

STANDARDS FOR THE GROWING, HARVESTING, PACKING AND  
HOLDING OF PRODUCE FOR HUMAN CONSUMPTION RELATING TO  
AGRICULTURAL WATER

**Public Meeting**

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R E C O R D I N G

MR. KAWCZYNSKI: Good morning, good evening, all depends on where you're joining us from. Welcome to the FDA Agricultural Water Proposal Public meeting. We'll get started here at the top of the hour, so about two minutes. My name is Mike Kawczynski. I will be monitoring today's live meeting and again, as I do say, it is a live meeting, so every once in a while, to all my presenters and all that, as you know the rules let's try to keep those cameras off and muted until it's your turn to speak.

If we do run into any technical glitches or if the panelists need a reminder, that's when you'll hear me jump in. There is a lot of elements to today's meeting and we will get started here in about one minute and we should end somewhere around 6:00 this evening. So I really do appreciate your time and, like I said, in one minute I will hand it off to my colleague Cathy McDermott.

All right. Welcome to the Agricultural Water Proposed Rule Public Meeting. I am Mike Kawczynski and let's get this ball rolling. Again, this is a

live meeting, so I'd like to hand it off to my colleague Cathy McDermott who is going to kick us off. Cathy, take it away.

MS. MCDERMOTT: Thank you, Mike. Welcome to today's FDA public meeting, the standards for the growing, harvesting, packing, and holding of produce for human consumption agricultural water requirements proposed rule.

As Mike mentioned, my name is Cathy McDermott and I'll be moderating today's public meeting and I'd really like to thank all of you for joining us today. The purpose of this public meeting is to discuss the proposed rule on agricultural water which was issued under the FDA Food Safety Modernization Act.

These public meetings are intended to facilitate and 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. The public meeting agenda, speakers biographies and a document entitled

"how to comment" are posted on the FDA website on the meetings page. The public meeting is being transcribed and recorded and will be posted to the public meetings page on FDA's website.

The slides will also be posted. The transcript typically takes a little longer, perhaps a few weeks, and any other questions on the proposed rule we do encourage you to submit them to our mailbox which is [agwater@fda.hhs.gov](mailto: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.

MR. YIANNAS: Thank you for being here today to discuss FDA's proposed rule to revise certain agricultural water requirements. As someone who has spent three decades 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 and to further protect consumers. Now, before we begin, I know these are challenging and busy times for

everyone, so 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 agricultural water.

This 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 feel so strongly about this that I've said, this proposed rule, if finalized, will be a game-changer when it comes to the safety of fresh produce.

That's right, a game-changer to advancing the safety of fresh produce. I'll say more about this in just a moment.

The proposed rule we'll be discussing today would require farms to conduct comprehensive assessments that would help them identify and mitigate hazards in their pre-harvest water used to grow produce.

If finalized, it would replace some of the existing quality and testing requirements for pre-harvest agricultural water for produce, other than sprouts, under the Produce Safety Rule.

Now, right at the outset, let me tackle a question I often receive. It's this question, Frank, why has this taken so long?

Listen, I hear your concern and I know it has taken us a long time to reach this point, but I can assure you that it was time that was needed and well spent.

We have worked closely with farmers and other stakeholders to ensure that the standards we propose are ones that are workable and improve produce safety. We want to get this right. No, 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 - offer a path forward that we believe is both practical and feasible for growers and protective. of public health.

As you will hear, this isn't a one-size-fits-all approach. We have considered the wide diversity of water sources and wide diversity 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 has been clear since we started these conversations that, no matter whether you're in a government office or standing in a field of leafy greens, our goal is the same: To keep produce safe for the benefit of consumers everywhere.

Today, you are going to be hearing a lot more about this proposed rule from my colleagues in FDA, as well as from other experts in the public and private sector.

You'll be hearing a lot about the "what". What's in the proposed rule, what do people like about it, what opportunities are there for improvement, and so on. The what.

But before I leave you to get on this with this important conversation, I'd like to share my thoughts on the "why" of this proposal. In other

words, just WHY do I believe this proposed rule 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. This idea of safe water dates to antiquity. Now, in the 21<sup>st</sup> 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 the water used in agricultural food production be safe too.

Think about it, all of food production relies on water, whether it's seafood (wild and aquaculture), livestock production, or produce.

And when it comes to fresh produce, this is critically important, because many fruits and vegetables, if contaminated, will not receive a final "kill step" to eliminate pathogens before they are consumed fresh.

We know how important fresh fruits and vegetables are to an overall healthy diet and, for



that reason, we want Americans to eat more fresh produce -- not less.

And we recognize that when you consider just how much fresh produce is consumed every day by American families, literally millions of servings, the vast majority of those fresh fruits and vegetables served are safe.

That said, we also know that when outbreaks of foodborne illness occur, they are 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% of foodborne illnesses are associated with produce.

And while produce can become contaminated several different ways, agricultural water can serve as a conduit of the pathogens that have caused produce-related foodborne outbreaks. So, that's why we've proposed this rule - and why - just why - this rule is so important. It's to prevent produce related illnesses, increase consumer confidence, and to help

bend the curve of foodborne illness in this country, once and for all.

Let me give you a second "why" -- why this rule is important. We all know this proposed rule is a critical step in our continued implementation of FSMA. It is 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.

So, many have asked, just "why", why do we 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 pre-harvest 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 application on farms.

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

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

We worked to identify solutions that would be practicable and workable across a variety of operations, while still achieving our public health 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 best to effectively manage pre-harvest ag water quality.

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

We believe this systems-based approach is flexible enough to accommodate a variety of water systems, uses and practices, as well as advancements in agricultural water quality science.

It could help farms manage their agricultural water more effectively and help identify potential sources of contamination on adjacent and nearby lands that might otherwise go unnoticed and unaddressed.

So how are we going to get all of this done if the rule is 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, if finalized.

We'll work with state regulators, the National Association of State Departments of Agriculture, 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 approaches, 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 agricultural water requirements and that produce imported from abroad is held to the same food safety standards as that produced domestically.

If finalized, we're confident this proposal will result in fewer outbreaks in the U.S. related to produce and will further protect public health. Importantly, this proposal demonstrates that we meant what we said when we drafted the foundational rules to implement FSMA.

We said then, and we say now, that food safety is not something 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.

There is a lot the government can do to keep food safe. And there is a lot that industry can do.

But there is so 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.

MR. SUMMERS: Well, thank you, Cathy. And hello, everyone. It's a privilege to be here with you today. The USDA's agricultural marketing service and 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 that everyone who posted and participated in farm visits, who conducted listening sessions and participated in many, many,

many meetings, all of that work has 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 the specialty 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 had worked to achieve a delicate balance ensuring public safety through the prevention of food borne illness while also responding to the growing community's concerns about the feasibility of complying with the proposed water requirements and the complexities surrounding pre harvest water use among other unique water usages.

USDA has worked hard with our partners conducting food safety outreach to help the produce industry prepare for compliance with the Food Safety Modernization Act. The 2021 agriculture water

proposed rules consistent with the approach the agriculture marketing service used. What we designed are good agricultural practices auto program which places an emphasis on risk and water usage. So growers who currently utilize the USDA gap audit programs so 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 something we said consistently since FSMA was passed that, you know, consistent with our approach since food safety modernization was enacted, AMS will always continue to align our audit program requirements to the FDA's regulations.

You know, one of the ways AMS helps the produce industry prepare for compliance is through our partnership with FDA and Cornell University by way of the Produce Safety Alliance. These partnerships enable us for the funds for education and training events.

Through the Produce Safety Alliance, 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 in January and is continuing 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, the Produce Safety Alliance will continue to work with growers and educators to provide training on agriculture water requirements as we move from this proposed rule to a final rule and we thank the members of the Produce Safety Alliance for this partnership and their commitment to assist the produce industry in understanding and implementing the regulations.

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

Agriculture is expanding its food safety outreach program. This initiative provides funds for delivering custom training on FSMA regulations for small to midsized farms, beginning farmers, socially disadvantaged farmers, small processors, and small fresh fruit and vegetable wholesalers.

With AMS, we continue to implement the specialty Crop Block Grant Program. These grants are allocated to state and territories to enhance the competitiveness of specialty crops grown in the United States. Since 2006 when this program began, USDA's 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 at the end of January, last month, we (Inaudible) of \$72 million to be awarded for specialty crop block grants this year. And, you know, AMS will continue to work with our

partners throughout the USDA, the FDA, academic institutions in the industry to ensure specialty crop producers are provided the knowledge, the tools and the resources needed to comply with 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 provided in these opening remarks and thanks to the FDA for doing this very important work for being committed partners to 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 our nation's food system by 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 that the outcome is reflective with a unique and diverse spectrum of American agriculture. And with that, thank you very much, Cathy, for allowing me to

address the group. I hope you all have a great meeting today.

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

MR. ASSAR: Thank you so much, Cathy, and hello everyone out there. My name is Samir Assar, as Cathy mentioned. 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 moving forward.

I greatly appreciate all of your hard work and time over the years and may we be the first to say

that they couldn't do it without so many of you that are out there, that have helped us by informing or thinking along the way, so thank you to helping us get to the point we are today.

I can also speak on behalf of the team by saying it's great to be in this position to propose this systems based approach to ag water that would strike the important balance of achieving our public health goal of minimizing risk from the consumption of produce and at the same time providing flexibility to account for the diverse farming community.

And as you've already heard from Deputy Commissioner Yiannas, this is the most important and challenging section of the rule, produce safety rule as well as, you know, for food safety because of the universal use of water in farming and its role with contributing to outbreaks.

You've heard us say even at the earliest stages of the PSR rule making that we are committed to getting the rule right and you've seen this commitment play out with the complex ag water area as this is our third proposal for ag water which isn't easy for us to

do, to put it lightly, to do this amount of rulemaking. However, we all recognize how necessary it is for FDA to do everything in its power to get it right. And even though we're so happy to be here at this point of the rule making process after so much heavy engagement during the FSMA journey, we know that there is work still left to be done, much more 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.

This is as much your rulemaking as it is FDA's rulemaking and so I'd just encourage you to take advantage of this and any other opportunity that we extend to make sure that we get it right. And with that, I'll hand it over to Kruti Ravaliya to provide an overview of ag water requirements that we issued in 2015 and some important activities that have informed where we are today with a new set of ag water proposed

requirements. You'll hear from me again during the Q&A session and as I moderate a panel. Thank you. And, Kruti.

MS. RAVALIYA: Thank you, Samir. Sorry, I had a mute issue for just a second. Thank you so much, Samir, I appreciate the opportunity to present to everybody this afternoon both on the 2015 produce safety rule requirements to set the stage for where we landed with the notice of proposed rulemaking that was issued at the beginning of December.

So we'll start -- okay, so many of you may remember the requirements that were issued in the final rule of the produce safety rule in 2015 had requirements that were specific to water misuse in the growing of fresh produce, our cultural water. And those requirements involved provisions that were specific to the safe and adequate (Inaudible) quality for that water. It also has provisions around inspection of the water system that's under the farm's control. There were provisions around water treatment if a farm chooses to treat the water. There were requirements around water that -- water testing and

how that testing could be done and then additionally microbial criteria for the water that's being used and there were different purposes identified within those provisions and then also there were corrective measures that were identified in the event that the water, the test results for the water that was being used exceeded the numerical requirements for specific applications. And then there were also requirements around record keeping for those provisions.

For water that's used during the growing, during growing activities for produce other than sprouts, we had previously identified a testing frequency and that testing frequency was dependent on whether the water was a ground water source or an untreated surface water source. For the untreated ground water source there was a lower testing frequency and for untreated surface waters there was a higher testing frequency. And that kind of captured the execution around variability of surface water sources versus ground water sources.

Additionally, there was a requirement around a keeping a microbial water quality profile and so the



data used to inform that profile would be collected over the course of two years but no more than four years to set up an initial profile and then that initial profile would be annually updated with a minimum number of samples to continue to update the water, the profile for that water accommodating the, you know, potential varying nature of that water source.

Under certain conditions, that profile would need to be recharacterized if there were changes that were significant enough and we believe that this profile would enable farms to understand their water source and be able to make appropriate application decisions, management decisions on how best to use that water in the growing of produce other than sprouts.

We also had identified microbial criteria for that profile and so water that's applied during pure harvest activities had two different sets of values that were used in this profile and so one would be the geometric mean and the other would be a (Inaudible) threshold value.

So the geometric mean was 126 or less (Inaudible) and this physical threshold value before ten or less of (Inaudible) per 100 mL. And so those numbers would be the decision making threshold for whether water was acceptable for use or not.

If the water exceeded those numerical values, the geometric mean and the (Inaudible) threshold value, farms would be required to take a corrective measure as soon as possible but no later than the following year. A corrective measure in those requirements could have been something like applying a specific amount of time between the last irrigation and or last application and harvest and/or between harvest and end of storage.

Farms could also apply a calculated log reduction during those activities, post-harvest activities such as commercial washing. Growers would also be required to reinspect the entire affected water system that's under the farm's control among other steps, making changes to ensure that that water meets those criteria.

Growers would also have the option to treat the water and treatment would be required to be done in accordance with the provision, the requirements outlined in those provisions.

For the initial stakeholder engagement that we conducted over the course of 2015 through 2017, FDA conducted a webinar where we had almost 400 participants. FDA estimates discussed significant provisions of the rule and answered questions and so this webinar involved the entirety of the produce safety rule with ag water being one part of the content discussed. And (Inaudible) discussed the regulation of a series of public meetings that were held in the US and abroad.

Between 2016 and 2017, FDA also conducted outreach and education to inform stakeholders about the produce safety rule requirements through speaking engagements, participation in conferences, and those conferences were convened by a broad range of stakeholders.

We also conducted educational farm visits with stake partners across the US. Those farm visits

were across the US varying states. We went to Alaska, Arizona, California, Colorado, Georgia, Maine, Maryland, among other states and through these farm visits together with speaking engagements, conferences, coalition meetings and questions that were submitted to the rule, I mean, submitted to the FMSA technical assistance network, excuse me, FDA gained a really great understanding of the diversity of operations, water systems, and current use practices along with why numerous industry stakeholders found certain provisions in subpart E to be difficult to understand, translate, and implement in their operations.

In particular, the preharvest microbial quality criteria and testing requirements that required farms to establish microbial water quality profile for each water source for non-sprout covered produce.

So recognizing those feedback, FDA, for example, some of that feedback included that the requirements were inflexible, they were imposing a one size fits all approach that's difficult to implement

across the wide variety of sources, uses, and practices that are covered by the rule.

The requirements were also too complicated to understand and implement such as the calculation of the geometric mean and physical threshold value. Additionally, stakeholders found that it was difficult to implement because (Inaudible) farms with multiple preharvest agricultural water sources would be required to establish an individual microbial water quality profile for each agricultural water source.

So in 2017, FDA took action in response to that feedback. FDA announced intent to consider ways to simplify the requirements that were published in 2015 and we also held other stakeholder engagement meetings and two of those meetings would be discussed in further on the subsequent slides. The first was a (Inaudible) trust and Robert Wood Johnson Foundation sponsored collaborative forum and then there was also the Produce Safety Alliance Agricultural Water Summit, both held at the end of 2017 and the beginning of 2018.

We additionally did other educational farm visits, held additional listening sessions, and reviewed comments that were submitted to various dockets.

In 2017, September of 2017, we also issued a compliance date extension to extend the compliance dates for subpart E or (Inaudible), excuse me, to -- for covered produce other than sprouts and this additional time that was allotted by extending the compliance dates was intended to allow consideration of approaches to address those issues as well as to identify opportunities to enhance the flexibility of these requirements beyond those that were reflected in the final rule while continuing to protect public health.

At the collaborative forum that was sponsored by the Pew Charitable Trust and the Robert Wood Johnson Foundation, forum participants identified several possible alternatives for preharvest agricultural water requirements and those included retaining the microbial water quality criteria and testing requirements and issuing companion guidance to

further clarify how to comply and interpretation around those requirements.

Another potential solution included replacing the existing quantitative requirements with a qualitative standard and then issuing a subsequent companion guidance to further clarify. Another option included adopting a private industry standards and guidance as a short term measure while we continue the research on agricultural water and hazards that may be introduced to the agricultural water or another option included performing a multiyear quantitative microbial risk assessment to identify index and/or indicator organisms that can be used to characterize risk associated with agricultural water across a variety of conditions.

Another area that was identified for consideration included a qualitative standard, standards around data sharing, and the need for additional guidance. At the Produce Safety Alliance Water Summit FDA subject matter experts joined more than 250 other participants to discuss implementation

challenges around subpart E which is the subpart relevant to agricultural water.

The summit participants identified several complex factors that were associated with agricultural water including the variability in water source quality, the method of water application to the crop, commodity characteristics that influence vulnerability to contamination and then also regional climatic effects.

