UNITED STATES FOOD AND DRUG ADMINISTRATION

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

Virtual Public Meeting

Data and Technology in the New Era of Smarter Food Safety

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A P P E A R A N C E S

Laurie Farmer
Director, OSCP
ORA, U.S. Food and Drug Administration

Lauren Finnegan
Advisor, Communications and Public Engagement
CFSAN, U.S. Food and Drug Administration

Adam Friedlander
Policy Analyst, CORE
CFSAN, U.S. Food and Drug Administration

Vinetta Howard-King
Director, OHAFO-East
ORA, U.S. Food and Drug Administration

Michael Kawczynski
Project Manager, OCD
CFSAN, U.S. Food and Drug Administration

Glenda Lewis
Director, Retail Food Protection Staff
CFSAN, U.S. Food and Drug Administration

Jim Jones
Deputy Commissioner for Human Foods
U.S. Food and Drug Administration

A P P E A R A N C E S

Mark Moorman, PhD
Director, Office of Food Safety
CFSAN, U.S. Food and Drug Administration

Ruth Timme, PhD
Research Microbiologist, ORS
CFSAN, U.S. Food and Drug Administration

Chris Waldrop
Senior Health Scientist, OAO
CFSAN, U.S. Food and Drug Administration

C O N T E N T S

C O N T E N T S

P R O C E E D I N G S

GREETING & HOUSEKEEPING/LOGISTICS

MS. FINNEGAN: Good morning. The U.S. Food and Drug Administration is pleased to welcome you to today's virtual public meeting on "Data and Technology in the New Era of Smarter Food Safety." I'm Lauren Finnegan, a health communications specialist with the FDA's Center for Food Safety and Applied Nutrition, and I will be your moderator today, along with my colleague Michael Kawczynski.

The New Era of Smarter Food Safety Initiative was launched in 2019 to signal a new approach to food safety, leveraging technology and other tools and approaches to create a safer and more digital traceable food system. Today, during the morning session, you will hear presentations on FDA's current thinking on the potential for new, innovative or different data and technology activities to create a safer food system, while the afternoon session will be reserved for public comment.

Here are a few notes before we get started. The meeting agenda, speakers' biographies and a

document entitled "How to Comment" are posted on the FDA's public meeting webpage for this event. This meeting is being transcribed and recorded and will be posted on the same webpage when it becomes available. The recording should post within a week, and the transcript will be posted within a few weeks.

It is now my pleasure to begin our meeting by introducing Jim Jones, FDA's deputy commissioner for human food, to provide opening remarks.

OPENING REMARKS

MR. JONES: Good morning. I am so glad that you are joining us for today's public meeting on the New Era of Smarter Food Safety. As you are likely aware, we are in a transition period waiting for Commissioner Califf's proposal for unified Human Foods Program to go through the external review required for all federal reorganizations. But our work has not slowed, and our approach going forward is already taking shape.

Now and in the future, we are focused on making food about wellness through ensuring food safety, enhancing food chemical safety and improving

nutrition, and technology and innovation are critical to meeting these goals, as are you, our stakeholders. Your input and engagement are essential to helping us to identify and leverage those innovations that can make us more efficient and effective in achieving our mission to protect public health through a safer, more nutritious and sustainable food supply.

From the early days of the New Era of Smarter Food Safety through our most recent work, your expertise and collaboration have been integral to the tremendous amount of important work that has been accomplished in the past five years, as you'll hear throughout the course of the morning. We are here today because there's an opportunity for us to refocus New Era on those technologies and innovations that can turbocharge the advancement of food safety.

We are looking to you to help us chart a path forward. Through our work together today, we hope that you will share your thoughts on what you see as the most important areas for us to leverage technology and data under New Era. This feedback, along with the comments received to the accompanying

docket, will be used as we identify the areas FDA will prioritize for New Era.

I encourage you to think about food safety from all aspects, from foodborne outbreak prevention and response, from the farm to the facility to the point of sale, from testing the laboratories and fields, to our inspection and compliance actions. There is little in the modernized world where data and technology do not make a difference. With our limited resources, the question is where can we make the biggest differences for the most people.

We know that advancements in predictive analytics, the use of intuitive and effective data sharing systems and artificial intelligence, along with increased participation in GenomeTrakr and virtual reality-assisted training, we can help prevent foodborne illness outbreaks. But we also know that in a resource constrained environment, prioritization is key, that if we are spread too thin, we may miss an opportunity to create largescale, long-term, positive public health changes.

We also know that there is a lot at stake.

For every foodborne illness outbreak we prevent or contain, we reduce the devastating toll experienced by those impacted and their families, and we also avoid the tremendous waste caused by recalls that cast nets that are overly wide because we lack critical information to target only the implicated products.

So today, as you consider the possibilities we have thought of and those that we have not, I encourage you to think what you do best. Think strategically and big, share with us your experience and insights, and work with us to reshape our future into one where we are more efficient and effective in meeting our public health missions, and where foodborne illness outbreaks are a thing of the past. Thank you, and I look forward to working with you together.

MS. FINNEGAN: Thank you so much for those remarks, Deputy Commissioner Jones. I'd now like to introduce our next speaker, Adam Friedlander, one of the co-leads for Core Element 1: Tech-Enabled Traceability. Adam, I'll turn it over to you now.

