maybe hasn't been considered, please submit that to the

docket. Please share with us. We have access to everything that everyone is taking a look at. We have done what we consider to be an exhaustive review of the available science, but I mean there is always the possibility that we've missed something. So please share. And we look forward to hearing from stakeholders.

DR. DUCHARME: And this is Diane. I'll finish up the comments here from the group. I took a lot of notes on the last public comments and it's moving away from that one size fits all, working with those educational organizations. We keep saying this systems approach, but we've to go teach that systems approach to our growers, incorporating terms that are adequate, safe and reasonably necessary into that system thinking so it's accomplishable by our farms. And make is easily transferable and translatable and having more technical assistance in completing those water assessments. So we're listening. We're taking notes. Please submit your public comments because we will be working with as it evolves. It's important to get it right. You heard the value of knowing what

water quality is on a farm. So thank you all for being with us today, sharing with us your thoughts. Back to you Cathy.

MS. MCDERMOTT: All right. Thank you all for your thoughts and thank you for the great presentations you did today.

So at this time, we will hear closing comments from Dr. Susan Mayne, who is the Director of the FDA Center for Food Safety and Applied Nutrition.

CLOSING COMMENTS

DR. MAYNE: Good evening, everyone. I know after a long day, many of you are eager to log off and see your loved ones. So I will try to keep my remarks brief. First, we appreciate all of you for taking the time, not just today, but over the last several years to discuss the very important topic of agricultural water safety.

Since finalizing the Produce Safety Rule, many of you have shared feedback that certain agricultural water requirements in the final bill were complex and challenging to implement. We appreciate the feedback and have spent time having meaningful

engagements with many of you: farmers, industry association, consumer groups, academia, other scientists, state partners and more, to unpack this incredibly complex issue.

You have welcomed us onto your farms and into your community. You have joined us in discussions. You've submitted comments and engaged with us in other ways. And I think this is an issue we can all agree we need to address in a way that works for everyone while protecting public health.

The proposal discussed today is a reflection of our engagement over the last several years. And during this rulemaking process, we are determined to continue to listen to your thoughts and concerns and then work to develop final requirements that protect public health while meeting the needs of the agricultural community.

We know, perhaps more than ever, that this rule is very much critical to achieving the public health benefits envisioned by FSMA. Recent outbreak investigations have continued to point to agricultural water as a potential factor contributing to produce

contamination. Those same investigations have also enhanced our understanding of how preharvest agricultural water can become contaminated and contaminate produce.

The proposed rule is built on the lessons we have learned, but it's also flexible. So as we learn more information through studies and outbreak investigations, interactions with growers and as science evolves, we will evolve with it to ensure that the water used to grow produce continues to be as safe as possible. Today you also heard about our commitment to helping stakeholders understand the proposed requirements. One way we aim to do this is through our work in developing the online tool you heard about earlier. While agricultural water assessments were identified as a promising approach during outreach activities, we also heard loud and clear that farmers would need additional educational tool to support those assessments.

We are excited to offer this resource as we believe it will be extremely useful in helping stakeholders understand the proposed requirement. As

you heard, we're hoping to roll out a version of the tool that is based on the proposed requirements soon. Once available we welcome feedback from all stakeholders.

We also recognize that our state partners are often the boots on the ground. We appreciate the responsibility that they will carry incorporating this requirement if finalized into their produce safety programs, helping farms to implement them and verifying compliance through inspection. We plan to work with them every step of the way and like before, feedback is going to be essential to ensuring this rulemaking is as successful as it can be.

To close, I want to remind everyone to please comment on the proposed rule so that we can consider your input as we develop the final rule. We know, even after reading through the proposal and listening to the presentations today, many of you may still have questions. We have a mailbox available were questions can be sent, agwater@fda.hhs.gov, and a team is monitoring that mailbox daily. While we will do our best to answer all questions to the best of our

ability, there may be times where, because this is an open rulemaking, we won't have the answers just yet or we legally can't say more during this deliberative phase of the rulemaking. We know this might feel frustrating but we aren't at the finish line.

So this is your time to share data, experiences, thoughts, and concern. It is your time to share your thoughts on how you would like to see the FDA tackle compliance and implementation of this rule. We don't want to skip ahead through this important process and make interpretations about a rule before it is final. So even if you are reaching out to us separately, I really do encourage you to also submit your questions and thoughts the docket, which will be open until April 5th.

I want to thank you all for joining us or today's discussion. And I hope you all enjoy your evenings with their loved ones.

MS. MCDERMOTT: Thank you, Dr. Mayne, for your remarks. And with that, this ends our public meeting. Thank you for joining us today. Enjoy the remainder of your afternoon. Thank you.

(Whereupon, at 2:20 p.m., the proceeding was concluded)

CERTIFICATE OF NOTARY PUBLIC

I, IRENE GRAY, the officer before whom the foregoing proceedings were taken, do hereby certify that any witness(es) in the foregoing proceedings, prior to testifying, were duly sworn; that the proceedings were recorded by me and thereafter reduced to typewriting by a qualified transcriptionist; that said digital audio recording of said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

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IRENE GRAY

Notary Public in and for the

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I, SONYA LEDANSKI HYDE, do hereby certify that this transcript was prepared from the digital audio recording of the foregoing proceeding, that said transcript is a true and accurate record of the proceedings to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

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SONYA LEDANSKI HYDE