Summit participants also identified agricultural water assessments as a promising approach for science-based management decisions that could take the complexities of each farm into account. Participants also recognized that additional educational tools would be needed.

In recent years, there have been a few produce related outbreak investigations and from those investigations we've learned some more about how water can play a role. Those outbreak investigations have highlighted the role that preharvest agricultural water can play as both a contributing factor in the



introduction and as a spreading the source of contamination to cover produce.

Those outbreak investigations also highlighted issues that could be associated with activities that are conducted on adjacent and nearby lands and they also underscored the decades of scientific research on preharvest agricultural water as a potential contributing factor in the introduction and spread of contamination to produce.

So taking all of that feedback into account, FDA found itself with some options to move forward and some of those options included keeping the 2015 requirements as they were published but issuing additional guidance outlining more flexibility may be available and/or appropriate. For example, we considered data sharing and implementations as one category. However, we found that stakeholders indicated that guidance alone could not overcome the difficulties with using and its alternative microbial quality criteria or sampling frequency provision of the produce safety rule and based on that feedback, we

concluded that guidance alone would not be able to address that issue.

A second option that we considered was to conduct a risk assessment and research followed by rule making based on the comments and dialogue at the collaborative forum and stakeholder engagement. We could issue guidance based on preharvest water use on industry standards while research was conducted to develop sufficient scientific information. We also considered the conclusion of the qualitative assessment of risk which included information related to outbreak and other information and also concluded that it's not necessary for FDA to conduct additional risk assessment or issue guidance based on industry standards before conducting a rule making to establish preharvest standards.

We considered an option around retaining the 2015 requirements where the preharvest standards were -- we continued to believe that the existing rule with mandated testing frequency and water standards would, if they were implemented, result in overall improved agricultural water quality and improved public health

but understand that if there is confusion and infeasibility that those would undermine successful implementation of preharvest agricultural water requirements for non-sprout covered produce.

Then in that case, the desired public health improvement is not likely to result. And, lastly, we considered rulemaking to change the preharvest agricultural water requirements. In light of all these things, we concluded that the most appropriate approach would be to undertake rulemaking. And in the next presentation I will go over the proposal that was issued in December.

Again, thank you so much for the opportunity to present to you this afternoon on the contents of the Agricultural Water Notice of Proposed Rulemaking. This proposal focuses on the preharvest agricultural water requirements that have been proposed.

As an overview, this proposal is intended to address stakeholder concerns that are the concerns that were relevant to the complexity and practical implementation challenges with the preharvest

agricultural water testing requirements that were issued in 2015 which is what I just presented on.

This proposal would replace the preharvest microbial quality criteria and testing requirements in the produce safety rule with a systems based preharvest agricultural water assessment. This proposal also adds definitions for agricultural water assessment and agricultural water systems.

Written agricultural water assessments would be conducted once annually and whenever a chance occurs that increases the likelihood that a hazard could be introduced to produce or food contact surfaces. Farms would be required to evaluate factors and determine whether a corrective measure or a mitigation measure might be needed to implement based on the outcomes of that assessment. The proposal also includes expedited mitigation measures that would be required if they're finalized for hazards that are related to certain activities associated with adjacent and nearby land.

The Agricultural Water Assessment is composed of a variety of elements and the following factors

would be required to be within this agricultural water assessment if it's finalized as written. Growers would be required to consider the agricultural water system as a whole, so understanding the location and the nature of the agricultural water source, how that water is distributed and the degree to which the system is protected. So considering all of those factors together will help a grower have a good understanding of where potential risks may lie within the agricultural water system itself.

Growers would also be required to consider how the water is applied to the covered produce. Is it applied via overhead irrigation or is it applied via drip irrigation and then also consider whether or not there is an interval between the last direct application and harvest, considering whether the crop is being grown requires an irrigation or a water application three weeks prior to harvest versus a water application the night before harvest.

And then also whether or not there are any crop characteristics that would make the produce susceptible to surface adhesions or internalization of

potential hazards, so considering the differences between a cantaloupe surface or a tomato and understanding whether or not there may be a rule played by those crop surfaces rather than or in addition to the water that's being used.

The grower would also consider whether or not there are any environmental conditions that may contribute to the introduction of hazards into or onto the systems and so that could include whether or not there is heavy rain, whether there are extreme weather events like droughts, earthquakes tornadoes, whether or not there are higher temperature or lower temperatures and whether or not there is a level of UV exposure.

Growers would also have another, another category within the assessment and as I had talked about in the 2015 requirements, there were codified requirements for testing but you may notice that there are no longer codified requirements for testing microbial quality of water. If a grower chooses to conduct any type of microbial water quality testing, those results of that testing would fall under this

other category and so looking at water from a systems based approach, we recognize that there are a lot of factors that play into water and how it moves through an operation and recognizing that testing may not capture all of the information necessary to make effective management decisions.

So we realize that all of those other elements that I just described around environmental conditions, crop characteristics, the agricultural water sourcing system, those all play a role in helping growers understand how water can present risk and testing is another piece of that puzzle. So growers can use testing to determine whether or not and how a rainfall event may impact their water source but it's not necessarily the only decision making piece that's needed in understanding how to best apply water.

Previous requirements in 2015 were focused around a specific window of time and didn't necessarily accommodate how water may be used in more than -- in ways that are not specific to the time of harvest, so understanding that water can be used in

transplants, setting of the transplants and maybe not necessarily used later on or maybe that water source is not necessarily used later on in the growing season. And so being able to capture information around those different types of water sources is also necessary to be able to understand how risk can be introduced and how hazards can be introduced into the system.

And so we'll talk a little bit more about testing on another slide. But if finalized, these preharvest agricultural water assessments would be written and would require supervisory review of those assessments and determinations that would have to occur based on those assessments.

This proposal also takes into account findings from recent outbreaks, so as I mentioned in the previous presentation, the lessons learned from outbreak investigations in recent years have played a role in how we look at how water plays a part in outbreaks. And so assessing how adjacent land can contribute hazards and water can take those hazards into an operation is also an important piece to



remember. So this assessment would include consideration of adjacent and nearby lands that are related to animal activities, application of biological soil origins and the presence of untreated or improperly treated human waste.

Farms would also consider the nature of the water system and the proximity of adjacent nearby land so that water system as well as the topography of the surrounding land. So there is a lot of information about, you know, the wider perspective of the water and how it is drawn to the farm and how it's used on the farm.

Also considering the effects of fencing, containment, or other measures that are employed to prevent animal access to water sources or distribution systems as well as considering whether there are barriers that might influence runoff sources and distribution systems, so considering earthen diversion burns, ditches, and other types of barriers.

So based on this assessment, a grower would -- there are four options to consider. So if through the assessment a grower determines that the

water is not safe or not of adequate sanitary quality for its intended use, then the grower must immediately discontinue use of that water and take a corrective measure before resuming use of that water for preharvest activities.

In this case, this is, the grower would have to take immediate action. In the subsequent cases, there is a little bit more time in between collection of information and applying an action. So in the next category, there are risks that are identified or hazards that are identified that are related specifically to biological soil amendments of animal origin, animal activity, or untreated or improperly treated human waste. In this case, if hazards are identified that are related to these three specific categories, then a grower must implement mitigation measures promptly and no later than the same growing season.

Next, if a grower identifies that there is a hazard that is not specifically related to the categories around animal activity, biological soil amendments of animal origin, or untreated or

improperly treated human waste, then the grower has two options. The grower may implement the mitigation measure as soon as practicable but no later than the following year or the grower may test the water as a part of the assessment and then use all of the information collected through the assessment and water testing and implement a mitigation measure as needed based on the outcome of that assessment and testing.

So the testing would be used to continue to inform the assessment of any additional data that can be used in the decision making process.

Lastly, if a grower determines that there are no known or reasonably foreseeable hazards for which a mitigation is necessary, then the grower would continue to assess regularly, at least once a year, and adequately maintain the water system.

So this chart looks a little bit complicated. Based on the outcomes that I just described, this flow chart is another representation of that chart. So on the left, if you see the top blue box, the grower would identify the conditions of the assessment, so they would say based on my evaluation of my identified

conditions, factors, inspections and maintenance of my ag water system, so that includes the whole assessment, anything and everything that would be used to inform this assessment, the grower would then follow the decision making tree of this flowchart. So the first decision that we would come to would be whether or not the water is safe or of adequate sanitary quality for its intended use.

If the grower was to answer yes that the water is not safe or not of adequate sanitary quality for its intended use, you go down to the red box. Immediately discontinue the use and apply a corrective measure before resuming use of that water. If the grower says that the water is not -- answers no to the question of the water being not safe or not of an adequate sanitary quality for its intended use, then you would continue on to say -- to determine whether or not there are conditions that are reasonably likely to introduce known or reasonably foreseeable hazards and those would be specific to -- so if you -- then the next question would be specific to adjacent or nearby land.

So first you would determine whether or not there are any conditions. If those conditions are -- if there are no conditions, then you would determine that you continue to inspect and regularly maintain. You see that green box at the bottom in the middle. If you determine that there are hazards, then you would continue to determine whether or not those hazards are specific to animal activity, biological soil amendments of animal origin or untreated or improperly treated human waste.

If you determine that the hazards that are identified are specific to those categories of hazards, then you must implement your mitigation measures promptly and no later than the same growing season. That's the box all the way to the right.

Conversely, if you look at the boxes on the bottom and determine that your hazards are not specifically related or not clearly and directly related to animal activity, biological soil amendments of animal origin, or untreated or improperly treated human waste, you have two options. Those two options again include applying mitigation measures as soon as

practicable, but no later than the following year or apply water testing as part of the assessment as a whole as part of your information gathering process.

If you look at the bottom right yellow box, that's the water testing box and then once you have conducted your testing, you then return to the blue boxes on the left where you would continue to make that decision making process using all of the information that you have captured.

So farms that are going to collect samples and are going to test their water would be required to (Inaudible) collect those water samples immediately prior to or during the growing season and that water must be representative of how the water is being used. The water could be tested for generic e. coli or another scientifically valid indicator organism, index organism, or another analyze that's relevant provided there is information to support its use.

The sampling frequency antimicrobial quality criteria would have to be appropriate to assist in determining alongside these other factors whether or not the mitigation is necessary. And farms could

choose to use a sampling framework antimicrobial quality criteria that were identified in the 2015 produce safety rule. So growers that have data over the last few years that were collected in the way that it's been outlined in the 2015 requirements that data could still be used in the decision making process for this assessment.

Regarding mitigation measures, farms would have the flexibility to choose from a variety of mitigation measures. Those could include making changes as necessary and could include repairs. Growers could also increase the time interval prior to harvest to a minimum of four days unless it was otherwise supported by test results or scientifically valid information. Growers could also increase the time interval between harvest and end of storage and/or conducting other activities such as commercial washing.

Another mitigation could include changing the water application method, treating the water, or taking an alternative measure. Additionally, the proposal identifies a corrective measure, and a

corrective measure is an action that's taken in response to a finding where agricultural water is not safe or not of adequate sanitary quality for its intended use and therefore requires immediate response if a grower wishes to resume use of that water.

We've heard from stakeholders already about confusion around the difference between the mitigation measure and a corrective measure and so the two differences, one is in a more immediate approach and one is a not immediate but still expedited application.

We have additional clarifications that have been identified within this proposal. We are proposing to reorganize subpart E in its entirety to more clearly delineate which provisions apply based on how the water is used. The proposal, the way that it's outlined in the proposal would not alter the requirements for sprouts, water use during harvest, packing and holding or for treatment. Those provisions remain the same.

There are a number of exemptions that have been outlined in the proposal. If finalized, covered



farms would exempt from conducting a preharvest agricultural water assessment if they can demonstrate that their preharvest agricultural water meets certain requirements that would apply to harvest and postharvest agricultural water. If that water is received from a public water system that supplies or meets requirements of the Safe Drinking Water Act, provided that the farm has results or certificates of compliance demonstrating that the water meets the relevant requirements or the water is treated in accordance with the standards that are outlined in the produce safety rule.

We know that you are also very interested in hearing more about compliance dates as the compliance dates for the large farms began on January 26, 2022 for subpart E provisions for covered produce other than sprouts.

I assure you that this is a high priority for FDA as well. In the proposed rule that was released last fall, we focused on the standards themselves and did not propose any new compliance dates. As previously announced, we are exercising enforcement

discretion for the agricultural water requirements for covered produce other than sprouts for all produce subpart E provisions applicable to such produce while we work diligently to address compliance dates.

We also conducted a regulatory impact analysis. The preliminary economic impact analysis or economic analysis considers various costs and benefits that are associated with proposed rule compared with the current preharvest agricultural water testing provisions in the 2015 produce safety rule. We estimate the benefits of the proposed rule would result from illnesses averted as a result of the proposed provisions relative to illnesses averted as a result of the current provisions.

Additionally, we discussed qualitative benefits of the proposed rule stemming from increased flexibility for covered farms, comprehensively evaluate their agricultural water systems. As discussed earlier today, these changes to preharvest agricultural water provisions are being proposed in part to address practical implementation challenges of

the current preharvest agricultural water testing requirements in the 2015 produce safety rule.

We estimate costs of the proposed rule that may result from various sources. One of those costs could include that result from reading the rule, conducting preharvest agricultural water assessments, conducting mitigation measures when necessary based on the outcomes of the preharvest agricultural water assessments and associated recordkeeping.

This slide provides a summary of the estimated costs and benefits of the proposed rule compared to the current preharvest agricultural water testing provisions. The cells highlighted in yellow 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. Sorry, my slide stuck. Let me redo the last slide.

This slide provides a summary of the estimated costs and benefits of the proposed rule compared to the current preharvest agricultural water testing provisions. The cells that are highlighted in

yellow 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. And that concludes my presentation. Thank you so much for the opportunity to be here today.

MS. MCDERMOTT: Thank you so much for that excellent presentation, Kruti. I know you covered a lot of detail there and I'm sure everyone appreciates it and thank you for being so thorough in your presentation. We will now be taking a break and I will give it over to Mike.

MR. KAWCZYNSKI: All right. So it looks like we are a little ahead of time, so we are going to take -- it looks like we're going to take a full, 15-minute break. So, I'm going to set the timer right now and with that, we will reconvene at, it looks like, 1:15 Eastern Time. So with that, see you back in 15.

(A recess was taken.)

MR. KAWCZYNSKI: All right. And welcome back from our break and I'm going to -- let's, we're going to move on in our program. Cathy, take it away.

MS. MCDERMOTT: Thanks, Mike, welcome back, everybody. I hope everyone took advantage of a small break there. I now would like to introduce our second set of FDA presenters. They are 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 and handing off to you both now. Thank you.

MR. KAWCZYNSKI: Michelle, you are muted. Unmute your phone, please. That's all right.

MS. SMITH: Okay. And thanks for that, Michael. I'll start this presentation talking a little bit about the background about why FDA has been working on an agricultural water assessment builder and give a brief overview of our current thinking about the assessment builder. I'll pass the presentation to Chelsea to share more details about the development of this tool and to give everyone a preview of what the tool looks like right now. She'll

pass it back to me and I'll talk a little bit about what we have in mind for next steps.

So as you've heard, after the final Produce Safety Rule issued in 2015, stakeholders through a lot of different venues shared feedback for some of the requirements, especially those for preharvest agricultural water testing were difficult to understand and implement across a wide variety of agricultural water sources, uses and practices in the produce industry. And as these concerns as well as possible approaches to addressing them within the focus of numerous outreach activities over the last few years.

Kruti talked about quite a few of those activities including the 2018 Produce Safety Alliance Ag Water Summit and at that summit, attendees identified agricultural water assessments as a promising approach. At the same time, there was also general consensus that additional education, training and other tools would be needed to help farms conduct those assessments.

So in light of this feedback, we've been working to develop an agricultural water assessment builder and at a really high level this tool is meant to be user friendly, designed to help users identify and understand the proposed requirements, it incorporates information from the proposed rule and from the qualitative assessment of risk and other aspects of the 2015 Produce Safety Rule as appropriate.

And you should note that use of this tool is optional. The tool itself is not required, just the provisions that are specified right now in the proposed rule and if the rule is finalized, the tool would be updated to align with the requirements in the final rule and also on feedback received on those initial tools.

Also, keep in mind that this tool is not intended to stand alone with respect to ag water assessments, but the use of this tool could supplement and not replace other technical assistance, education, training, and experience.

Likewise, other technical assistance, education, and training could supplement the use of the tool. Now, in developing the tool, we followed several guiding principles including that we wanted to allow users to input dynamic information about their own farms into this tool. The user's data will not be shared with FDA or the federal government. It's data for the use of the user.

We also wanted to make sure that the tool would be built in such a way that users could access that tool regardless of their computer's operating system, whether it's Windows or Mac and that it would work across all common browsers. We also wanted to make sure that the tool could be used either on a computer or on a mobile device such as a phone when you're out in the field.