DATA AND TECHNOLOGY IN THE NEW ERA OF SMARTER FOOD

SAFETY

CORE ELEMENT 1: TECH-ENABLED TRACEABILITY

MR. FRIEDLANDER: Good morning, and thank you all for joining today's public meeting on the New Era of Smarter Food Safety. My name is Adam Friedlander, and I'm a policy analyst in FDA's Office of Coordinated Outbreak Response and Evaluation Network in the Center for Food Safety and Applied Nutrition. I'm also the co-lead for our tech-enabled traceability initiative, Core Element 1 here at FDA, and I'm very excited to give some remarks today about the background of our tech-enabled traceability initiative, some of our key accomplishments, and really, I'm looking forward to hearing from you today about how you envision the future of this initiative.

So we know that tech-enabled traceability has grown in awareness over the last several years, and for far too long, we've relied on very manual processes to investigate foodborne illness outbreaks here in the United States. And this tech-enabled traceability initiative, we believe, puts front and center a focus on using technology and data to improve

public health outcomes around the country and the globe.

We know that better food traceability data can result in fewer foodborne illnesses and deaths. In a world where traceability records were predominantly paper-based and very manual processes on the industry side, the same was true at FDA, where we're relying on a variety of records such as purchase orders, invoices to try to triangulate the eventual source of the outbreak.

These traceback investigations at FDA could take days or weeks, and some of these outbreaks led to significant market withdrawals from the product, and we weren't even able to find the root cause of the illness. We know that we need faster identification for that source of contamination and the rapid removal from the market, and we believe that by harmonizing the definitions for traceability data, we can more rapidly and accurately link products and shipments together and ultimately stop that source of the outbreak.

So early on, when we first started this New

Era Initiative, we knew that we had to write a traceability rule under FSMA Section 204. And before we wrote the proposed rule, we leveraged this initiative, which is FSMA-based, people led, to try to understand where the industry was in their traceability journey. And we did many listening sessions and we learned from some of the leading experts in the food traceability space, and that did inform the proposed rule.

But this New Era Initiative is not a regulation. And the eventual final rule of the traceability final rule was predominantly based on the public comments that we received to strengthen even the proposed rule. And we know that it's going to be a very long journey ahead to truly make food traceability at the speed of thought a reality. But we have already seen so much innovation within the food industry ever since we finalized the final rule in 2022.

But this New Era Initiative is more than about a final regulation. It's about going above and beyond that foundational level of key data elements

and critical tracking events and truly leveraging that data to not only think about how can we improve this from a food safety perspective, but thinking about some of the other benefits of food traceability as well, such as better visibility within your supply chain or having a better understanding of where the greatest need for certain product may go in the supply chain.

And we have also heard loud and clear from the food industry that data interoperability is incredibly important. So instead of relying on one system to track the entire food supply chain, is there a way for data systems to talk to each other so that it doesn't require just one system? You can still leverage many different IT systems, but you're still ultimately seeing that same food traceability language. And this is something that we're incredibly excited to continue to see progress on and see the innovation that's taking place every single day.

But we know that collaboration is going to be a critical component of how we move forward in the future. We need to bring multidisciplinary teams

together. We need to bring the food safety folks, the IT folks, the legal folks, marketing and supply chain, a variety of teams need to come together and tackle this issue.

So we know that the industry can voluntarily work together to improve upon some of the greatest operational, organizational and technological pain points that we're currently seeing. But we are very confident that through collaboration, we can make great progress in tech-enabled traceability.

You know, I just want to highlight some of our key successes in our current activity that we have here at FDA and our tech-enabled traceability initiative. We have had over 70 listening sessions and tech demos with the industry since 2020, and we learned so much during each of these, and it's incredibly impressive to see. We have also hosted the tech-enabled traceability challenge, where we had over 90 submissions from all over the world provide a snapshot into what they're doing to reduce the barriers of entry into leveraging traceability technology.

And then IFT also produced an independent report highlighting some of the key outcomes and themes from this challenge. There is also a tech talk that was centered around food traceability, where some leading experts from the food traceability space provided a lay of the land of the current situation in tech-enabled traceability, and from an internal perspective, we have taken in the last few years and developed a prototype for our product tracing system, and now we're in the process of developing this product tracing system internally. And we're excited to continue sharing resources with you all about this PTS.

Currently we're producing a tech-enabled traceability video series where we're highlighting certain service providers who participated in the traceability challenge. And we've already released one of the episodes, but we have a few more on the way. So we're very excited to showcase those videos and roundtable discussions with you all.

From an international outreach and engagement perspective, we know that this is a global

food supply chain, and it's going to require global harmonization and collaboration. So we're in the future looking to continue doing outreach with international governments and international industry groups as well to try to speak the same food traceability language.

And we're also developing different software tools that are going to support those traceability efforts. We've already highlighted some of those technological components on our website, talking about our product tracing system. But we look forward to sharing more information about some of the tools that we're leveraging, not so people can duplicate or replicate what we're doing, but so that they can consider the technologies that we're using in their own digital transformation journeys.

And then lastly, we're participating in a group called SHOP. And that's organized by the Association of Food and Drug Officials. But it's really looking at the role of consumer purchase history data during outbreak investigations. And we know that with the food traceability rules that the

records really end at the point of receiving at retail. But we know that during the first leg of an investigation, we rely on what did that sick patient or customer eat that made them sick.