Users can save their progress and return later to finish it or to do a reassessment. Users can also save the information they've inputted as a PDF for their own records or other purposes. And at this point I'll turn things over to Chelsea who will say a little bit more about the development process for this



tool and what it looks like right now. So take it away, Chelsea.

MS. DAVIDSON: Great. Thank you, Michelle, and good morning or good afternoon, everyone. I really appreciate you all joining us for this. We're really excited to talk a little bit more about the builder. I know a lot of you are as well, so I'm very pleased to be able to present this. As Michelle mentioned, it's hoping to give a quick overview of the process that we used for development of this tool and also give kind of a sneak peek of what our current thinking is on the tool and what it might look like which we are going to issue some time soon.

So in terms of development, we did seek a stage-wise approach to this. So the first stage of that was really the development of the information (Inaudible) as a lot of this was what types of questions we would be asking, what their response prompts would be, as well as identifying if there were any areas where could provide some additional information that could help to provide a bit more background on the questions being asked to help the

user and really maximize their experience with the tool.

The second stage of development was focused primarily on IT's side of things, so this was broken down into three different steps. So the first one was focusing on the IT aspect of the assessment factors and so these are the pieces that Kruti had discussed earlier such as, you know, questions about your water system, how you're applying your water, environmental conditions, things like that.

In the second stage of IT development was really focused on questions around determination through outcomes and measures. Between the two of these, this really makes up the bulk of the builder at this point.

And then the third stage of IT development was focused on a reassessment, so if you do want to go back at a later time and, you know, change something or something new happened with your system that might impact some of your determinations, you would then have the opportunity to go back, make those changes

without necessarily needing to start from scratch with the tool.

So once we've had all the IT developed, we then moved on to testing for our third stage. So this began with some internal testing that we did and this was really focused on ag water subject matter expertise review as well as IT review and this was largely just looking to make sure that we had factual accuracy throughout but also checking for the technical functionality, so making sure that if you select, you know, either yes or no to a certain question it would direct you on to the next page correctly making sure that (Inaudible) skip any important systems, aspects of the systems, things like that.

And so once we completed that internal testing, we then shifted over to testing with a small group of external users to provide us with some preliminary feedback on the tool. So this really focused on feedback such as, you know, the useability of it, how the navigation worked and whether it made sense to use and was understandable, whether it be

additional information provided throughout really helps to answer the question and just in general, you know, whether this would be a useful, helpful tool for stakeholders to use.

And so where we're at currently is evaluating that feedback that we've gotten in through some of those external users in determining what changes we can make not only in the short term ahead of this version 1.0 release that we're hoping to issue soon, but also longer term. That, you know, given more time, we might be able to make some improvements to really increase the user experience of the tool.

Okay. So I mentioned that the builder is mainly made up of two different sections, so the first one being the assessment factors and the second one being the decisions and determinations related to outcomes and measures. So within this first section on the factors that you would consider, they input a few scoping questions, so things like do you use preharvest ag water, do any of the proposed exemptions apply to your operation, then of course depending on how you answer those questions under the proposed

rule, you may or may not be required to actually even do an assessment. So it just helps to kind of pull out some of those people or operations that wouldn't necessarily need to follow these proposed requirements.

So from there it goes onto the actual factors that you would consider under the assessment and these are intended to align very closely with what we have in the proposed (Inaudible). So the first section of the -- this part of the system focuses on water system components, so this would be questions around your water source, your water distribution system, and really kind of gearing you towards thinking about whether or not they are perceptible from potential sources of hazards.

From there it goes on to a series of questions about what those actual potential sources might be, so this would be animal impact, biological soil amendments, untreated or partially treated human waste, other water users, and then just in general as a catchall any other potential sources of hazards.

And within these, we have a number of questions that are really intended to help the user think through, you know, the likelihood of those actually introducing hazards into your water source such as the proximity to the water source, you know, whether there is any runoff that's likely to occur, for animals, you know, whether they have direct access, things like that.

From then we move on to questions about crop characteristics including whether there is anything that might impact microbial adhesions to be crop surfaces, water use practices including both the method and timing of application and then onto environmental conditions which not only can impact the quality of the water itself, but also if there are hazards introduced to the covered produce, whether there is any potential opportunity for risk reduction due to environmental conditions.

And then the last part of this section is focused on other relevant factors which is really intended just to be a general catchall for any

information that wasn't captured earlier. My computer froze for a second.

Okay. So then the next section of the tool, like I said, is focused on determination through outcomes and measures. You would take into consideration all of the information that you would put into the tool up until this point and then think through at a, you know, a big systems level approach saying, you know, the first question you ask is whether there are conditions that would make your water not safe or adequate for a sanitary quality.

So if that's not the case, then you would go through and think about conditions that are associated with adjacent nearby land. So this would be focused specifically on land uses for animal activities, biological soil amendments or untreated or partially treated human waste. If none of those conditions are present, then you would then move onto those other conditions that might be there and if there are those other conditions, then as Kruti discussed earlier, you would have the option to either go straight to mitigation measures or to test your water and then

consider those results along with all of the other information that you had looked at previously in the builder. So this section is really intended to help you walk through that decision making process that is outlined in the proposed codified.

And I also mentioned that we wanted to kind of give everyone a sneak peek of what our current thinking is on what the builder will look like and point out some of the handy features that we've incorporated into this. So what you're seeing on the page now is the screenshot of the landing page for the builder and just a few things I wanted to point out on the upper right hand corner, it does say that it does support modern browsers, so Chrome, Firefox, a lot of the key ones.

As Michelle mentioned, you can also use this on Mac and Windows devices including phones and tablets, so there won't be like a specific application to download for the builder on phones or tablets but you can still access it through the browser on those devices.



In the upper left hand corner, we have a button that if you click on it, it actually pulls up a navigation pane which I'll show you on the next slide and this is really helpful to track your progress, you can see which sections you've completed, you can also use it to kind of jump back and see questions that you've already been asked or if you're -- if you can't remember how you answered then you can go back and look at it easily there.

And the last thing I'll point out on this slide is that you'll see next to the title there is a little I with a circle around it and these symbols are sprinkled throughout the builder and this refers to when there is more information available to look at. So if you click on this, you'll get a popup that provides, you know, some helpful background information, if there are any definitions, things like that that will really help you answer the questions a bit more fully and help you understand what our thinking is in asking those questions.

So on this slide on the left hand side, this is the navigation pane that you get when you click

that icon in the upper left hand corner. And so I mentioned that it does help you to track your progress, so as shown here, the green sections are those that you've already completed and the light grey ones means ones that you haven't yet gotten to start inputting information on, so it helps you kind of keep track of where you are within the builder and also, like I mentioned, if you did want to go back and look at some of the previous information, you can easily click through and go directly to those sections here rather than having to toggle back and forth through each question individually.

And on the right hand side, this is what the more information popup looks like. So in this instance, we just have some helpful definitions that might be good to consider as well as links to helpful resources at the very bottom and for many of these popups that are sprinkled throughout the builder, there also will be a lot of additional information such as contents on the proposed rule itself, some are qualitative assessment of risk, or if there is anything relevant from the 2015 Produce Safety Rule

that you would still want to consider as part of these proposed assessments, we've included that language there.

There are a couple of different ways that question can be asked throughout the builder and also different ways for responding to those questions. And so what you see on the screen, you'll see that every page kind of starts off with general instructions or what the question is for you to read through. And then, like I said, there are a few different ways that you can respond to these. So can you guys still hear me? I just got a network lost issue. Mike, are you able to hear me?

MR. KAWCZYNSKI: Yes, we can.

MS. DAVIDSON: Okay. If someone else is able to control the slides, I can just keep on going. So I think I'm on slide 11, so it shows a couple of different ways that you can answer questions here. So for the -- for this question in particular, the proposed exemptions, the way you would respond is through using this dropdown option. So you would click that hand then you would select which of the

proposed exemptions would apply to your system and then for the majority of the questions throughout the builder there is also a comment field where you can type in more of a narrative response to your question and, you know, provide any additional information or some clarity on, you know, why you're responding to it in that way and if you think there is anything else relevant to bring up.

And then at the bottom of each --

MR. KAWCZYNSKI: Just take a moment. Take one moment. I'd rather you get logged in. that's okay. Let's just take a moment to get you logged in there because this is what happens when we have a live, it does happen. Looks like everybody's VPN had a little glitch there, so I see -- so let's just get everybody back in the room. We're just going to take a quick unexpected break while everybody gets back here. Again, that just happens to be -- there you go. And let me make you back, Chelsea, are you back to -- there you go, you got your -- so you can have your slides up. All right?

MS. DAVIDSON: Okay. Perfect.

MR. KAWCZYNSKI: There you go.

MS. DAVIDSON: Okay. Fantastic. I think where I left off was pointing out the page controls at the very bottom of the page, so these are in each one and allows you to either move back to previous questions or once you've filled in the answer to the question that you're currently on will allow you to move forward.

So this next slide just shows another type of way that you might be asked to respond to questions for this. There is a series of questions that you're asked and then you'll be prompted to either select yes, no, or not applicable and at the bottom of each of these lists there's also an opportunity to provide some additional text just to give a bit more of a narrative fill in for why you answered some of these questions in this way, so this might be why or why not some of these questions are applicable, if you don't do some of these things, why you don't think they're relevant or necessary to do, things like that just to really give it a bit more flavor to the responses that you've been putting in.

And the last thing that I'll touch on before passing it back over to Michelle is the save function that we have for the builder, so at the bottom of each screen you'll see that save button and if you click that, you will be directed to this slide with a popup. It has two different options for saving, so the first one, the save for import, this really has to do with what Michelle had discussed earlier about us not wanting the users data or information to be saved in the browser specifically. So if you are working on this, you get part of the way through, you don't have time to finish it but you want to come back to it at a later time, or if you complete it but you think you might want to edit the builder and your assessment down the line, you can click this save for import button, it'll save your data and information to your local device and then when you're ready to resume the assessment, you'll just upload that file and it'll jump right back where you left off, so it really makes it as user friendly as possible to kind of limit the need to have to go back and start from scratch with these assessments.

And then the second option for saving is this save for viewing button and this basically downloads a PDF report of all of the information that you've put into the system that you can then save on your local device just for reference whenever you might need it. this is not an editable file and it's not something that you could use to then upload to the builder at a later time. But, again, it is kind of just a good reference and resource for you to have on hand if you did want to save it to your device to look back at later. And so with that, I think I will pass it over to Michelle and Michelle, if you could be sure to unmute yourself. Thank you.

MS. SMITH: Okay. Thanks, Chelsea. So as Chelsea mentioned, we've just finished the external testing with a small group of people and these folks provided us with a lot of very appreciated, substantive feedback. We're currently reviewing that feedback and working with developers to determine which suggestions can be incorporated in a timely manner and which we need to save for later. And we've had to kind of triage what we've heard from the small

group because we do want to get the tool available to a larger audience. So once this feedback is incorporated, we do plan to publicly issue version 1.0 of the builder which will include the various functionalities that Chelsea talked about.

But keep in mind that version 1.0 is the initial ag water assessment builder tool. Longer term, if the rule is finalized, we proposed to update the builder based on final rule requirements and feedback received from the builder such as its usability and how understandable the information provided is and some of the other features that even in initial feedback have been suggested that we can consider improving.

We've also heard stakeholder desires to have a tool available in a format that does not require Internet access such as a paper format. And so we have heard that loud and clear and it's on our list. We've also heard about interest in the tool in languages other than English. So when we're at the point where the tool is in a stage where it makes sense to do that, that's what we intend to do.



And so when this tool becomes available, we're really excited to be able to share it and we appreciate any feedback you may have on it. In addition, as noted earlier, use of this tool is optional, not a requirement. The tool could supplement but not replace other technical assistance, education, training, and experience just as other education, training, and technical assistance could supplement use of the tool. So keep that in the back of your mind as you're looking at this tool when it comes out and really we're looking for feedbacks that can help us make this tool and the whole process as valuable as possible. So thank you for your time and attention and I'll pass it back.

MS. MCDERMOTT: Thank you to both Michelle and Chelsea for that excellent presentation. We'll now hear from Diane Ducharme, Consumer Safety Officer with the Division of Produce Safety who will speak to training, education, and outreach around this proposed rule. Diane.

MS. DUCHARME: Thank you, Cathy. Good morning, good afternoon. I am Diane Ducharme. I'm

part of the FDA, the Center for Food Safety and Applied Nutrition in the Division of Produce Safety and part of the Produce Safety Network. So I wanted to share just a little bit about Produce Safety Network. We are regionally located and specifically designated as support to the efforts of farmers, regulators, and other key stakeholders for implementing the produce safety rule.

We provide support through providing regulatory and technical assistance by answering those questions and conducting the outreach education and training. So I'm here to share with you a little bit of what we envision in respect to the training, education, and outreach as we work within the proposed rule towards the development of that final rule and its implementation.

While the specific training, education and outreach needs are yet to be fully outlined, FDA has many lessons learned from the development of the proposed produce safety rule published in 2013, the supplemental notice of proposed rulemaking in 2014, as well as through the final release of the rule in 2015.

And we intend on applying those lessons learned a bit and building upon those as we develop our training, education and outreach for this proposed rule. From the processes leading us to the final produce safety rule, FDA has forged communication pathways with the establishment of meeting platforms, identification of our state partners and those contacts and building those relationships, importantly extending those communication efforts to our farmers, the farming community and produce associations both domestically and internationally.

We recognize that effective and frequent communication that provides that ability to explain FDA's current thinking and obtain the feedback as we're doing today in these public meetings are essential for educating each other.

Right now we're working to raise awareness on the proposed Ag Water Rule. Stakeholder engagement began shortly after the proposed rule published in the Federal Register with outreach to key external audiences representing federal and state partners, consumer groups, and trade associations and many

others. Additional engagements are continuing to be scheduled as we receive those requests, and I'll share with you at the end of the presentation how you can ask for that presentation should you want to.

FDA has initiated communication with our partners on the expectations and what has changed in light of the proposed 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 water sources.

Importantly, while we work with the proposed rule for the ag water, produce remains subject to the provisions of the produce safety rule as applicable and the adulteration provisions of the Federal Food Drug and Cosmetic Act. FDA recognizes the important role that states and educators play. We are all working together towards the development of that final rule and the incorporation for the produce safety rule implementation.

That process includes working with stakeholders to hear concerns about this proposal and

other concerns and incorporating those into that final framework. As Chelsea mentioned earlier, we know you're also interested in hearing about the compliance dates and she noted that the compliance dates for large farms began January 26, 2022 for subpart E for subpart provisions for all covered produce other than sprouts.

I assure you that this is a high priority for FDA as well. The proposed rule that we released last fall focuses on the standards themselves and did not propose a new compliance date. We are exercising enforcement discretion for the agricultural water requirements for covered produce other than sprouts for all subpart E provisions applicable to such produce while we work diligently to address the compliance dates.

So if the proposal is finalized as written, the agency intends to work closely with our state regulators, the national association and state departments of agriculture, educators and others including the Produce Safety Alliance to provide that necessary training and update towards the

implementation of these changes to the agricultural water requirements.

A couple of examples of integration and collaboration for consistency during the proposed rule are offered here. We have a couple of slides that have been incorporated into the food safety training within the standardized produce safety alliance curriculum and within FDA's produce inspections for regulatory training or FD226 and these specifically address the proposed Ag Water Rule, FDA's decision to exercise enforcement discretion on the compliance states, also how growers can utilize good agricultural practices to maintain and protect the quality of their water sources. And that there are no changes to the current implementation of the produce safety rule until the final rule is published.

A couple of other examples of us working together with our partners, the Produce Safety Alliance has recently held office hours that were extended to researchers and extension educators to collaborate as subject matter experts, to ask questions and kind of get discussion going.

So although the subject matter experts in that arena and the PSA team might not have been able to answer each of those questions, the intent of those discussions was really to improve clarity around what is currently proposed, help to identify maybe the comments that FDA can receive on that proposed ag water rule revision, and revisiting how growers can then submit their comments so that their voices can be heard.

Another example is working with our FSMA partners, NASDA that represents the produce safety rule programs from the state have established five one hour virtual regional meetings that are organized to actually present the proposed rule and the proposed changes and then address how comments can be received.

So as you can see, we're actively working on the development of a framework for training, education and outreach and welcome your support and ideas as this evolves. FDA recognizes that we stand on the Food Safety Modernization foundation. We can better protect public health by 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 collaborations, these collaborative efforts can support the integration of this Ag Water Rule if finalized into a nationally consistent produce safety rule.

So I would be remiss if I didn't share a little bit about some of the technical assistance and as we look forward, FDA understands that we need to provide that continuum of technical assistance as we work towards that final rule and implementation while engaging with our stakeholders and colleagues is essential. We are, as they say, gathering steam, defining those processes that take into consideration the aspects of consistent messaging. The proposed rule requirements for the intended audience is to be workable across the produce farm of all sizes, both domestically and foreign, recognizing that there is a wide variety of water systems, uses and practices.

We also need to consider that these proposed requirements are designed to be adaptable to future advancements in agricultural water quality science and



technology. And so we recognize that to fully realize the benefits of the proposed Agricultural Water Assessment, farms must understand and translate those requirements to their operations working with other partners, education, outreach and training materials and then the addition of the online tool that Michelle and Chelsea just spoke about will be critical to help ensure that farms can conduct with a robust water assessment evaluation we envision within the proposed rule.

So again, I would be remiss without mentioning some of the fact sheets that are available on [fda.gov](http://fda.gov). There is the overall agricultural water assessment fact sheet on the proposed rule and the elements of the proposed rule considers it has components in it of the factors to consider, the corrective mitigation measures, the reassessment records and exemptions as outlined by Kruti earlier. So that's going to be your little cheat sheet of everything that Kruti went through.

There is also an expanded table that talks further about the factors to consider and so as farms

look at doing these water assessments, they can look further into the definition of some of these words and then considerations for other factors. Of course, the overall website for the proposed rule is there on this slide set. Most of you can just Google that, proposed Ag Water Rule. If you're not able to do that, please reach out and we will send that to you. And as was outlined, the agricultural water assessment builder is coming soon and so as FDA focused first on developing the proposed rule and that proposed rule is setting the ground work for that ag water assessment builder. So you will see that hopefully soon.

And, again, I want to highlight that the Produce Safety Network remains a resource for you, so if you're not able to get those online tools, please reach out to one of us. Of course, the website is here. You can certainly Google Produce Safety Network, that will work as well, and you can find any of your representative's emails or phone numbers.

And then as we continue down this road, I want to share again that please continue to show your comments to the federal docket, the federal docket

number is number SBA-2021-M-471 and can be found on regulations.gov.

Remember, should you have any questions about the content of the proposed Ag Water Rule or should you want FDA to speak at one of your engagements of conferences, please submit that request to the email [agwater@fda.hhs.gov](mailto:agwater@fda.hhs.gov). And with that, I'd like to thank you for your attention and I will pass it back to Cathy.

MS. MCDERMOTT: Great. Thanks so much for that great presentation, Diane, we really appreciate it. So we will now move 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 open for any and all of our panelists to answer.

The panel will consist of all of the presenters that you saw this morning as well as Charlotte Christin, the Director of the Office of Priority Policy Initiatives with our Office of Food Policy and Response. So thank you all for being able to take these questions today. I'd now like to see if

we have our caller from the Amish community on the phone to begin.

MR. YODER: Good afternoon. This is Jonas Yoder from the Food Safety Education Team. We would like to thank FDA for being open to all size farms. The question that I have for today would be will FDA provide guidelines to educate the small plain growers or will each individual state provide the guidelines?

MS. MCDERMOTT: Kruti, I think you need to unmute.

MR. KAWCZYNSKI: Give me a second, Kruti, I'll help you unmute.

MS. RAVALIYA: Thank you. I'm going to toss this question to Diane.

MS. DUCHARME: Thank you, Kruti. Hello, Jonas.

MR. YODER: Hi.

MS. DUCHARME: So in answering your question will FDA provide guidelines to the Amish for education; is that correct?

MR. YODER: Correct, yes.

MS. DUCHARME: So -- thank you for your question, Jonas. So FDA will be working with our partners to develop the training, education and outreach and it will be specific to the proposed rule should that be finalized as proposed. We will not start any of those trainings until we do have a final rule and as always we've worked with the Amish community as well as educators, we continue to commit to that plan and that framework.

MR. YODER: Thank you.

MS. DUCHARME: Thank you.

MS. MCDERMOTT: Thank you for calling in with that question, Mr. Yoder. All right. Our next question, how does the regulatory process work and when can we expect a final rule?

MS. SMITH: Cathy, this is Michelle. I'll take that one. Federal rule making generally follows a notice and comment procedure where an agency publishes a proposed rule explaining current thinking and the agency's proposed approach. The proposal is assigned a docket number which Diane talked about published in the Federal Register and the public has a

specified amount of time to review the proposal and provide comments on it and that's where the ag water notice of proposed rulemaking is within the rule making process right now. FDA will consider all relevant comments submitted in a timely manner in developing the final rule. And it's difficult to predict how long it will take to get to a final rule, especially at this stage.

It will depend in part on the feedback we receive and some of you may remember, and as Samir mentioned in his opening remarks that when we were working on the Produce Safety Rule we published a proposal, a supplement to the proposed Produce Safety Rule was issued that included a number of topics including ag water in 2014 before we went to a final rule making because FDA realized that the initial proposal was going to need to possibly change significantly to align with the goals of the regulation.

And so from comments we got on the supplemental we made additional changes. FDA issued a final regulation and as most of you are aware, we

reassess that as well. And so we want to complete this rulemaking as quickly as possible, we also want to get it right and because the regulatory process could take many deviations, we're unable to provide an expected timeframe on publication of the final rule at this time but we're taking every step that we can to make this as transparent a process as possible and folks will know how things are going at each step of the way. So I thank you for that question, Cathy.

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

MR. ASSAR: Thanks, Cathy, I'll go ahead and take that question. This is Samir. And this is a really important question that we get quite a bit with proposed regulations and I'll be very direct about it in that no, we -- there is no expectation and no, the community should not be implementing these new proposed requirements, but this proposal as we talked quite a bit and Michelle also talked about in her last response and not a final rule and so 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 and we again look forward to all of the engagement that we're doing on the proposal including this public meeting to determine an appropriate course for the final rulemaking.

While we are in this process of rulemaking, we do encourage farms to follow good agricultural practices to ensure that water is suitable for its intended use. Farms are responsible for ensuring that the food that they produce is not adulterated under the Food, Drug, and Cosmetic Act. So thank you for that great question and the opportunity to be very clear about enforceability or compliance with the proposed rule.

MS. MCDERMOTT: Great. Thanks, Samir. Our next question, how do you see the agricultural water builder tool being used by growers and other stakeholders?

MS. SMITH: Okay, Cathy, I'll start that one. As Chelsea and I were talking earlier, the tool and development represents the agency's current thinking about a tool that can help growers understand the



requirements for conducting an ag water assessment and getting started, gathering more information on the factors to consider, and inputting data about their own operations and water systems and I'll punt over to Chelsea if she wants to say a couple more words about where the builder is at this stage in time.

MS. DAVIDSON: Yeah. Thanks, Michelle, just the only thing to add, I do want to emphasize that this was very much this version 1.0 that will be coming out soon, it was very much just an initial release, so we're viewing as part of a longer term project and once it is out there and available for users to begin working and playing around with, we're certainly open to feedback on what works, what doesn't, if there's anything else that can be improved, truly make this as helpful a tool as possible for growers. I know as Michelle mentioned earlier that the feedback that we've been receiving through the external user testing has so far been incredibly helpful in identifying not only some of the short term changes that we can make ahead of version 1.0 release, but also some of the longer term changes

that we could incorporate down the line for potential future updates and I'm sure that that type of feedback will continue to roll in as other users do get a chance to begin playing and working with the tool once it is out there and publicly available. So thank you.

MS. MCDERMOTT: Great. Thank you to you both. Our next question, can you describe a plan for implementation of the regulation when it is finalized?

MS. DUCHARME: I think I can take that one, Cathy. I'll try and we'll see what -- if I answer it completely. So FDA does recognize that education, outreach and training will be critical as to help ensure that the farms are able to conduct the robust water assessment, evaluations (Inaudible) within this proposed rule. The online tool FDA is developing can certainly provide some valuable assistance to growers in evaluating those potential risks associated with the agricultural water sources and in determining those management strategy options.

We also recognize that FDA and state partners must have the necessary training and tools to verify compliance. So specifically working through the FDA

state produce safety implementation cooperative agreement program where states have developed their own produce safety programs will be working on targeted regulatory training and further will work with the states on extending that education to the farms to facilitate that compliance.

We're committed to that early engagement and close partnerships with the state regulators, the National Association of State Departments of Agriculture, educators and others including the Produce Safety Alliance in developing the training plans for both industry and regulators on the preharvest agricultural water assessments and that we ensure consistency in that exceptional approach. We still remain committed to continuing to educate before and while we regulate. Thank you, Cathy.

MS. MCDERMOTT: Thank you, Diane. Okay. Our next question. What will compliance and enforcement for the rule look like?

MR. ASSAR: I'll go ahead and take this one, Cathy, and appreciate again the question. It is challenging to predict exactly what compliance and

enforcement will look like around a proposed rule, but there are certain things that we can share and commit to right now. And, again, as Diane eluded to, the work that we have with the state to do training, the state regulatory partners are going to also play a -- we envision them playing a key role in implementing the Produce Safety Rule as well.

Some states already are taking the lead for conducting routine farm inspections in their states. If finalized as proposed, FDA in the states would assess a farm's compliance by reviewing records and observing practices and conditions on the site. They would review written agricultural water assessments that were talked about earlier in this public meeting to determine if the farm evaluated all the required elements of the assessment including consideration for agricultural water sources, distribution systems, practices as well as adjacent and nearby land uses for hazard identification purposes. Again, all of this was mentioned earlier and the inspections would include a review of test results, if any, that were used to inform the assessments and whether the

assessments and the supervisory review occurred in a timely manner.

If finalized as proposed, FDA in the states also would review the farm's written determination on any measures to implement based on the results of the assessment together with the finding from inspections and maintenance of agricultural water systems under the farm's control. So, again, appreciate that question. I know people are looking ahead towards compliance and enforcement. We are not there yet, but those items that I shared with you, we can safely say that we will do.

MS. MCDERMOTT: Great. Thank you, Samir. 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: I'll take that question, Cathy. Yeah, you can definitely use the data that you've collected over the last few years to help your decision making process. If this proposal is finalized as written, water quality testing is one

piece of the decision making process that the assessment walks the grower through. So water quality testing can provide useful information and can help a grower, you know, more clearly make a better management decision about how to use that water appropriately in a safe manner. The flexibility that's written into the assessment to include the testing components allows the grower to have flexibility around what the water is being tested for, the threshold for which the microbials (Inaudible) for which the tests should be held against and then also a specific testing frequency that would be relevant for the scenario that the grower decides to apply testing. And so all of that is flexible to be used to allow testing to be used in a manner that would provide useful additional information in conjunction with the assessment. Thanks for that question, Cathy.

MS. MCDERMOTT: Great. Thank you, Kruti. Okay. I think we have time for one last question. How does this proposal affect small growers, a definition of less than 25K?

MS. RAVALIYA: I'll take that question as well. So if this proposal is finalized as is, all of the exemptions and exclusions for farms that are in the final produce safety rule continue to apply including the exemption for farms that have an average annual value of produce sold during the previous three year period of \$25,000 or less adjusted for inflation. Thank you.

MS. MCDERMOTT: Great. Thank you, Kruti. Thank you to everyone that submitted these great questions during our registration process and thank you to all our panelists here today in answering those questions. So, Mike, I think now we will -- we have a lunch break coming up.

MR. KAWCZYNSKI: Yes, we do. Thank you, Cathy. And, again, I appreciate everyone who's presented and all of the comments made, but just to give everybody a break and stretch their legs, and again, we are running a little ahead of time, so which is nice, we'll be able to get everyone out of here a little bit early today. Let's take a look at, we are at, we'll just call it, we'll round it up to 2:15 and

we were scheduled to take a 30 minute break; am I correct on that, Cathy? That was what the original plan was?

MS. MCDERMOTT: 45.

MR. KAWCZYNSKI: Oh, 45 minute break. So we planned on taking a 45 minute break. All right. So we will reconvene at 3:00 p.m. sharp. All right. So I will put the time up.

(A recess was taken.)

MS. MCDERMOTT: Welcome back, everyone. I hope everyone got a little something to eat and drink and thanks for staying with us for the next part of our public meeting. We're going to go to some panel sessions now. I'd now like to introduce a panel with our state regulatory colleagues moderated by FDA's Wendy Campbell, the Division Director of Partnerships Investments and Agreements in our Office of Regulatory Affairs. Wendy, handing it off to you.

MS. CAMPBELL: All right. Thank you, Cathy. As Cathy said, my name is Wendy Campbell. I'm the Director of the Division of Partnership Investments and Agreements. In my division we serve as the



project managers for the Office of Regulatory Affairs State Contracts and Cooperative Agreements which includes the State Produce Implementation cooperative agreement.

FDA heavily relies upon and greatly appreciates the collaboration with our state regulatory partners under this cooperative agreement. So it's truly my pleasure today to serve as the moderator for this panel with our state regulatory partners. First I'd like to introduce Don Stoeckel, he is a Water Quality Specialist with the California Department of Food and Agriculture as well as Steve Fuller, he is the Assistant Director with Food Safety and Consumer Services with the Washington State Department of Agriculture. Thank you both for being here with us today. So I will ask a few questions of each panelist so we can obtain your state perspective on this proposed rule.

Don, I will pose the first question to you. In your role with the state, why is agricultural water important for food safety?

MR. STOECKEL: It's really hard to underestimate how important water is to agriculture, to California's agriculture. We provide over half the domestic fresh produce that Americans consume and we're the top producer of broccoli and other crucifers, lettuce and leafy greens, cantaloupe, melons, the list goes on and on. So safe produce is crucially important to public health, in particular think about the dietary and nutritional value of fresh fruits, dried fruits, vegetables, nuts, herbs.

California also made a huge investment in farm to school space because of the nutritional benefits. State produce is important to the economic health of the California Agricultural section. We represent \$30 billion in fruits, nuts, tree nuts and vegetables in 2020. So when funny things happen, the cost can be huge.

As an example, the damage estimated for the 2018 (Inaudible) e. coli outbreak in romaine lettuce, it was estimated by UC Davis economists it cost about \$300 million economically which is one thing but we also have to think about the 62 people who became ill

or who were named to become ill and got -- and with links to that outbreak and also 25 of them were severe enough to be hospitalized.

So in general, we may never know with precision how much foodborne illness is caused by water issues because a lot of foodborne illnesses are never reported. Even among those that are reported, most aren't linked to any particular outbreak or particular commodity or a definitive contamination source because it takes time for illnesses to get reported, recognized, traced to a commodity in a growing area. By that time, a lot of the evidence is gone so the investigators hardly ever get a chance to determine if the root cause was actually from water use compared with other factors that we also know are important like conditions (Inaudible) harvest, soil amendments, wildlife, domesticated animals and worker hygiene.

It is easy, though, to note that both water and fecal solids flow downhill. They comeingle and all of California's produce growing land is irrigated, much of it with service water. So water, especially

service water directly contacts a lot of fresh produce grown, harvested, and sold today.

Considering that California really has an outsized fresh produce productivity and reliance irrigation, so we know that without irrigation water, the US wouldn't have enough healthy nutritious produce for our collective diet. So in our rule managing safe and appropriate use of water, the CDFA produce safety program helps to attain public health goals including produce safety and we feel that effective management of ag water and ability to make good water use decisions is really vitally important. Back to you, Wendy.

MS. CAMPBELL: Thank you so much. Steve, I'll ask you the same question as well. In your role with the state, why is agricultural water so important for food safety?

MR. FULLER: Thanks very much, Wendy, it's a pleasure to be with you today. At the risk of being obvious, agriculture is tremendously important in Washington State, it's a huge economic and cultural driver and water is absolutely a vital part of that.

Like a lot of places in the country, there are towns up and down the Columbia River here in Washington that owe their existence to agriculture and Washington agriculture is incredibly diverse. There are hundreds of crops and commercial production, large scale production crops covered by the produce safety rule would include things like apples and other tree fruit, berries and onions.

We've got lots of different water sources, probably over half of our covered produce farms used surface water at least partially, ground water, municipal water, combinations thereof, lots of different application methods from overhead, (Inaudible) and frost protection, cooling water, et cetera.

In northern states, seasons of the year are very important to Washington agriculture and we have the (Inaudible) environment. A lot of people think of Washington State as being pretty rainy and in western Washington that's true and in eastern Washington there is a pretty heavy reliance on irrigation for agriculture.

You know, we've been blessed to have a relatively good safety record with covered produce so far, but the risks are absolutely real. As one example, we've been watching the global movement of Cyclospora hazards in berries. I don't think there's any reason why Washington State is inherently more safe than other parts of the country or the world when it comes to Cyclospora hazards and so we want to try to get ahead of that before it arrives here in the northwest and I think these proposed changes to preharvest ag water rules overlap into identifying and addressing known risk factors for Cyclospora, so that's going to be very important for us.

And then, you know, the red onion outbreak in 2020 that was mentioned in the preamble to the proposed rule, FDA identified contaminated irrigation water as a leading hypothesis. I think that was really significant for raising awareness of some risks in a crop that I think people think of as relatively safe. So definitely believe that it's worth investing in the safety of preharvest ag water.