So how do we tie in the records from the consumer all the way back to that point of receiving at retail? It's a gap, and we know that there are some industry groups already out there who are trying to solve this, and that's an example of going above and beyond the rule and leveraging traceability data. And we're just very excited to see this level of collaboration and ingenuity happen in our supply chain.

So, today I'm most looking forward to getting feedback from you all on what you believe the next five years, ten years, 20 years look like for tech-enabled traceability. On the screen you'll see several questions. And we're going to put these questions in the docket. And I hope also during the oral comments today that we'll hear from you on some of these ideas.

If you have any other ideas beyond just

these questions, we're very eager to learn and to listen for you, but we're very interested to understand how we can improve traceability, leveraging technology, leveraging data to improve public health outcomes. So we're very excited to hear from you all, and just wanted to say thank you all for joining today.

And I'll leave with this. We know that at FDA we can only do so much to improve food traceability across the industry. But we rely on working with industry, government, academia partners, and this is a global effort too. And together, we can reduce that burden of foodborne diseases and truly leverage the power of data to improve the public health outcomes for our U.S. and global population. So thank you all so much and I'm looking forward to hearing from you.

MS. FINNEGAN: Thank you so much for your presentation, Adam. Next, I would like to turn it over to Mark Moorman and Vinetta Howard. They will be presenting on "Smarter Tools and Approaches for prevention and Outbreak Response."

CORE ELEMENT 2: SMARTER TOOLS AND APPROACHES FOR PREVENTION AND OUTBREAK RESPONSE

DR. MOORMAN: Well, hello. My name is Mark Moorman. I'm the director of the Office of Food Safety at the Food and Drug Administration.

I'm thrilled today to talk about a topic that our team cares deeply about, and it's the Core Element 2: Smarter Tools and Approaches for Prevention and Outbreak Response. I'll take you back to the Food Safety Modernization Act to introduce this topic. You know, that was an overhaul of our country's food safety system, directing the FDA to develop a number of regulations aimed at preventing foodborne illness.

But, you know, like many things in life, life happens. Along the way comes technology that is evolving so rapidly and the question that New Era asked us to struggle with is how can we deploy this technology in a way that assures and improves public health. FSMA didn't envision that. New Era does.

The Core Element 2 seeks to do a couple things: first, to advance the use of root cause analysis, and I'm not going to talk about that today.

That's a topic I would love to talk more about because our team has been doing a lot of work on it. Our objective here is to introduce or to advance the use of root cause analysis by all stakeholders, including the FDA, to create a culture of learning. You know, in life, you can't solve a problem you don't understand, and that's what root cause analysis is there to do to help you to understand what happened.

What I will be spending more time on today is the second area, and that is where we seek to strengthen the safety of our food supply by looking for novel approaches, and these novel approaches are based on data and data sharing. I'll also be wrapping up by talking about a tremendous tool that we have called the GenomeTrakr.

You know, if you're in this webinar today, you've benefited from the use of better data. I'm guessing right next to you right now is a cell phone. And with that cell phone, well, you've probably used it. You've used data to help you get to the right destination and perhaps even on time. You've used that cell phone with that data to be able to order

something online and have it received at the right location and in fact probably got notified when it was delivered.

Well, a good friend of mine, a great colleague to those of us in food safety, Frank Yiannas, has said better food safety begins and ends with better data. And he is absolutely right. Our quest in this Core Element 2 is to better connect to that data and use it to make better decisions or better, even better predictions.

As you'll see here, our scope isn't just the FDA in the use of this data. What I hope you see is that we're looking to create platforms or tools that can be applied by all the stakeholders in the food safety arena.

Today specifically, I'm going to be talking about data, our use of that data, our use of that data with these tools called artificial intelligence and machine learning. I'll also be talking about data sharing in what we call data trusts. And then finally, as I mentioned, I'll be talking about this game changing tool called GenomeTrakr.

So, my first job out of school, I worked out in the Oakland area, and I would look out over these massive docks where all these containers would be launched. And I remember thinking, new in the food safety world, how do the import folks know what to Screen? How would you know what to sample to find out what could be unsafe or violative? Imagine you're that person.

Well, as it turns out, the FDA has been at this for a while, and it has good systems. One that's called PREDICT, which is a risk-based tool to be able to know what to sample, which of those containers to sample. Well, in the universe of data predictive analytics, we're using these tools called artificial intelligence and machine learning to help us to make better predictions.

Now we started with the application of machine learning with seafood. And you might say, why seafood? Well, because about 90 percent of the U.S. food seafood supply comes in from outside the United States. A huge amount is imported. And the team has worked through three phases. We're in the midst of

phase three right now. Phase one was a proof of concept. Could we apply machine learning? The second was to integrate this machine learning into our existing PREDICT systems. And we're today at phase three. We're using this tool, machine learning, to better determine what we could sample to find violative compounds. Well, what could those be? It could be disease-causing organisms. It could be seafood decomposition, the presence of unapproved antibiotics or other hazards.

Now, we've also developed an AI-powered emerging chemical hazard intelligence platform, which is known as horizon scanning. Very excited about that tool.

So where are we today? Well, as you know, like me, you go through the grocery store, there's more than just seafood that's imported and so we're looking to apply machine learning to other imported foods coming to the United States.

We're also looking to apply machine learning to domestically produced foods. And then thirdly, and very importantly, we're using this tool to try to

understand what are those drivers of contamination, the drivers of those violative foods, what is causing those foods to become a problem or risk to public health.