MS. CAMPBELL: Absolutely. Thank you. I think agriculture is such an important part of so many state economies, especially for both of your states, but also from that public health perspective and just for all consumers to have access to safe produce. Very important. Steve, I'll give you the next question here. What was your initial impression of the proposed rule?

MR. FULLER: Well, thanks very much. Definitely a lot. There, you know, on its surface I think the proposed rule is conceptually fairly simple and then as you dig into it, it gets complicated quickly. Very high level I'd say, I think FDA deserves a lot of credit for the process here. I think one of the things that people were really concerned about with the idea of FDA and states starting a mandatory regulatory program over covered produce was concerns over lack of experience and lack of core competency in that area and so I definitely think going slow in order to go fast and try to get that right, the right approach. So I think it demonstrated some regulatory humility on FDA's part to

ask for feedback on their earlier approach, listen to those concerns and then attempt to improve the proposal.

You know, when it comes to regulatory things, I think there is a natural tension between having a clear prescriptive standard that applies with everybody identically and then having a more adaptive standard that adjusts to different fact patterns and I think what FDA heard from the feedback on that first iteration was the strong desire for an adaptive approach that adjusts to all of the combinations of water sources, delivery systems, crops, et cetera and was responsive to the ever growing body of scientific knowledge. I know I've heard from large portions of Washington State's agriculture industry that they're really pretty happy with the additional flexibility in the assessment approach and more specifically the ability to consider the characteristics of the crop itself as part of that assessment, so I think those are some big wins in the proposal.

You know, one of the things that strikes me as kind of interesting about the proposal is that it



includes both the requirement to perform an assessment and an option to exempt out of the assessment if the grower can meet one of the bright line standards for demonstrating compliance through groundwater testing or water treatment or (Inaudible) water source. So when I mention that regulatory tension between prescriptive and adaptive approaches, I think what we actually see here from FDA is FDA trying not to choose one scheme over another but to instead recognize that with appropriate accountability, both schemes can actually be successful and that they're willing to allow growers to choose which scheme they'd rather be in.

So one of the things that I like about the assessment approach is that it reminds me of one of those foundational principles of food safety and that's that we don't test products into safety. If we have a crummy system and a clean test, we should not be confident in that product's safety. Our belief about product safety comes from our belief in the system that made the product and then we use testing as a means of additional verification. So this sort

of strikes me as like being (Inaudible) for ag water and I think that's a positive thing. There are going to be some challenges that come from this type of adaptive proposal and we'll probably get into that in one of our next questions.

MS. CAMPBELL: We do actually, Steve, and since we're already kind of on that train of thought there, I'll pose the next question to you and then go over to Don and get some thoughts from him. So do you feel that the proposed rule provides a clear framework for stakeholders while still being flexible enough to accommodate the diversity of agriculture?

MR. FULLER: Yeah, so that's a really good question. So flexibility and clarity are both really important, but I think they can be competing values and sometimes they have to be held in tension with one another. So it's going to be easier for a rigid and prescriptive system to be clear, for example, than it is for a flexible system to be clear. So I would say that this assessment approach is very flexible and that that's a real strength. In the proposed rule itself, I'm not sure that the clarity is there and by

that I mean that if I'm a grower or a regulator, I'm not sure what exactly is required for an assessment or to what degree. So, for example, how much does the grower need to know about what's happening on adjacent parcels, so that's going to be a challenging thing to know what's happening on your neighbor's property, so how much of that is a grower expected to know or how well does animal activity need to be characterized. There's kind of a spectrum, a amount of information, specificity of information there and I think it might be challenging to know exactly when we've crossed the threshold for acceptability on some of those elements of the assessment.

I think it may be that additional guidance documents can provide the necessary clarity. I was watching with great interest earlier today on the presentation about the assessment builder. I appreciate the progress on that, but I think that some of this guidance is going to have a big impact on the feasibility of the proposed rule for growers, so I think we can probably expect more substantial grower

feedback after some of that guidance is released and I'm really interested to hear those thoughts.

I think at this point, this proposal is still a little bit conceptual and so some growers may be hesitant to provide feedback on what they know at this point. So I think we may hear more as we go forward, open to hearing that and sort of adjusting some of my thoughts accordingly.

MS. CAMPBELL: Thank you. Very good point, Steve. Don, can you give us your thoughts? What's your initial impression of the proposal?

MR. STOECKEL: I'll second a lot of what Steve just said. When people ask me the first day the rule dropped, what do you -- how do you feel about this? I said, well, there is not much to not like about this rule. It orients covered growers towards the hazards that they can encounter and their unique operations. It includes systems based thinking, it has flexibility for the operations to make risk management decisions based on their own realities. They manage conditions that might result in hazards getting onto covered produce. And the other thing is,

the -- in the case of the exemptions, the, as Steve said, there are some bright lines that those revised requirements allow for straight and unambiguous path to compliance.

One of the things that I thought was a little confusing to me and maybe this is just a language issue that (Inaudible) that words are important, the understanding that hazards as we're talking about hazards, specifically we're talking about just the bacteria viruses and protozoans and when we're talking about risks, we're talking about the probability that that hazard actually causes illness and so one thing I really like is that we're looking for the hazards in the waterways and then we're talking about how do we disrupt that pathway toward contamination, so it just mirrors some of the gaps things, some of the things we've been teaching for years in the PSA global training course. We're going to focus on the hazards like managing the quality of the force water, we're going to focus on the pathway, the contact with produce, particularly direct application methods and we're going to focus on the likelihood that illness

results from contamination if it happens by giving time for die off in the field using that -- using the four day requirement.

So these are all good things. There's always a but and in this case, we feel that as this is a great step in a positive direction, it's also important to put a couple of concerns on the table and one of those is the bright lines are so very attractive. Farms are going to seek -- many farms may seek exemption from the process of creating an ag water assessment or they may look for some of those safe harbor mitigation measures that are broadly applied and if you use those mitigation measures without thinking about them, sometimes there may be a lack of -- we may not be getting the produce safety benefits that we think we're getting from those measures.

So some of the specific concerns are, and just, these are just thoughts to put on the table and consider, the exemption that relates to groundwater knowing that groundwater is generally a safer option compared to surface water might drive growers to use

more groundwater. And in California we have substantial concerns about salt water intrusion, ground level subsidence and other issues that come from overdrawing on our finite groundwater resources.

Another option that's going to be fairly appealing is treatment. Treatment can effectively reduce the water related risks. The concern is that by using chemical or physical treatments were consuming a lot of energy, there are climate change issues associated with that, and then there are also potential effects of chemically -- putting chemically treated water into the soil in terms of soil health and soil fertility that haven't yet been fully and comprehensively understood.

And then finally, a couple of mitigation measures, specifically the four days or more for in field die off and the use of swimming water quality standards that FDA continues to stand behind in the preamble, there's a lot of scientific debate and question about whether those are appropriate for broad use. For specific uses, absolutely, but for broad application, there are some concerns those may not

lead to the, again, risk reduction outcomes that we expect.

So not to -- these concerns can be addressed. Let's be positive and look toward the future. If we have a collaborative approach among policymakers, researchers and industry in the same way that FDA showed a commitment in 2017 with that Pugh Collaborative Food Safety forum discussion that Samir mentioned and the 2018 PSA hosted Water Summit that Dr. Ravaliya mentioned, these things are great collaborative opportunities. And just to go back to the Pugh Forum, a couple of things that Samir said during that were that outcome, our rule needs to be scientifically based and valid, commonly understood and able to be clearly interpreted by those who implement and those who enforce, practical and cost effective for all parties and at least equivalent to the current framework as related to public health protection.

We see a clear path forward to achieving those goals as the proposed language is finalized. The first supporting tool that I got to preview but



can't say anything about yet, the ag water assessment builder, it's close to release. We anticipate that it's going to be of great benefit. The FDA will continue to work collaboratively with stakeholders to meet the need for additional supporting tools and guidance. I heard over and over this morning that this is the beginning of a long pathway for all of us towards achieving the goals of safer water and risk reduction and produce safely.

So talking to our host, to the participants on the call, I do appreciate this chance to speak with you and just to call out one of the main benefits of an opportunity like this which is to understand FDA's current thinking, to formulate meaningful, practical comments that are going to guide us all to a regulatory system that's feasible for the growers, measurable for the inspectors, and protective for consumers. That's a lot of thoughts, but those were my first thoughts.

MS. CAMPBELL: Thank you so much, Don. It's very interesting as you discuss as we make efforts to improve food safety, what the environment's impact to

that can be. So thank you. Steve, I'll turn it to you. Is there any additional hurdles or challenges that you anticipate for growers or regulators?

MR. FULLER: Yeah, thanks, Wendy. Probably there are for both. I'll start with regulators. That hits a little closer to home for me. So as the state performing produce inspections under the produce safety rule and as a coregulator with FDA, my mind immediately goes to thoughts about how we're going to implement this assessment approach and the flexibility that's such an important feature of these assessments is also going to be harder to regulate. I think there are some things to watch out for here and that's states, FDA and associations like NASDA are going to need to work hard together to mitigate.

So, for example, inspectors evaluating assessments are going to have to think critically about complex fact patterns and come to some reasonable conclusions. So at issue are going to be things like the accuracy and completeness of the assessment, determining how severe the hazards are, the appropriateness of identified corrective actions

or mitigations, you know, Don mentioned that four day withholding time, you know, is that going to be the magic solution to every hazard or is some additional evaluation going to be necessary there.

So everybody is going to want inspections to be consistent across state, federal, and international inspections. That's a very high value for us. That's going to be harder with this adaptive approach than it would be if we had a more prescriptive approach. So I would also say that because reasonable people can disagree about the content of assessments and their conclusions.

We're also going to need to watch out for things like our implicit biases and the possibility that they are going to unintentionally influence our decisions. So when we have kind of an open flexible approach, that has some real benefits and it's going to come with additional people related challenges.

I'd also say inspections are going to take longer and contain more records review. So we regularly hear from growers about their legitimate concerns with audit fatigue, so it's worth keeping in

mind that assessments are going to require more human resources from both growers and regulators.

And I'll touch on a couple of things for growers, but I did want to acknowledge that I think growers are coming up a little bit later in the overall presentation. We are very interested to hear what they have to say. So I'm not going to try to be exhaustive, of course, when it comes to growers and they can speak for themselves, but a couple of things that occur to me are that diversified growers are probably going to find it difficult to complete an assessment for each of their crops due to lack of resources, available research on things like surface adhesion and the infiltration characteristics for their different crops and just the volume of work that is going to go into that assessment.

So I think it's also true that meeting the criteria for exemption will also be a challenge in some cases as many of these farms in our state use at least some surface water, so some of these growers are likely going to default to treatment. I think Don mentioned that a little bit earlier and I totally

agree. Treatment is a deeper rabbit hole than we probably have time to go down today, but just briefly, it's going to have its own technical challenges, so finding appropriate EPA approved chemistries, understanding pH, maybe there are going to be implications for complying with organic standards simultaneously and then some of the stuff that Don started to mention about unknown impacts on soil health and the environment. I really don't know what it means for large quantities of preharvest ag water containing chlorine to regularly be sprayed onto fields and I think soil health is something that we're focused on more and more these days and probably more attention is needed there and I think there's some unknown impacts around those kind of things.

MS. CAMPBELL: Thank you. And, Don, we have one final question for each of you. If you could describe your ideal implementation plan and the partners that should be involved?

MR. STOECKEL: So this is just an opinion but the implementation should be scheduled and it should be phased in based on availability of data and science

based guidance. Steve did a very nice job of describing in his last thing some of the challenges that are going to be faced when a grower and an inspector are both looking at the same thing and if they don't have full, clear, concise data that they can use to evaluate it and have a conversation, who's to say whether it's appropriate or not? So that guidance is just going to be really important, guidance and training for the inspectors and for the growers.

It's going to allow them to know what compliance looks like, the extent to which compliance with minimum standards of produce safety rule meets farms goals and public expectations for produce safety. So some of the specific needs would be courses for inspectors, outreach such as OFRRs or something similar that has a focus on the ag water assessment and how to match those ag water factors and determinations with appropriate mitigation measures that aren't too restrictive, that aren't too costly or that actually meet the goal that the farm has.

The availability of training (Inaudible) fully understood by the farm such as translation. There are a lot of areas of the US including a lot of California, if we rely exclusively on regulatory style phrasing in English or Spanish, we're not going to reach many of the farm operators and we're to allow them the opportunity to learn how to do this appropriately, so I would really emphasize that.

Since some of the, in terms of roll out, we're already enforcing sprouts, so we know that's already done in subpart E. Provisions dealing with water during and after harvest could easily be implemented next because the changes to postharvest water requirements are modest. They mostly relate to the numbering system. But after that, I would say that there is a real benefit by allowing a long pause that's going to be filled with hard work for science policy training before the preharvest water requirements are enforced. That way inspectors and growers aren't faced with inspectional situations. If a grower decides to use a four days and pray approach to mitigating their risk and the inspector doesn't

feel like four days is going to meet the need in that situation, where do they find the data to make that argument with each other and come to an agreement on that? All of this is going to take a substantial financial time energy investment on part of FDA that would be easier and more relevant by involving the many hands, the external partners that we're already engaged with and could engage with further.

Primarily, a diversity of farmers and farm support organizations because this isn't going to work if the growers don't know what to do. Academic researchers contribute to that industry, researchers that bring along with them research opportunities, industry policymakers and audit standard holders. And then I have to throw out a call for the educators, especially extension, the Produce Safety Alliance, local food safety and collaborative and (Inaudible) food safety collaborative along with NASDA that are already doing so much good work in collaboration with FDA to bring FDA's learnings to the regulated community.



I don't want to overlook organics and all the other stakeholders whose knowledge, skill, and dedication to make this work can make it work. So that's my dream situation and we'll see how it happens. Thank you for the question.

MS. CAMPBELL: Thank you, Don. Steve, any additional comments?

MR. FULLER: Yeah. Thanks, Wendy. So there's a lot to say here. You know, if you just give a regulator pie in the sky about what would ideal implementation look like, there is a lot that could be said so I'll try to be brief.

Number one, I say go slow to go fast. Regulators are going to need to continue to exhibit some humility and restraint while we all figure this out. I think this is an area where lots of damage could be done if we were to charge ahead, so definitely understand the frustrations over how long this is taking and I think it needs to take some time in order to allow everybody to be maximally successful.

The new compliance dates are going to need to be far enough out for everyone to figure this out, same kind of idea. I would say additional investments in education and outreach on assessments specifically, harness our partners at extension to push out lots of information and lots of languages and culturally relevant techniques as Don was eluding to, funding to support research into adhesion and internalization characteristics of different crops would be important information for supporting growers who may not be able to do that themselves.

On the people side of things, we're going to have to work hard in government to attract and retain people into the regulatory system that can think critically and exercise sound judgment. Successful implementation here is going to rely on high performing people and there is a lot of upheaval in human resources right now across the country and frankly government is pretty slow to respond to these kinds of social changes, so we're going to need to work really hard to do things well there.

Redoubling our efforts to train and calibrate inspection staff, there's lots of good work already being done for other parts of the Produce Safety Rule through partnerships with FDA, the states and organizations like NASDA and we're going to need more of that for preharvest ag water.

I think some of our larger industry associations will develop tools and training for their members. We already enjoy close collaborations with our industry associations and we really appreciate their solid partnership. These rules are going to open up some new avenues I think for further collaboration, maybe there are some ways to streamline both assessments and regulatory reviews for certain segments of the industry. We look forward to building on those partnerships.

I wanted to thank our research and extension partners who have been great to work with and developing new tools and resources, lots of opportunities there. I'd say we're also interested in exploring whether there are some opportunities for some of the upstream providers like irrigation

district, maybe to provide something like sanitary survey results or other health club resources to their customers that maybe could support some pieces of individual farm assessments. We'd be interested in working with those partners on those kinds of things. So I apologize for the really rapid fire bullet points there, but lots to say.

MS. CAMPBELL: Thank you guys and this has been just an outstanding panel this afternoon. So we look forward to continuing to work closely with our state partners on this proposed rule and I definitely appreciate your insight in these discussions today. And now I'd like to hand this off to Samir for our next panel discussion. Samir.

MS. MCDERMOTT: I'm going to step in real quick here, Wendy.

MS. CAMPBELL: Oh, thank you, Cathy.

MS. MCDERMOTT: Wendy -- no worries. Wendy, Don, Steve, thank you so much. That was an excellent discussion. We really value our relationship and input from our state regulatory partners and thank you all for being here. I'd now like to introduce our

second panel of stakeholders moderated by Samir Assar, our Director of Division of Produce Safety. Samir.

MR. KAWCZYNSKI: Make sure you're unmuted, Samir. Unmute your own phone, Samir. There you go.

MR. ASSAR: Yeah, appreciate the last panel. My name is Samir Assar. It's a pleasure to join you again. I serve as a moderator for this next panel with our external stakeholders who have an interest and work on issues related to produce safety, so appreciate them for joining. I really, I greatly appreciated the last panel discussion from our state regulators. Don and Steve both had a lot to say and it was hosted very well, moderated incredibly well by Wendy as well.

You heard about how important engagement is to this process and you heard from our state regulatory partners about their perspectives about the proposed requirements. Their feedback was positive in taking -- in us taking a systems based approach in this proposed thinking but they certainly made it clear in many different ways that there are challenges that lie ahead and really providing details about how

to implement this flexible rule and underscored the need for us to continue to work as partners and as collaborators with community that really, you know, needs to be involved in implementing this rule effectively to ensure a level playing field which is important.

So with this panel we have leaders representing other organizations that have a vested interest in agricultural water and produce safety to share their perspectives on the ag water NPRM and produce safety and I'd like to introduce Sonia Salas, Assistant VP, Food Safety Science and Technology at Western Growers. We've got Sarah Sorscher I believe, I don't see her yet but she will be coming on hopefully on camera and she is the Deputy Director of Regulatory Affairs in the Center for Science in the Public Interest and we have Eric Deeble, the Policy Director for National Sustainable Agricultural Coalition. Thanks so much to the panel for taking the time to join us. I greatly, greatly appreciate it.

That was a very brief introduction of the panel and in the interest of time, I would encourage

folks listening in to the public meeting to refer to the bios that are linked to the public meeting to learn more about the panel members and the organizations that they represent. I will kick this off by asking questions of each of the panelists similar to Wendy's approach and we will be talking about the proposed rule and I'll start off with you, Sonia.

Sonia, you as a, again, working for Western Growers who represents local and regional family farmers growing fresh produce in Arizona, California, Colorado and New Mexico, I'd love to hear your perspective on why agricultural water is important for food safety?

MS. SALAS: Thank you, Samir. Can you hear me now?

MR. ASSAR: I can hear you perfectly fine. Thank you.

MS. SALAS: Perfect. Thank you for the opportunity and also I want to say I appreciate the perspective of members of the previous panel on these questions (Inaudible) importance of providing safe

(Inaudible). To answer your question, agricultural water quality is important because on the farm, contamination can come from different sources. So if we think about the growers who represent, for them agricultural water, it's definitely a factor to consider.

We are aware of the FDA (Inaudible) investigations (Inaudible) fresh produce have determined that (Inaudible) pathogens in the agricultural water. So knowing how to manage water quality, it's critical to really advance food safety and reduce any potential for safety risk that could happen during the production of fresh produce. So from that perspective, it is important for us to understand how to (Inaudible) agricultural water quality.

MR. ASSAR: Wonderful. Thank you so much, Sonia, appreciate that. Sarah, you represent the Center for Science and Public Interest, an independent science based consumer advocacy organization. What are your perspectives on why agricultural water is important for food safety?



MS. SORSCHER: So this rule really helps address two different public health problems that are related and the first is the direct burden of food borne illness. So we know that produce is an important cause of food borne illness, it's among the top causes of illness for salmonella and e. coli and we know from FDA investigations over the years but much of that risk is rooted in water.

But then there's also this indirect public health problem around consumer confidence and this can seem like a secondary concern but it actually has the potential to cause even more harm than the direct impact. Because unhealth diets contribute to so many deaths of Americans every year, almost 700,000 of us are dying every year from diet related disease and we know that diets that are rich in fruits and vegetables can help improve those numbers and yet nine out of ten of us aren't getting enough vegetables. Eight in ten aren't getting enough fruits, and for us having confidence in the safety of our produce specifically is a really key component to addressing that crisis.

And as we advance with the sciences as we develop new methods to detect food borne illness and better understand it, we're getting better at connecting the dots between illnesses that once would have sort of flown under the radar because we couldn't see their cause and this puts us on the cusp of solutions but it also means that we're seeing risks that we didn't see before, the blinders are off, and that can have a negative impact on consumer confidence.

And so, you know, the answer to the problem isn't we can't put the blinders back on. You know, we know these risks are there. The answer is really to address the risk because, you know, to both these problems, we have to make sure that the produce not only feels safe but that it is safe and, you know, to do that we have to make sure the water is safe. So that's what we're aiming to do with this rule and I think all stakeholders are really united in that goal.

MR. ASSAR: Thank you so much, Sarah, I appreciate that and as with everything else in produce or in food safety, it's a balancing act and yes,

addressing the risk at the same time, fostering access and accessibility of fresh produce which is so good for the diet is incredibly important so I appreciate those comments.

Eric, you represent the National Sustainable Agricultural Coalition. It's an alliance of grassroots organization that advances the sustainability of agriculture food systems, natural resources and rural communities. Let's hear your perspective on why agricultural water (Inaudible) food safety.

MR. DEEBLE: Well, thank you, Samir, it is a pleasure to talk with you today and to serve with such a vast group of stakeholders on this call. Water safety, food safety, it's essential to the members of the coalition, many of whom are or represent small diversified growers, sometimes organic, sometimes not who want safe, healthy food grown by a legion of small family farmers that earn a fair living from their production and that make their food available to everyone at an affordable price in their own communities.

And so many of the folks that are members of NSAC or organizations that are members of NSAC that serve farmers are selling to smaller diversified growers and often these farmers are selling into their regional markets or they may know their customers directly.

Food safety is a serious point of pride for our producers and they want to do the best for the people they grow for. To our farmers, food safety isn't an abstract public health concern. They're trying to do the best they can to keep their friends, families, and communities safe. But the diversity of our producers farms and the fact that they're often at a smaller scale means that they face a great deal of complexity and often they may be using equipment, irrigation, processing, washing, et cetera across many different types of produce production operations.

And so they're looking for a rule here that is clear, that is risk based that works for small growers with complex systems that's practical and achievable because, again, an abstract or a rule that is too complex to comply with or one that is

insufficiently specific is a challenge for them and something that can come with technical resources sufficient for them to ensure safe production.

And we very much share Sarah's concerns about the issues of diet and making sure that there are adequate fresh fruits and vegetables available to everyone in their community so that they can be healthy and be well.

MR. ASSAR: Thank you, Eric, I appreciate that and yes, an important element that you touched on is the -- how practical it is to implement the rule and how important that is for the community that you represent. So I appreciate that comment.

Sonia, I'll go back to you and ask you for just your overall thoughts on the proposed rule. You touched on it a bit but if you can -- if you'd like to expand on that more on your thinking on the proposed rule?

MS. SALAS: Thank you, Samir. Yeah, first of all, from our perspective, we appreciate the agency moving from a restrictive approach to a more system assessment, a risk assessment based approach. We do

appreciate that because of some of the problems that were just shared from the previous panelists regarding flexibility, so our overall impression is really that the approach is going to provide flexibility in how to assess and manage water and that's important. It's going to help the industry to get to the right place.

However, with that flexibility, we see challenges, right, and challenges related how companies are going to be conducting these assessments, right? There are going to be some (Inaudible) certainly. We can see that it could be also ambiguity and I say that because for diverse stakeholders there was reasonable foreseeable hazards (Inaudible) different things so if we think about diverse understanding of what that means, how do we define it, how to manage it, that's really going to present challenges to your point, right, with the flexibility. So there are going to be limitations and we feel that having help on how this is going to be done is going to be really critical.

There are barriers related to current knowledge but also research gaps that will have to be

overcome in order to have successful implementation of this new approach. So I think that's really our overall impression and we're really looking to find ways to provide some solution and suggestions as you are seeking for feedback, so thank you for that question.

MR. ASSAR: Yeah, thank you, Sonia. I appreciate it. You touched on something that we haven't talked about a lot today which is the research element, the science element, recognizing that there are questions out there that need to be addressed and this proposed framework with the flexibility does allow for us to account for emerging science and technology to build into it moving forward, so definitely appreciate that comment. Eric, I'm going to go to you for the same question. What are your overall thoughts about the proposed rule?

MR. DEEBLE: Well Samir, for many of the folks on this call, it may come as a bit of a surprise that on initial review, many of the members of the coalition were quite positive on this rule. The initial rule raised a great deal of concern with our

coalition and members of the coalition submitted comments to this effect in large volume, but this rule seems to be much more in line with what our members have been advocating for for many years and that is a sensible, approachable risk based approach. And so we really do feel that it is much improved.

I think Steve Fuller mentioned previously, you know, he said that the rule seems very simple at first but there is an additional layer of complexity once you start to dig in and we still remain a bit concerned about some of those complexities and, of course, will comment on each of those points, but overall, we think that it is much approved.

We do like that the approach is an adaptive one and we think that an adaptive system will work best for small and diversified growers and we appreciate that there is flexibility within the rule and that it wasn't the one size fits all approach of the previous version of this rule and we appreciate that testing is not necessarily required in the absence of risk and that there are clear red lines for that risk assessment. So I think that overall while



there are some perhaps questions to be asked and maybe some mild reservations in points, generally quite positively inclined.

MR. ASSAR: Thank you, Eric, certainly fair enough to point out that there are questions that remain on the proposed rule. Again, given the flexibility of the framework as well as, you know, there is -- this is going to be evolution of a process over time even if we do finalize the proposed rule as is, there is a lot more for us to do with you on this and you've been very active.

Your organization has been particularly active with us in providing comments throughout the years on FSMA as well as, you know, produce safety and as you pointed out, agricultural water which is really again guiding us to where we are now today with a new set of proposed requirements. Sarah, I'm going to propose the same question to you. Do you have any thoughts that you wish to share about the proposed rule?

MS. SORSCHER: Yes, I have a few. So for starters I think this rule was really an opportunity, right, it was an opportunity after we've see all of

these outbreaks in produce to help restore confidence and for consumers that this -- these problems we've been seeing were going to be addressed and I think, you know, the agency is introducing steps that are going to move us forward. I think introducing water assessment for preharvest water, this has real potential to be a foundation for something better because it helps interstate partners look more comprehensively, and the growers look more comprehensively at all of the potential sources of risk, more so than the original rule because that had leaned so heavily on generic e. coli testing to verify that water was safe for preharvest use.

Unfortunately, the testing that was in the original rule wasn't a reliable measure of whether the water was safe and that standard, it had been an effort that was pulled together after the 2006 spinach outbreak, it was never really proven to be a reliable indicator of risk, and certainly we've seen recurring outbreaks among growers who were using that standard over the years that have really been a testament to the failure of that standard to protect us and it

also, it creates a false sense of security when you have a bright line rule on the books but that rule isn't really protecting and accomplishing the goal that it should be then that's a false sense of assurance that you followed it. so the FDA was right to take another look at that standard. I think the challenge is that the alternative we have, and many people have touched on this, it trades this bright line rule, this pass/fail test for an obligation to do a more subjective assessment. It's a hazard assessment where industries really determining for itself what are the risks, how are we going to mitigate them, and this really puts the ball back in industry's court to identify the problems and the solutions but we know that they don't have the solutions, that's why we're seeing the outbreak.

And actually, some members of industry come to the table with very different capacity to put research into finding those solutions. And so in the long term, while this framework has the potential to grow into something more meaningful in the immediate moment, it's lacking in the specificity that's really

needed to provide that assurance that the problems are being addressed and there's too little to guarantee a minimum quality baseline has been met for these assessments and to really distinguish what is a good assessment from what is an inadequate one.

So FDA could be doing more to fill those gaps now in the rulemaking and guidance layer but also in the rulemaking to create a standard here and we have, you know, three avenues we'd encourage FDA to explore. One, to require testing is part of the assessment process. Now, FDA has said in the rule that microbial testing only needs to be done as part of the assessment if applicable, but that doesn't really tell you under what conditions would it be applicable.

And we're moving from a position where it was necessary to test under all circumstances to one where it's completely up to the individual grower and FDA can do more to state that a validated microbiological testing is going to be expected as part of a good assessment and they don't have to require a specific test, it could be a method that's validated by science, it could safe harbor specific methods that

could evolve over time but it should be expected and if there are circumstances where it's not warranted, then they can lay out that out as an exception but not making it completely up to the grower to decide.

Second, they can incorporate more clarity around what makes an adequate risk assessment and really look at risk as opposed to just hazard because right now the grower has to list out potential hazards but they could offer direction about how to rank and prioritize those hazards based on their risk level. You know, the rule talks about addressing some hazards before you use the water, some within the growing season, some within a year. They should be more specific, you know, which hazards do you need to address immediately? Which can you wait for the full growing season? Which are ones that you can address in a year?

We also need to make sure that if they're using mitigation measure as part of their response plan that it's validated and adequate. So if we're talking about four days as a die off period, you know,

what's the evidence that supports and validates that standard?

And then, finally, just thinking about risk assessment as a tool, the scope is actually fairly narrow in this rule, right, it applies to preharvest water but in places we're still falling back on that generic e. coli testing and that looking at the water source. So for sprouts and preharvest, for example, if you're meeting the source and the testing requirements you don't have to do the risk assessment and you don't have to do it for preharvest if the water meets those standards.

But we know from outbreak investigations that you could have municipal water and you could be doing the generic e. coli testing and you could still have risk. So in January, for example, FDA released results from its investigation of a hydroponic grower where there had been a salmonella outbreak and in that case they had been using municipal water, they'd been testing weekly for generic e. coli and somehow they had two different strands of salmonella creeping into their system and one caused an outbreak.

And so in that case under this rule, they wouldn't have had to do a water assessment but you know, really every grower should be thinking through all the risks comprehensively and not falling back on the testing as an assurance of safety. Those are my few thoughts.

MR. ASSAR: Thank you so much for that. I appreciate all of that. I liked how you framed it as a foundational proposal but you again pointed out more work needs to be done. You've also pointed out, you know, your thoughts with respect to requiring microbial testing, the value of that in certain situations and really taking the assessment approach from a broader perspective as well. So thank you for your comments. And so let me go ahead and go back to you, Sarah, if I could, please, on what do you feel like the lessons learned over recent years from implementing other parts of produce safety rule that would be relevant to agricultural water?

MS. SORSCHER: So I couldn't think of a response on this that directly answers your question, but I will say that just in terms of lessons learned

over the years, you know, we have seen on the testing standards that the leafy greens industry gets -- was implementing that standard and we saw it, you know, industry, you know, in conversations around the rule was also struggling to implement it outside that context in sort of a variety of circumstances that we see in the produce industry and that, you know, the version of compliance that was -- might have arrived at how we proceeded with that standard was with probably even not meeting the vision that FDA laid out, so even further undermining the effect of that standard.

So I think, you know, the challenge and the question is to return to this is just what are you going to replace it with. Right? We know that it's a very important part of the assessment to understand the quality of the water and whereas the old rule was inflexible and couldn't evolve with our understanding, we have an opportunity here to do something that is -- that can evolve with the science. It's just really a question of making sure there's clarity around what the expectation is and really the expectation should



be that water is tested, maybe not necessarily under the standard proposed in the rule but under a standard that's validated by science.

MR. ASSAR: Thank you so much for that. We absolutely look forward to your comments in that regard. Appreciate that, Sarah. And I'll turn it over to you next, Sonia. What do you feel like the lessons learned over the years from implementing other subparts of the produce safety rule that would be relevant here for agricultural water?

MS. SALAS: Yeah. Thank you for that question. I do want to touch on a few points that were mentioned by Sarah, so I'll probably go back to them but (Inaudible) I want to say about the actual learning is that we know that technical assistance, training, outreach, there was an easier way for growers to implement the other provisions of the rule and so that approach seems to work when there were farm readiness reviews that was also helpful for them and, you know, that type of approach, it is something that we see that could work for what we're trying to do here.

And Sarah touched on so many different points, so I don't even know where to start, but the one thing I do want to make sure I say is that we anticipate many challenges, right, and those mainly because what we see is a responsibility is placed so heavily on the grower. So there is flexibility if we get that but with this comprehensive assessment, they are expected to find all the possible sources, routes of contamination and how are they going to determine what is a reasonable foreseeable hazard, how, you know, they are going to get into investigating adjacent (Inaudible) that could impact the quality and safety of the agricultural water.

Working with the produce industry and other industries, we know that there is a need for a holistic view on how to manage quality and safety when it comes to water. So I just feel like in going through learning how to manage water quality we have to think about how we're going to deal with adjacent uses. Right? So from that perspective, perhaps it's something the agency is looking into how to work with other entities, how to help growers so it doesn't fall

into, you know, they finding a solution for something that is not always under their control, right, something that in many cases they might have access to but in many cases they won't have access to. So I would think that learning from what we're seeing about implementation of the rule, there is a need to think about how to work with others with your neighbors and how the agencies, the different entities can help in that regard.