So as I mentioned, we are using machine learning to make better predictions at import and looking to apply it to domestic foods. The request that you've heard from Deputy Commissioner Jones is to help us. Well, give us the gift of feedback. What other food safety problems could be solved through the use of artificial intelligence and machine learning?

We're also asking questions. Are you, is your firm, is your area of food safety using machine learning, predictive analytics? Thirdly, what limitations exist? This is a great tool, but what limits us from being able to apply this against our food system? And then thirdly, what can FDA do to provide or facilitate the application of machine learning to the food safety system?

Please give us that gift of feedback for our use of artificial intelligence and machine learning. We're, as you can tell -- you can hear the excitement

in my voice. We're big on this. We think there's tremendous applications, but it's bigger than FDA. The applications are bigger than the FDA, and we want to be champions of this technology.

So I've talked about artificial intelligence and machine learning as part of this Core Element 2.2 on predictive analytics. I'll take you to a different component of this, and it's on data sharing. And you might ask why would anybody share with a regulatory agency their data? Why would anybody do that? Well, I'll ask you, and we have a lot of discussions in the agency about this, to think about it differently.

You see, many of the categories that all of us worry about have known existing hazards that have been in that category for quite a long time. It's there. We can either deal with it or not deal with it. If we're going to deal with it, we need to visualize it. We need to come together and to compile the data that is out there to be able to better visualize that data and for all of us to have to be able to visualize it and make better decisions about the data.

There are many categories that have existing hazards, and we want to apply the seafood data sharing platform that we've built to seafood, but as you'll see, we want to apply it to other categories.

We have worked with our federal and state regulatory partners to be able to compile that data, and we've had a lot of success. With this seafood data sharing platform, we've worked with a platform built by Creme Global that is enabling us to see these toxic elements, to see PFAS. There's enormous amounts of PFAS data that we've pulled into this, aquaculture residues, seafood decomposition, marine biotoxin data globally. It is profoundly exciting and the ability to visualize the data, the levels, the regions, is very exciting.

So where are we going with this? Well, we've built a heck of a tool, but like any tool in your toolbox, it's only going to be as good as your ability to use it and to apply it. And we're looking to take this tool and expand it to other categories of the grocery store. There's many.

So we would ask for feedback on what are

some of those application areas for this data sharing platform. We want to work with partners that have data. You know, on any given day, industry is doing a lot more testing than the regulatory agencies are. But, having come from industry, I can tell you that there's not nearly the amount of sharing across the category, across an industry and there's often very little sharing with the regulatory agencies.

We're trying to change that. Yes, we are a regulatory agency, but we're putting our prevention hat on and we're trying to build a tool that enables or that addresses of the concerns that many would have of providing that information to a regulatory agency. Could it be blinded? Yeah, we can work with that. Aggregated data? Yes, we can work with that. We know that there's trade secrets that have to be protected, but we know in our core that the way through this, with these hazards and for better protecting health is by using these platforms, this platform to share data, to bring partners in, to understand the data.

I will tell you that we're very excited to work with a leader known as Western Growers. These

are produce manufacturers, produce growers out West that have been working with the FDA to be able to share their data. We're working through the concerns that exist with sharing data, but I believe we are going to get there.

We have a very strong desire to be able to conduct predictive analytics with all of you on this information. We also want to encourage industry to use the data and the technology. There's a lot of exciting stuff out there in the area of sensor technology, data digitalization. This is a very exciting space.

So the feedback that we would request is what food safety challenges are out there in your part of the world that could be addressed through data sharing. What are they? We're happy to talk with you about that. Me and my team would be happy to talk with you. We're partnering with our Office of Compliance to be able to build these data sharing agreements. What data would you share in this public-private trust?

And I'll finish up with this, the

GenomeTrakr 2.5. If you've never heard of this, I'll explain it. And it's an area that many of us have a lot of passion for in the agency. It is a tremendous public health tool. So what is it? Just like you and I have fingerprints, so do bacteria, so do parasites, so do viruses. These fingerprints are encoded through their nucleic acid sequences, just like you see there, the G and C and the A and T of DNA. Those are their fingerprints.

Whole genome sequencing does just that. It determines the entire sequence of that genome, of that organism. What do we do with that information? It enables us to make associations. If there's clusters of illness, we're able to see that, well, there's more than just one person. In fact, as you dive into this, these people all appear to have consumed the same food. Oh, and by the way, we're able to find that that same organism was in that growing arena or that manufacturing facility.

It enables us to connect dots. And that's the beauty of this GenomeTrakr tool. The FDA established the GenomeTrakr. It's a laboratory

network. We've got it in 28 states, and we're looking to get it in the remaining 50. It really is the case of as a kid when you would just add water to a sponge. This literally is adding water to the sponge. There are resources that are needed to be able to conduct the training and to bring forward the technology to these remaining 25 states to be able to use, to be able to determine these whole genome sequences and to be able to submit them for bioinformatics analysis.

Just to illustrate how important this is, the FDA, there's about 150 FDA regulatory actions per year, per year that are informed by this GenomeTrakr. It's a tremendous tool.

So what do we need? Yes, we are asking for feedback, but it's very clear here. There's no secret. We really do need funding to be able to expand this from the existing 27 to all 50 states. We would be able to build a continuous flow of pathogenomic data, genomic data from humans and animals gathered by the CDC and the USDA and FDA partners. We'd be able to detect the signals, and that's the beauty of this tool.

There is just so much work that's been done in this data space, and we at FDA see tremendous opportunities in this Core Element 2. We're very excited to work with all of you and would welcome the feedback on how else we can use these tools of predictive analytics and data trusts and GenomeTrakr. And with that, I thank you.

MS. HOWARD-KING: Good morning. I'm Vinetta Howard-King, director of FDA's Office of Human and Animal Food East in the Office of Regulatory Affairs.

I'm also the lead for several goals under the Core Element 2 of the New Era of Smarter Food Safety blueprint. Specifically, I lead goals under 2.3, domestic mutual reliance, 2.4, inspection, training and compliance tools, and 2.6, recall modernization.

As we build on the progress we've made in implementing FSMA, the New Era of Smarter Food Safety blueprint centered on three main principles: people-focused and led, FSMA-based and technology-enabled.

Over the past three years, we've had many successes and some challenges that we've had to

continue to work through, like funding and resources. But some examples of successes under 2.3, domestic mutual reliance goals, include establishing domestic mutual reliance partnership agreements with state regulatory agencies that allow FDA and states to leverage inspectional coverage. This helps to reduce redundancy and allows each organization to focus on the highest priority work.

Harmonization of food testing methodologies used by state and federal labs, including collection, sample collection, analysis and reports. Last year, over 8,000 micro and over 6,000 chemical food samples were analyzed by state laboratories, resulting in 21 human food recalls, two consumer advisories, eight firms or countries being added to import alert, and one FDA outbreak notice. We've also enhanced IT platforms to allow better data sharing with state partners to include system to system reporting, firm search and history, produce safety farm inventory and inventory reconciliation.

During the COVID-19 pandemic, FDA worked with our industry partners to develop, pilot and

implement remote inspectional tools. In the domestic arena, these remote regulatory assessments are a voluntary process that allow industry to share pertinent information with FDA prior to us conducting onsite visits. For example, for firms with a demonstrated compliance history with FDA, we've used remote regulatory assessments, or RRAs, to verify corrective actions to previous inspectional observations. This verification is done prior to an onsite visit by FDA. It has led to focus and time saving interactions between FDA and the firm doing the future onsite inspection

In the foreign arena, FDA has been able to utilize RRAs to both verify corrective actions and assess compliance with FDA food safety laws and regulations with firms that are located in countries and regions where there are State Department security concerns that prevent onsite inspections. We have found RRAs to be an excellent educational tool, as many foreign firms are not as well versed in our food safety regulations, so they are very appreciative of this outreach opportunity. Again, industry

participation in RRAs is a voluntary process.

FDA continues to work to modernize our recall process, which includes better recall communications and the use of technology. For example, in April 2021, FDA rolled out its enforcement report subscription service that allows consumers and industry to sign up for email notifications of new and updated recalls that are posted to the FDA's enforcement report.

Since the initiation of the subscription service, there have been updates to the service that allows for subscribers to subscribe based on keywords such as specific allergens. As of February 2024, there are over 11,000 active subscribers to the enforcement report subscription service,

And FDA continues to be very interested in your feedback, as we are always looking for ways to make our service more useful. So please feel free to use the link in my presentation to send your feedback to FDA.

Other recall modernization activities include the public meeting held last September 2023.

As you know, FDA's recall process is enterprise-wide, meaning our recall process covers the multitude of commodities regulated by FDA; for example, human and animal food, medical products, cosmetic and tobacco products. As a result of the recall modernization public meeting held last September, FDA received over 200 comments that were relevant to food recalls. We're still reviewing the public comments and plan to share the summary and outcomes in the near future.

Now let's talk about next steps. We plan to continue our work on establishing and enhancing domestic mutual reliance partnership agreements with our state partners. They have proven to be invaluable in our efforts to promote and enhance an integrated food safety system. We're looking at ways to enhance inspectional tools using artificial intelligence, machine learning and GeoWeb mapping technology. We want to explore different training modalities to include virtual reality. We will increase our efforts to effectively monitor and modernize the human food supply chain oversight.

We want to work collaboratively with

external partners on food recall solutions to better communicate recall information to the public. I look forward to hearing your feedback and to working together on common sense solutions. Thank you.

MS. FINNEGAN: Thank you for those presentations, Vinetta and Mark. We will now take a 15-minute break, and when we return, we will hear from the director of the Office of State Cooperative Programs at the Office of Regulatory Affairs, Laurie Farmer.

(Break)

MS. FINNEGAN: Welcome back everyone. Now we have Laurie Farmer presenting on Core Element 3: New Business Models and Retail Modernization.

CORE ELEMENT 3: NEW BUSINESS MODELS AND RETAIL MODERNIZATION

MS. FARMER: Hello. I'm Laurie Farmer, FDA's director of the Office of State Cooperative Programs. I am the Core Element 3 co-lead with my colleague Andreas Keller, and I'll be sharing the work of the team with you today.

Core Element 3 is about ensuring the safety

of produced and delivered using new business models and modernizing traditional retail food safety approaches. When considering food safety and risk management, we have a global food supply. Consumers are more knowledgeable about safety and want immediate access to ready-to-eat goods. Innovation and technology, including data analytics, are tools to leverage.

The questions that we have been working to answer and areas we want to hear feedback are how do we support innovation yet still ensure food safety and e-commerce? How can we use technology to monitor and gather data on sales of food through e-commerce to better understand the supply chain and identify sources? How do we modernize the retail food protection system in this country, and how can we work with retail food safety stakeholders to encourage innovation and technological development, digital tools, data sharing and training methods to control foodborne illness risk factors?