MR. ASSAR: Thank you so much, Sonia, you raised a really good point around, you know, adjacent and nearby land use you know, have their identification around that and how although the rule does focus on what is under the farmer's control, there are things that are outside of the farmer's control and so moving forward, you know, there should be kind of a broader approach to working with the community at large, not just the produce community but also others that are kind of in that adjacent nearby land use mix to kind of foster food safety, produce safety to bring everyone along. I appreciate that comment. And, Eric, I'm going to turn it over to you

next for the same question. What are the lessons learned over the recent years from implementing other subparts of the PSR, the Produce Safety Rule?

MR. DEEBLE: I think an important rule is to listen to producers and to advocates for public health and to demonstrate some regulatory humility I think was the phrased used and I think the FDA has done a very good job in -- with this particular rule. I think some of the things that we can learn from previous implementation efforts are the importance of clear guidance documents that farmers can rely on and reference when they're doing their risk assessments in this potentially new forum and making sure that the FDA is sharing that guidance and insight with those who train farmers as well so that they can help them comply with these new rules.

The alternative curriculum is a fine example of that and making sure that the information to assist farmers is available to advocates and trainers like those folks who are providing gap certification who are known and trusted by farmers who will welcome them onto their operation, have the tools that they need in

order to provide assessment and mitigation practice insights.

And I think something else that FDA has done with increasing skill and dexterity is expanded outreach to ensure that they're reaching every farmer and while it is far from perfect, I think that making certain that there are options available for farmers whose first language is not English or maybe limited in their technological bandwidth or may abstain from technology entirely, making certain that they have the opportunity to come into compliance with existing provisions of the rule has also been quite good.

I think one other element or perhaps two other elements would be the staggered implementation and enforcement discretion in those early years of implementation and certainly we think that both of those principles should apply to this portion of the rule as well.

MR. ASSAR: Thank you, Eric, I appreciate that and appreciate the good comments on the outreach that we've done so far. Certainly we're looking to do the best that we can. It's important to us and you

heard from Diane about what we're doing around outreach and education and training moving forward but, you know, we know we can always get better and we're looking to continue to work with the community to do that. So definitely appreciate that. And while doing so, we will continue to exercise regulator humility as you pointed out. I appreciate that one.

The next question will go right back to you, Eric. If you could change one component of the proposal, what would it be and why? This is not a question that we, you know, we overtly ask at a lot of meetings, but this is an opportunity to hear from you about where we need to change, what your thoughts are and where we need to change things.

MR. DEEBLE: Well, if I could change any one thing in this rule, it would be the amount of clarity that is provided. And obviously this is one step in a lengthy process of the creation of a new regulation, but I would say that there are a couple of areas of concern including risk which has been brought up by several other folks who've spoken today, how do you know what is a reasonably foreseeable hazard, what

types of mitigation practices will be acceptable and again we have an overwhelming concern with the sustainability of our farming operations, so ensuring that the mitigation steps don't negatively impact soil health and that they're suitable for organic producers is very important.

And I think, you know, we certainly would like to know a little bit more about how FDA personnel will be trained, what kind of guidance documents will be made available to them, and that they will be able to use some degree of enforcement discretion and do so consistently and pragmatically and we would also like to talk a little bit more perhaps about recordkeeping and trying to create appropriate forms of recordkeeping that work for producers that are not overly burdensome and are practical use to the enforcement personnel.

And so I'd say that's a lot of different things, but really what we would like is additional clarity and we think that's forthcoming and so we are excited to see the comments from the folks that are on this call and other organizations as well as continue

to receive input from our members about those points that we would like to include in a comment.

MR. ASSAR: Perfect. Thank you so much, Eric, I hear you on the clarity. We're on board with that. Sarah, I'm going to go to you. You've already shared your thoughts about some of the things that you would like to change in the rulemaking process, but yet, is there anything that you would like to, you know, kind of reiterate that, reinforce or add anything to what's been mentioned already? We'd love to hear from you.

MS. SORSCHER: Yeah, I think just in general having more clarity around what makes an adequate assessment, you know, including that expectation of microbiological testing as being part of a good risk assessment but just being able to offer that guidance, you know, in part because just recognizing that growers do have a different level of sophistication and also that the FDA may in some cases be in a better position to find the answers and to understand what an appropriate method is. So being able to put that in both now in the rule but also in guidance coming out



later is really critical to making this actually work and move the ball forward.

MR. ASSAR: Thank you so much, Sarah. Sonia, if you have the power to change one component of the proposal, what would it be?

MS. SALAS: This is a hard question because I was thinking about things here, but I think (Inaudible) in adding clarity and I'm thinking about two things here, one regarding this agreement that could be anticipated between FDA personnel and also produce companies when it comes to assessing, right, the water, agricultural water safety.

So it might be good to consider guidance regarding how to resolve and anticipate this agreement because they could happen, right, if there is a lack of clarity or different interpretation on how to address the specific issues, but the big also bucket that I think about regarding guidance is probably the FDA could add a section or maybe think about how to work with, and I mentioned this before, other agencies and entities regarding collaboration when it comes to implementation of the rule because it feels that it is

not reasonable to give the grower full responsibility for the safety of agricultural water without considering other uses and the role of other agencies and entities in water quality safety. So maybe strengthening that portion can be something that I would suggest as a potential change.

MR. ASSAR: Thanks so much, Sonia. We'll go on to our next question. Based on what you've seen on pre harvest agricultural water use on farms, what do you expect the main challenge and hurdles would be? It's really important for us to understand as we, you know, work on -- through this rulemaking process to understanding what the hurdles would be. So if you could share that with us and I'll go to you first, Eric.

MR. DEEBLE: Thank you, Samir, and I apologize for answering that question sort of in advance in my previous question, but I do see a couple of places where we know that we're going to have some challenges and I would say the first is probably that element of risk and what is a known or reasonably foreseeable hazard and how do you have complete

information about what your neighbors may be doing on adjacent land.

And then, you know, when -- I guess this is perhaps outside the context of what we're talking about is what happens if a farmer is reliant on one source of water and there is an upstream or an adjacent land use pattern that is negatively impairing their water? And where does the ultimate reliability for that risk rest?

I would say, you know, I mentioned mitigation and obviously we're concerned that mitigation and potential water treatment don't negatively impact soil health and that they work for organic producers and if a producer is required to take mitigation measures like that four day rest between application and harvest, what happens if they encounter a loss as a result and what does that mean to a farmer? And, again, is that perhaps an insurable loss?

We see some potential points of concern around compliance enforcement and timeline including again FDA training and the ability to use enforcement discretion and do so consistently and I had mentioned

recordkeeping and the fact that we want to make sure that it is not duplicative and it's not overly burdensome but it is of use to those folks who will be doing the reviews.

I would say that those are the places where we see the greatest challenges or hurdles in the rule but I think that they are generally manageable in the context of this new rule.

MR. ASSAR: Thank you so much, Eric, I appreciate that. Sarah, I'll turn it over to you.

MS. SORSCHER: Yeah, I mean, I think, you know, the central benefit of the rule is that it is flexible, right, it can grow with the science and that brings with it this challenge of knowing where and when to draw the line because, you know, there is going to be, you know, different levels of sophistication among growers. There will be different approaches taken by state regulators and this searches out what makes a good risk assessment and what makes one that really is not up to standard will be a huge challenge. And so I think, you know, obviously a lot of this can be fleshed out in guidance.

A term like what's reasonably necessary is one that can what's reasonable will change over time as best practices evolve, but there is some thinking that we can do now about what standard can we put in the rule where we can really peg enforcement off of those so that we can, you know, reject inadequate assessments or offer guidance on how to make them better.

MR. ASSAR: Thank you, Sarah. Sonia, any --

MS. SALAS: Yeah, so for that question, I kind of said this before, but we do see challenges with implementation. Right? Specifically the agricultural water assessments that you think about how growers are expected to conduct a comprehensive assessment. There are, you know, many questions regarding how far up stream they are expected to investigate and then also how far upstream they can actually investigate, so those are two different acts.

So that brings a challenge and (Inaudible) in a recent webinar we had Dr. Trevor Suslow (ph.) and Dr. Chandler Brock, well known scientists, they have managed water and researched for years and they both

said (Inaudible) where to go in a field and conduct an assessment, if they do a walkthrough through similar parameters, they might likely arrive at somewhat or even significantly different assessments because of how subjective it could be. Right?

So how then will a grower in the (Inaudible) some gap and limited information be able to have a comprehensive assessment that they could rely on. So again, it comes back to how that reasonable foreseeable hazard term is defined and if I counted correctly, I think it's over 70 times in the proposed requirement but it needs more clarity because it seems like, you know, that could be interpreted many different ways and so we still don't, you know, don't see that as a potential issue domestically but also internationally. We're thinking about how this is going to be implemented overseas and what the FDA plans are to help with those requirements internationally as well.

So it comes really to implementation and, you know, the flexibility is great but it comes with challenges, certainly.

MR. ASSAR: Absolutely. Absolutely agree with you on the challenges in terms of providing clarity around a flexible framework and the need to foster implementation within the -- among the foreign community members as well, so appreciate that.

I asked you earlier about a component that you would change. Sonia, where do you feel that it's important to kind of keep provisions and you feel like these are appropriate and necessary to maintain in, you know, from the proposal to the finalization of the rule? Can you share your thinking on that? What elements do you feel should stay from proposal to final?

MS. SALAS: Yeah, no, that's a good question. So those provisions have moved us from -- to move us to a systems based agricultural water assessment deem appropriate. However, we do encourage to the agency to have maybe a non-punitive implementation strategy that comes with it. And that could be with expanding the approach but supporting it with, it could be funding to address data gaps, even with support on

harmonized training and education for inspectors and for industry.

In the previous panel, it was mentioned that inspector calibration is important for implementation and same thing, (Inaudible) assistance will be great for the industry, so to support the implementation of those assessments just (Inaudible) others can help with and work with FDA on this, but you're asking what do we keep there. That approach seems reasonable to keep, it's just about how do we make it work. Right?

So maybe making some adjustments to it might be helpful but the approach makes sense so there is flexibility and also an opportunity for people over time to look back at their data and also think about data analytics that could inform for safety practices moving forward because it was a point Sarah made about testing and, you know, for more perspective, testing is a tool and it's important that also have limitations.

So if with this approach and with data analytics those growers are able to identify issues, risks, and then finding a proactive solution, their



resources would be better targeted to enhance with safety and so that would be something positive and the, you know, framework that you have can help with that if you're able to help also with data sharing and data analytics at some point.

MR. ASSAR: Thank you so much, Sonia. Sarah, what are your thoughts?

MS. SORSCHER: I also agree that the water assessment provision is a step forward and should be retained. I think there are other areas of the rule where, for example, the requirement that -- of having scientifically valid supporting data when you're using a method like commercial washing or other methods to reduce pathogens is a good one and I think it's worth thinking through maybe other areas where that principle might be applied to resolve this question of who really bears the burden of proof to show that this plan that you've put in place is controlling the risks appropriately. So I think certainly having the hazard assessment is a step forward. Maybe we can beef it up more and think of it in terms of risk, maybe call it a risk assessment and prioritize and rank, you know,

which activity should be a priority and which warrant immediate steps. But in general, I think that that is a very solid framework to build off of.

MR. ASSAR: Thank you, Sarah. Eric?

MR. DEEBLE: Well, I can't say that I've got much to add because I think Sonia and Sarah summed it up quite well. I think the coalition is quite supportive of retaining a risk based assessment tool and we think that that's really important because, you know, as Sarah said earlier, it allows us to continue to improve as the science evolves but also, and importantly for folks in the coalition is as our agricultural practices evolve, you know, we recognize that we need to change some things about the way we produce food in this country and we have to do so in a way that is more sustainable and one that addresses climate change and so it is important that the risk based assessment allow us to make those transitions in practice that make our farming more sustainable, things like perennialization and putting animals on pasture, silviculture, other more sustainable production methods. And so retention of that risk

based assessment which allows us to have a greater tree of complexity in our systems is something that we certainly think should be retained and are very supportive of.

MR. ASSAR: Perfect. Thank you, Eric, and I want to thank all of the panelists. I greatly appreciate all of your perspectives and I think it's important for you all to note as part of this public meeting that the framing of the ideas and the thoughts that were provided on this panel were done in a very good way in providing not only the thoughts but also the rationale behind the thoughts. So we appreciate your comments and we appreciate the comments that will be forthcoming. And with that, I'm going to turn it over to Cathy.

MS. MCDERMOTT: Thanks so much. Thank you to everybody for another really great discussion. We truly appreciate you participating in today's public meeting, taking time out of your schedule and again thank you to Wendy Campbell and Samir Assar for moderating. We will now take a 15 minute break before

our public comment session and I will hand it over to Mike.

MR. KAWCZYNSKI: Yep, thank you so much, Cathy, and let me just take a look here. So we are at -- somebody decided to unshare my screen there. Okay. So we are going to take --

UNKNOWN FEMALE: (Inaudible).

MR. KAWCZYNSKI: That's quite all right, I've got it. But anyway, yep, there you go. So we are going to take a quick break. We are going to come back at, let's see, it's 4:20, we'll come back at 4:35. That sounds about right. Yep, 4:35 we will return. So, again, 15 minutes. Thank you very much.

(A recess was taken.)

MR. KAWCZYNSKI: All right. And welcome back to our intercultural water public meeting. Thank you for joining us for a little break and I am going to hand it back to my colleague Cathy. Cathy, are you ready?

MS. MCDERMOTT: Yeah, I am. Thank you, Mike. Welcome back, everybody. We will now go to our public comment session. We are here to listen to stakeholder

reaction and perspective on the proposed rule on agricultural water. I want to welcome our public comment presenter. Thank you for taking the time to prepare remarks and also public comments. This afternoon we have a number of folks ready to give comments. Please ensure that you're situated so that you're ready when your name is called.

I will call each individual by name. They will have three minutes to present their remarks. Please 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. Joining us today during this segment will be the FDA subject matter experts who presented today. At this time, we will be starting the public comment process.

MR. YODER: Good afternoon. This is Jonas Yoder from the Food Safety (Inaudible). I'd like to thank -- take this time to thank everyone involved getting the proposed Ag Water Rule out so that it is possible for the small plane growers to comply, help lower the risk for public health. Flexibility, very handy can also be harder to control. Thank you.

MS. MCDERMOTT: Thank you, Mr. Yoder, for your comment. Our next public commenter is Sheldon Rabor (ph.) from Illinois.

MR. RABOR: Hello, I am Sheldon Rabor from the Arthur Produce Auction in Arthur, Illinois. I work with and communicate with a number of Amish and Mennonite produce farmers here in the Midwest. Our small and very small farmers are mostly positive on the new proposed agricultural water rule.

As with all food safety regulations, rules related to ag water must help achieve safe food with some full yet careful (Inaudible) practices. Growing produce on small acreages provides income and support for many individual families and to sustain our local family farmers who have grown safe food for many years, any practices are required by regulation cannot destroy the economic viability of small family farms.

The requirement for agricultural water assessments we believe is a much more practical approach to maintaining ag water quality versus the previous testing requirements, that those seemed difficult to nearly impossible to perform on a small

farm level but the proposed annual ag water assessment is already being done by many farms and is a good practical way to continue to evaluate ag water.

The explanation on method of application, explaining and recognizing a difference between methods of water application I believe is an important point. If the rule is written as proposed here, specifically recognizing that subsurface drip irrigation significantly reduces risk to contamination of fruit that will help the small farmer make an accurate agricultural water assessment.

The proposed exemption for untreated groundwater that meets the microbial water quality criteria and have no detectible generic e. coli based on testing is much more realistic and science based I believe than the previous requirements were difficult to nearly impossible testing requirements. We agree with that tentative conclusion at the end of 11243b.

And that proposal for the time interval of four days I think is also a help for the small farmer particularly for an unintentional water leak as a workable solution for a drip irrigation system where

if fruit is contaminated, that four day period the leak can be repaired without significant risk of contamination of fruit without a complete loss of revenue for the entire crop on something like a tomato crop.

In summary, I would just say that I feel that the proposed rule as written is practical and workable on small plain farming operations. We hope that the tentative conclusion in that proposed rule mostly remain the final conclusion in the final written rule. Thank you.

MS. MCDERMOTT: Thank you, Mr. Rabor. Our next public commenter is Emily Greep (ph.) with the International Fresh Produce Association.

MS. GREEP: Good afternoon. My name is Dr. Emily Greep, Vice President of Regulatory Compliance and global food safety standards for the International Fresh Produce Association which represents companies from every segment of the global fresh produce supply chain. We appreciate the opportunity to provide public comment today.



Ensuring the microbial quality of water use to grow, harvest, and pack fruits and vegetables is a complex and critical component of food production. Our predecessor association, United Fresh Produce Association and the Produce Marketing Association along with many others in the industry advocated for a rule that allows growers the flexibility to manage their agricultural water and implement mitigation measures according to the associated risk unique to their production environment.