This conversation is a request for feedback about where FDA should target our resources and leverage stakeholders and data and technology. What

are we doing well, what do we need to expand on and where are the gaps and how can we improve?

The FDA retail food program has been dealing with the growth of food e-commerce, including evolving delivery models. The challenges in new business models include issues stemming from delivery practices of meal kits and groceries, such as key drop deliveries to unmanned retail establishments, also known as micro markets, and even to robotics, where machines do everything such as making pizza or cupcakes in a vending machine. FDA's retail food safety team has been engaged and working collaboratively with all our retail stakeholders, as well as USDA FSIS in addressing these emerging issues surrounding meal kits and food delivery practices through guidance development and policy changes to the food code.

This includes working within the Conference for Food Protection on its e-commerce committee developing guidance for direct to consumer and third-party delivery services and guidance for mail order food companies. With FSIS, FDA developed a meal kit

video and infographics for consumers. Throughout this process, we learned that the biggest challenges faced by stakeholders are around regulatory scope. Stakeholders want to understand the regulatory framework and their role in it, as well as liability issues and who has the ultimate responsibility for the food delivered direct to consumers.

E-commerce of foods continues to grow and evolve as domestic and foreign companies increasingly use e-commerce sales platforms such as websites and mobile applications to sell food products and arrange delivery to consumers. We all felt the impact on the industry during the coronavirus pandemic. Consumers accelerated the utilization of e-commerce to make food purchases amidst the coronavirus restrictions. Our work has evolved and it is involved identifying and learning more about the production and delivery of human and animal food sold throughout e-commerce, understanding the food safety vulnerabilities, developing educational and outreach tools to combat the vulnerabilities, working with the Conference for Food Protection on its committee developing guidelines

for home delivery of food, and determining whether they existing regulatory structure provides adequate protection for consumers.

In reflecting on the foundational work already accomplished, we realized we need to focus efforts on emerging mechanisms and online platforms for food delivery and how to protect foods from contamination as e-commerce business models expand to meet the needs of modern consumers.

With our refreshed focus on technology and data, we're seeking feedback on how to use technology to monitor and gather data on food safety risks related to food sales through e-commerce and to better understand the supply chain and explore ways to improve our understanding of retail food e-commerce trends with enhanced technology. Also, we're seeking feedback regarding how to clearly define the regulatory framework for e-commerce and gather data in partnership with stakeholders to assess the extent to which the existing domestic and international frameworks operate to regulate food safety online.

We will also continue to work with the

Conference for Food Protection on identifying best practices and existing guidance that pertains to e-commerce shopping at retail. We will also work with them on developing a comprehensive guidance document for retail food establishments with best practices specific to e-commerce food shopping to ensure general food code recommendations are followed.

These recommendations would include; proper handling during the shopping process to ensure adequate time temperature control and prevent cross-contamination, construction and equipment requirements for areas where shopped products are held, procedures to address the items that were shopped but not picked up by the consumer, and any other concerns that may arise during the guidance development.

As we move from new business model to discussing retail food safety modernization, it's important to recognize that retail food protection is an integrated partnership program. FDA cannot modernize retail food safety alone. We rely on strong partnerships with stakeholders, including our state, local, tribal and territorial colleagues, the

Conference for Food Protection, the industry, academia and professional associations. Equally important is having good communication and strategic alignment. FDA has established deliberate, targeted partnerships in retail food protection. There are specific objectives and alignment with retail food regulatory associations and targeted efforts with CDC and industry to put research into action to provide tools for regulators and industry.

As part of Healthy People 2030, we're working towards reducing the burden of norovirus, the leading cause of foodborne illness in retail. One important avenue FDA is working toward addressing norovirus is through the AFDO norovirus workgroup. We're currently focused on employee health.

My team created a National Food Code adoption strategy that is completed by a toolkit designed by the association collaborative for use by state, local, tribal and territorial regulatory agencies to realize food code adoption in their jurisdictions. Retail associations have built on this effort, and I encourage you to think about how you can

build on the work I'm sharing today.

FDA requests that the CFP establish a conference for food protection food safety management systems committee to engage with stakeholders. Industry really needs to lead this effort to take us to the next level in building tools for small operators who have limited resources. They are beginning to build a toolkit, which will include templates and examples on topics such as employee health, and my hope is that these efforts will align with the AFDO Healthy People norovirus group where they are employee health-focused.

We have expanded our communication methods and sharing of information, including six podcasts and webinars ranging in topics from FDA food code adoption to the behavioral science of retail food safety hosted by groups such as Food Safety Magazine. All of these things can be easily found on the FDA New Era Smarter Food Safety website on the activity page.

In the area of expanding resources, the FDA retail food flexible funding model has dispersed over $22 million in a three-year period to over 500

regulatory jurisdictions for development, capacity building, mentorship and other special projects supporting the retail program standards. We have also awarded funding to regulatory associations to work with federal partners to collaboratively advance retail food initiatives to try to reduce foodborne illness.

FDA and CDC developed five strategic action plans, or roadmaps, that address key areas to improve retail food safety. These objectives align with the FDA retail food program's strategic plan and the retail collaborative's objectives. Our goal is full and complete adoption of the latest code nationally.

This is the biggest complaint we get from industry. Different code requirements depending on the version of the code the state has adopted. The roadmaps includes: developing a strategy to support national food code adoption. This requires an environmental scan, defining states' current code and anything unique in the state regulation, barriers for adoption, tools and support to address the barriers and then targeting states, including strategies to

move the needle.

Increasing the use of risk-based inspections and intervention strategies. This start with agreement on what risk-based inspections mean and what it looks like, ensuring implementation and putting in place interventions and measuring their effectiveness.

Increased use of FDA's voluntary national retail food regulatory program standards. The standards are a quality continuous improvement framework for retail food safety regulatory programs. These standards exist for manufactured program, feed programs, eggs and they're being developed for produce.

Improving foodborne outbreak investigation methods. We're starting with environmental assessment resources where we will centralize those, conduct a gap analysis, do course assessments, make development and the implementation of tools for the field.

We will increase the number of restaurants and other retail food establishments with well-developed food safety management systems that use active managerial control. FDA will be supporting the

CFP committee.

These strategic action plans provide a roadmap to align various projects, leveraging the strengths of each agency and group, and avoiding duplication of effort. Work in these areas includes FDA's internal workgroup activities, the Retail Regulatory Associations collaborative project, the CDC and FDA MOU activities, DFP's initiatives and the New Era for Smarter Food Safety work, and currently the association collaborative is reviewing these roadmaps and providing feedback.

The Retail Regulatory Association collaborative brings together representatives from seven member organizations with a role of improving retail food safety in the United States. FDA and CDC are members of this group. We leverage our combined strengths and resources to create and share tools and resources for food safety programs so they can use these to improve their food safety in their jurisdictions.

The collaborative's six objectives are poised to influence or benefit regulatory food

programs and the food safety culture within regulatory jurisdictions and at restaurants and other retail establishments.

Pictured here are many leaders within the collaborative. And this is a meeting where the FDA's deputy commissioner for food, Jim Jones, met with them. This was a 20-year vision of many to bring retail food safety regulatory associations together to target the reduction of foodborne illness risk factors in the industry.

The group has made a commitment to work together without funding. We have had the opportunity most recently to fund the work of our objective, and that has exponentially moved our collective work forward.

In addition to the association collaborative, we are also actively working with these groups on the screen to advance retail food safety initiatives. The Conference for Food Protection committees, the CFP has multiple committees that are progressing the work of New Era. This includes the previously mentioned food safety management system and

the e-commerce committee, as well as committees on food safety culture at retail. These groups include stakeholders from industry, regulatory, academia, as well as FDA and CDC.

I am very excited about a project the CFP is leading. It's a research project focused on enhancing food safety and quality through digital systems and advanced technologies. Industry collects a lot of information in this arena. Some examples include health department, their inspectional data, third-party audit data that could have significant value for predictive modeling. This has real potential.

The CFP is conducting a literature review examining the use of predictive modeling to enhance food safety, including behaviors and practices in the food industry. Focus groups will be convened to explore participants' experiences with data digitization and digital transformation. They will also discuss and explore the utilization of various technologies, artificial intelligence, augmented reality and machine learning to evaluate food safety and quality standards.

The AFDO Healthy People 2030 norovirus Group. This workgroup focuses on putting research into action in the prevention of norovirus contamination of food and services in retail settings. Activities will include identifying best practices, vulnerabilities, mitigation and prevention strategies, potential public health measures and identifying barriers at retail food establishments that will decrease the presence and spread of norovirus, including tool to help prevent employees from coming to work sick.

FDA and CDC signed an MOU to formalize the partnership between the agencies for the purpose of focusing on combined efforts on reducing foodborne illness in retail and food service establishments. The goal is to create practical, operational tools that are demonstrated effective through research in preventing foodborne illness.

In order to modernize retail food safety, it would be beneficial to have a national benchmark. We know some of the strengths that our national retail food safety systems have, but do stakeholders believe

it would be helpful to have an independent body conduct a review of the retail food safety system in this country and how FDA supports it? Would you find this data valuable, with the idea to ensure FDA is targeting and prioritizing the support needed for our primary customers who are state, local, tribes and territory jurisdictions?

The FDA retail program standards provide a framework on which retail food protection programs can access how they stack up against nine standards. They can identify gaps through this process and they can be addressed and their accomplishments get national recognition on our website. As you see on this map, these pockets of coverage are fairly vast, with 969 jurisdictions currently enrolled as of December 2023.

While this seems like a large number, it's still far from the 2,500-plus jurisdictions that regulate retail food in this country. A national study on retail food safety would help determine if there are potential weaknesses and further ways we can assist those jurisdictions that are not part of retail program standards, as well as better helping FDA

target and prioritize work to improve retail food safety.

Regarding retail food safety modernization, as we look to the future, we would like to explore with stakeholders how to leverage technological advances in food safety and data we collect in retail food space to advance the food safety and to prevent foodborne illness. Further advance the importance of facility and equipment design as preventive controls for retail food safety management, and particularly encouraging the development and use of commercial smart kitchen equipment capable of automatically monitoring temperature and temperature processes.

Exploring and encouraging the use of new training technologies to better reach the vast network of retail food protection stakeholders. Encouraging and exploring the use of new digital tools and incentives that prompt desired behavior, such as handwashing and managing manual temperature monitoring. Evaluating and analyzing new and existing retail food safety data sources, and encourage the sharing between stakeholders.