We commend FDA for proposing this systems based approach that not only allows but expects growers to account for changes in our understanding of science testing and risk mitigation. Given that roughly half the fruits and vegetables consumed in the United States are imported and because produce is grown in every region of the US, it's critical that the rule be able to accommodate the very different water sources, uses, and types of risks specific to a grower and region.

We appreciate that FDA has considered stakeholder input, reevaluated the rule, and proposed

a rule that moves away from a one size fits all approach. Identifying the presence or absence of a known hazard can be straightforward but determining the risk of that hazard to public health is rarely clear cut. It will take a substantial amount of training and educational resources to support growers in understanding how to assess and manage risk associated with agricultural water.

We appreciate the recognition of the important role that commodity specific guidance and other educational resources developed by industry stakeholders can play in supporting growers food safety and risk assessment decisions.

We encourage FDA to continue working closely with stakeholders as additional guidance and resources are developed. We recognize that water testing can serve as a tool in the assessment but as previous outbreaks have shown, testing alone is insufficient to answer the question is this water okay to use. When appropriately done, testing plays a key role in understanding baseline water quality. Many produce growers already test their water to satisfy third

party audit requirements and we don't expect this to stop.

We suggest that growers have the opportunity to leverage historical testing data that provide insight to their water system, but we also believe that testing for generic e. coli, which FDA proposes as a default, is limiting in some situations and that the rule ostensibly restricts growers from using more appropriate methods and analysts due to the lack of clarity in how to establish that an alternate method is scientifically valid.

IFPA will submit more detailed comments to the docket and we're happy to provide additional information at any time. Thank you again for the opportunity to offer comments on this important rule.

MS. MCDERMOTT: Thank you, Ms. Greep. Our next commenter will be Riley Buchet (ph.) with the Northwest Horticultural Counsel.

MR. BECHET: Good afternoon. I'm Riley Buchet with the Northwest Horticultural Counsel, a trade association that represents the growers, packers and shippers of apples, pears and cherries in the

Pacific Northwest. We handle about 70 percent of the apples, 87 percent of the fresh pears and 84 percent of the sweet cherries that are grown in the United States.

Food safety has long been a priority for our growers and packers who have a long history of widespread participation and programs from USDA gap to global gap and SQF. We appreciate FDA's extensive outreach in developing this rule including visits to tree fruit farms and packing houses in Washington, Oregon and consideration of the feedback we've provided.

Consumer health must be the goal of food safety regulations and programs and we commend FDA for taking a risk based regulatory approach that better considers whether potential hazards in agricultural water pose a risk to consumers across commodities and growing conditions. Unlike the one size fits all approach of the current rule on ag water, this proposal allows growers to better focus on the areas where risks are highest.

We also appreciate the rule's allowance for new science based information to be incorporated through grower's food safety plan as we better learn how to control the risk associated with ag water.

As this process moves forward, we encourage the agency to maintain the proposed criteria considered as part of the risk assessment including characteristics of the crop and environmental conditions. We also ask that the range of mitigation measures be maintained.

Further, we'd encourage FDA to provide regulatory language clarifying that growers should assess whether their current mitigation measures such as existing time intervals between water application and harvest, harvest and consumption or commercial washing, et cetera, are adequate to address identified hazards before assessing the need for additional mitigation.

We also ask that FDA clarify that mitigation may be looked at on a system wide basis considering multiple actions taken at various stages growing harvest and packing process where appropriate.

Finally, I'd like to emphasize three things.

First, as these assessments and development of mitigation as described in the proposed rule will be difficult for growers to undertake, especially for those who irrigate out of open canal systems.

Second, FDA must understand that there are areas, many areas where today data gaps still exist. Lastly, a certain level of judgment will be necessary for growers and regulators alike to determine whether a hazard is reasonably foreseeable and whether it's reasonably foreseeable to contaminate the produce or food contact in question.

Should this approach be adopted, we encourage FDA to work with growers to provide guidance, training, and technical assistance to growers and continue to educate before and while you regulate approach, as both growers and regulators gain a better understanding of how best to conduct these broad based assessments and we will be providing additional comments, written comments to the docket as well and I appreciate the opportunity to speak publicly on this today.

MS. MCDERMOTT: Thank you for your comments, Mr. Bechet. Our next public commenter will be Paul Johnston from Johnston Farms.

MR. JOHNSTON: Hi, I'm Paul Johnston from the State of Delaware. I'm a disabled veteran and so therefore I want to talk mostly about needs for disabled people. The other speakers have actually covered the issues about water safety and quality which we all agree on, but the one thing I wanted to touch base on was the website that you have for the ADA.

It is actually hard for a lot of disabled people to turn around and access because your website is so busy and when you put in the information that you're trying to get, it gives you a lot more other information. It'd be a lot easier if you had it more handicap accessible, this way we could follow the rules easier.

On top of that, your training videos on how to comply would be better if it was more audio based along with visual because what you have is some people with different disabilities have sometimes follow

along with a written requirement and understanding what the actual meaning was.

So by turning around and making your site more handicap accessible and putting out your literature and your guideline and the rules when they finally come out with the final rule on how for us to comply easier, by helping out the disabled by following what they need to understand and learn and follow your rules, it produces for a small grower that they comply and they produce high quality food safe for the consumption of their consumers, but it gives us the better chance to be part of the community and it helps us to enrich ourselves and enrich our families to be a viable part.

This is not much, it's just a little tiny thing that will help produce a high quality food for our communities but it helps keep a disabled and disabled veterans actually being a viable part of the community. Thank you.

MS. MCDERMOTT: Thank you for your comment, Mr. Johnston, we will take your comments into consideration and appreciate you calling in today.



Our next commenter is Sandra Barden with Barden Family Orchard.

MS. BARDEN: Thank you and thank you for your service, Paul, the last speaker. We appreciate that the assessments may ultimately replace the ag water testing. However, we would have appreciated that the four day die off science would have been incorporated in the initial rulemaking.

We think that the states should have autonomy in applying this law and rulemaking to growers in their own state with technical assistance from FDA. States will know better what situations need more attention than others. All United States growers should not be held accountable for higher risk situations on farms and other states industries and situations.

States should cater assessments to isolate those certain situations for attention without unnecessarily holding low risk growers to higher standards of performance. This will be understood a little better from a grower's perspective when you

listen to my comment number four which is after the next comment.

As a grower of tree fruit and berries in New England, we think that growers who have agricultural practices that exponentially reduce the possibility of exposure of produce to the water itself such as drip irrigation should be exempt from the testing requirement if the assessment criteria responses allow.

We'd also like to see an exemption for growers who certify that there will be no harvesting within four days of any surface water application to the crop. Again, if the assessment allows.

We disagree that testing should be required for every source every year for every grower. And now the comment I was referring to before, I'd like to speak to table five regarding the burden of compliance. The number of hours estimated for compliance must be put in perspective. The regulations that require time spent by a grower during the harvest season, that specified I think it was nine hours. There should be a multiplier there.

Our growing season is four months, three to four months and in certain situations when crops need to be harvested, they need to be harvested immediately. We make our entire annual income in a three to four month window, so the multiplier should be three to four times the amount of hours needed to comply if that is occurring during growing season.

So the time that we spend away from growing our crops which is almost a 24 hour schedule at times, that that should be accounted for and we would ask ultimately that any assessment for a low risk grower such as ourselves who use drip irrigation systems that are very close to the roots, we grow crops that are not on the ground. We have surface water that is, you know, not exposed, it's not in these open canals or any of that stuff, it's very isolated. We would ask that those assessments are 30 minutes or less for small farms or farms that don't have high risk.

And the last thing I'd like to say is that because there will never be a no risk situation and farmers are only part of the picture, part of a larger ecosystem of what happens, we would ask that the

federal agencies also ask the consumers to be responsible for washing their own produce and educate the public on that situation. We feel like that is a huge open hole that has to be filled. Thank you.

MS. MCDERMOTT: Thank you, Ms. Barden. Our next public commenter is Karla Gillespie with the Food Poisoning Bulletin.

MS. GILLESPIE: Hello, my name is Karla Gillespie. I'm a Food Safety Reporter with Food Poisoning Bulletin in Minneapolis. During the 11 years I've been writing about food safety, I've covered every major food poisoning outbreak in the US including 14 multistate outbreaks linked to packaged salads, spinach, romaine, or leafy greens and three outbreaks where the food source was officially listed as unknown but leafy greens are mentioned as common exposure in patient food histories or recalled in connection with the outbreak.

These outbreaks have caused serious illness. Right now there are two ongoing listeria outbreaks linked to packaged salads and each of them includes at least one fatality. The leafy greens e. coli

outbreaks I have covered since 2011 have resulted in 634 illnesses, 283 hospitalizations, 50 cases of hemolytic uremic syndrome which is a form of kidney failure and eight deaths and those are just the publicly announced multistate outbreaks. The actual totals are much higher.

According to the CDC, between 2009 and 2018, 40 e. coli outbreaks linked to leafy greens sickened more than 1200 people and often these e. coli strains are showing resistance to antibiotics. In 2017, several of these leafy greens outbreaks have either been caused by the same strain of e. coli (Inaudible) or linked to the same growing region.

For example, each year between 2017 and 2020 an e. coli outbreak have been linked to romaine lettuce or leafy greens from California Central Coast and each spring FDA has published an after action report on the outbreaks. The reports don't vary much from year to year. They all contain findings and recommendations regarding the use of ag water, root cause analysis, accurate origin labeling,

modernization of record keeping, mitigation of risk associated with adjacent and nearby land use.

To summarize them, cattle are the primary reservoir of e. coli (Inaudible). The farms associated with outbreaks are adjacent to cattle grazing areas. E. coli outbreak strains have been identified in samples of cow manure found uphill from fields and water samples from irrigation canals and in the sediment of an on farm water reservoir.

The FDA thinks cattle from nearby ranches are the likely source of contamination and because outbreaks often occur near the end of the growing season, there often aren't any leafy greens in the fields to test which is a significant barrier to solving outbreaks and preventing future illness. All of that is repeated in FDA after action reports from year to year, so it seems that these recommendations and the reports are not being followed by all growers.

The latest report did have one new thing and that was the characterization of cattle raising uphill from fields as a reasonably foreseeable hazard. As FDA notes in their report, covered farms are required

to implement science and risk based preventative measure of the rule but clearly all growers are not meeting this requirement. So looking at the proposed Ag Water Rule, some questions come to mind. First, given the confusion about foreseeable hazards, should the rule explicitly state that nearby cattle are a foreseeable hazard and define what is nearby and nearby to what? The farm, the water source, or both?

Second, are there metrics for environmental factors mentioned such as heavy rain or high winds or are those also left to a farm's discretion? Third, given the problem solving outbreaks that occur as growing seasons come to an end, should more consideration be given to timing of the once annual tests? Next, if the tests show that water is unsanitary, the rules as a farm must discontinue use and make mitigation efforts but it doesn't say what happens to the crop. What does happen to the crop and should that be stated in the rule?

Finally, on January 26, 2022, FDA posted a reminder to produce stakeholders that it intends to exercise enforcement discretion for all ag water

requirements for covered produce. What are enforcement measures available to the FDA and should those be enumerated in the rule? Thank you.

MS. MCDERMOTT: Thank you, Ms. Gillespie, and that concludes everyone who wished to make a public comment today. Thank you all for your remarks this afternoon and we do look for your full comments submitted to the docket. I'd now like to talk to our -- turn to our panel of subject matter experts for any final reflections.

MR. ASSAR: Hey, Cathy, appreciate all of the comments that were brought forward. Really, really, really good comments across the board. I really again love how those comments were framed with the rationale behind your thinking, so greatly appreciate the time and effort that you put into providing those.

We heard a number of things and there was just so much to digest in what you provided, so we're going to take it back and process it all and certainly consider it as part of our rulemaking process. I will say a couple of things that stuck out to me and I'll certainly ask my colleagues to also provide their



reflections along the way. There was definitely a great appreciation for a risk based approach and appreciation for the flexibility that the proposed rule offers. However, at the same time there's also a recognition of a need to provide guidance, technical assistance and outreach to help the growers understand how to do effective assessments and, you know, comply with other areas of the rule.

And so we are absolutely committed to doing the very best that we can to do that, recognizing that there are regional considerations at play. We have a produce safety network as Diane had talked about and their main mission is to work with the community to understand the regional commodity and condition considerations that should be accounted for and raise that to us and our guidance development, our education training and just our other work to help foster compliance.

We also heard from Emily about how industry has stepped up to develop commodity specific guidance and FDA has been part of that process as well. We'd encourage you to continue to step up. We really need

your help to help address all of the various considerations that need to be made in doing an effective evaluation of farms per the proposed rule.

So again, I'm just so happy with the comments that I heard from all of you and you can count on that we will be digesting those over the course of the rulemaking process and we are certainly committed to utilizing them to making the best rule possible for the community to follow. So appreciate that. I'll open it up for any of my other panelists to provide their reflections.

MS. RAVALIYA: Thank you so much for the opportunity today to all of the commenters for providing feedback. You know, this is the rulemaking process kind of live and hearing feedback from stakeholders and people who are interested in what we're doing is really how we come to a workable solution for everybody involved and I really appreciate hearing perspectives that are so diverse and I think the important thing for me that I took away from these conversations today is that there is so much that we need to consider as far as where

codifying requirements may lie, where guidance development may lie and really being able to tease all that apart in a workable fashion.

And I think, you know, remembering that this is just a proposal and this is kind of our first -- or not first, but this is the attempt to kind of throw out a new approach and a new concept for looking at water that's used to grow produce that's, you know, really starkly different from where we started in 2013 and you know, giving the opportunity to incorporate new science as it emerges and hearing from stakeholders about, you know, how they envision those kind of framework to play out is really -- has been really helpful.

And I just want to do a quick reminder that the testing is not a requirement of this proposal. It's one component of this assessment as a whole. So just a reminder that that's not a requirement for this proposal. Thanks so much.

MS. MCDERMOTT: Anyone else want to say anything? Or no worries if you don't.

MS. DUCHARME: I'll follow up. This is Diane. I did hear a lot of comments about reaching out, doing education and training, and we fully intend on working with stakeholders and really appreciate the acknowledgement that it's going to take all of us coming together, making sure that we're all getting it right, you know, as we go to the final rule and start those trainings. It's an important collaboration. So I look forward to working with all of you as this progresses and thank you very much for your time today.

MS. DAVIDSON: And this is Chelsea. If I can just add one thing really quickly, I think one of the key pieces that I've been hearing not only through the public comments at the very end, but also just throughout the entire presentation and the different panels that we had is that everyone really does recognize the public health importance of issuing these standards and it's something that we've seen not only in recent outbreak investigations but also going back decades with produce safety and understanding

that preharvest agricultural water can serve as a source of produce contamination.

I think we've said it many, many times before that we truly do believe that this is a gamechanger for food safety and so we're really excited to, you know, see and hear everyone's feedback as we consider next steps.

MS. MCDERMOTT: Michelle?

MS. SMITH: Okay. And I think that we've heard so many recurring themes that one of them that strikes me is that the new flexible assessment approach is very much appreciated by an awful lot of different people and then in the next sentence they say but it comes with challenges. And I think bottom line is that just because it's harder to do doesn't mean that we can't do it or shouldn't do it and I recognize challenges were an issue at the Produce Safety Alliance Summit when some people were saying well, we'd like to stick to the metrics because we know what they are.

But the other recurring theme was collaboration and working together and continuing to

engage different agencies and researchers and leverage the knowledge that we do have and the systems that we've put into place over the last couple of years to support the produce safety rules in general and so I think there is a lot of work ahead for all of us but with continued feedback and continued collaboration and support, I think we can end up getting to a really good place. So looking forward to hearing more comments. Thanks.

MS. MCDERMOTT: Great. Thank you to all of you today, our panelists, you did a great job with your presentation and appreciate all the work you've put into everything. We'll now hear comments from Dr. Susan Mayne, the Director of FDA's Center for Food Safety and Applied Nutrition.

DR. MAYNE: Good evening, everyone, and Happy Valentine's Day. 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 rule were complex and challenging to implement. We appreciate the feedback and have spent time having meaningful engagements with many of you. Farmers, industry associations, 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 communities. 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 and 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 contaminated 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 the 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 that 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 tools 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 requirements. As you heard, we're hoping to roll out a version of this tool that's 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 those requirements if finalized into their produce safety program 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 where questions can be sent, [agwater@fda.hhs.gov](mailto: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 yet. So this is your time to share data, experience, thoughts, and concerns. It is your time to share your thoughts on how you would like to see the FDA tackle compliance and implementation from 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 to the docket which will

be open until April 5th. I want to thank you all for joining us for today's discussion and I hope you all enjoy your evening with your loved ones.

MS. MCDERMOTT: Thank you, Dr. Mayne, for your remarks. And with that, this ends our public meeting. Thank you all for joining us today and enjoy the remainder of your evening. Thank you so much.

(Recording ends.)

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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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