Retail food protection is a team sport and all of us here today want to protect the food supply. It is an all these areas that we look forward to hearing your feedback from you today and in the docket. Thank you.

MS. FINNEGAN: Thank you for that informative presentation, Laurie. Our last presenter before we move on to the public comment session is Chris Waldrop, a co-lead for Core Element 4. Chris will be presenting updates about food safety culture.

CORE ELEMENT 4: FOOD SAFETY CULTURE

MR. WALDROP: Hi. My name is Chris Waldrop. I'm a senior health scientist in the Center for Food Safety and Applied Nutrition, and I'm also one of the co-leads for our work on food safety culture here at FDA.

Today I'd like to talk briefly about the work we've done regarding food safety culture here at FDA. We included food safety culture as part of our New Era of Smarter Food Safety because we recognize that in order to make dramatic improvements in reducing the burden of foodborne disease, we need to

do more to influence what employees think about food safety and how they show a commitment to this goal in their everyday work.

Food safety is the result of individual and collective behaviors, and behaviors stem from attitudes, perceptions, beliefs and values of both individuals and organizations. We wanted to better understand how those attitudes, perceptions and behaviors can be harnessed to improve food safety and we wanted to support efforts to make food safety a social norm across the food industry.

There are three key areas we have focused on in our work for food safety culture. First is to promote food safety culture throughout the food system. We know that more and more companies are working to develop and enhance a culture of food safety throughout their companies and in their facilities, and we want to support those efforts.

We also want to help promote best practices and examples of effective food safety cultures across the food supply, and we want to encourage other companies who may not yet have embarked on a food

safety culture journey to begin taking steps to do so.

Second, we wanted to promote food safety cultures throughout FDA. We want to explore internally our own culture of food safety within the agency, and we want to lead by example and learn from our own journey so we can better support food safety culture across the food supply.

Third, we wanted to develop and promote a smarter food safety consumer education campaign. While we often think about food safety culture in the context of companies and people producing our food, we also know that consumers have a role to play in food safety as well. We wanted to look at how we could better communicate with consumers about food safety and to do so using new digital tools, and we wanted to see if there were lessons from the work the food industry is doing on food safety culture that we could apply to our engagement with consumers to help influence their behavior when they're handling food in their homes.

I want to mention three accomplishments that we have done over the last few years. First, we

conducted a systematic literature review of the scientific literature on food safety culture. This helped ground us in the science of food safety culture and the work that's already been done. We learned that there's general consensus in the literature on how to define food safety culture, and we also learned that there is general agreement in the literature on the determinants of a strong and effective food safety culture. We posted our literature review on our website so you can examine these findings more deeply if you'd like.

We also learned there are a few gaps and areas we might want to explore further. First, more research is needed to assess the validity of assessment tools across different organizational settings, and we also learned that more research is needed to quantitatively demonstrate the connection between food safety culture and food safety outcomes, and I'll talk a little bit more about that in just a minute.

Second, we developed a training course for our investigators and other FDA staff. This was an

introductory course really designed to expose FDA staff to the concepts of food safety culture. The course looked at a number of different issues, including how you identify whether a firm has a good food safety culture and how to know the difference between a food safety program and a food safety culture.

Now this wasn't designed as a course so our investigators could begin inspecting a firm for a food safety culture; rather, the course serves as a food safety culture 101 so we could begin socializing the idea within FDA. We trained over 1,200 FDA staff in both our human and animal foods programs and the course is now available to our federal, state, local, tribal and territorial partners as well.

And third, we organized a webinar series with the Alliance to Stop Foodborne Illness. Hopefully many of you all were able to participate in at least some of the webinars we held over the past three years. This was really an opportunity for us to be able to collaborate with our stakeholders in both the food industry and the public interest community.

We wanted to elevate best practices, learn from some of the leaders in food safety culture and hear directly from our audience about the questions they had and the issues they were grappling with and wanted to hear more. In total, we had nearly 23,000 people register across the ten webinars we've conducted.

We explored a range of issues such as how to build a coalition of food safety culture champions across your organization. We talked about the importance of measuring food safety culture and provided some ways that you might be able to do it. We talked about storytelling and the importance that can play in shaping and reinforcing messages and inspiring employees, and we talked about how food safety culture and food safety management systems work together to improve food safety. And because people learn in different ways, we've also been posting white papers after each webinar that summarizes the content and highlights the key points of what was talked about in that webinar. These are all downloadable from FDA's website.

Our final webinar will be broadcast live

from the Food Safety Summit on May 9th, which will be both a virtual and a live event. We'll be looking at everything we've learned about food safety culture over the course of our webinar series as well as getting some fresh perspectives and new ideas. So we hope you'll be able to join us for that last final webinar.

In closing, I wanted to mention one area where we think new data could really help inform our work on food safety culture, and that is the linkage between food safety culture and food safety performance and to what extent a strong, mature food safety culture is predictive of food safety outcomes.

We're pretty confident that a mature food safety culture leads to positive food safety outcomes. But what data can we rely on to demonstrate that in a quantitative way? Are there ways we can look at data from the food industry that's maybe anonymized or disaggregated and use machine learning and AI to explore that correlation between food safety and culture maturity? With enough data, what insights can we learn about the development of food safety

measures? How can we better understand the drivers for food safety and food safety culture performance?

So that's an area we'd like to explore further, and we would really welcome your thoughts on that as well as other ways that data and technology can support our work on food safety culture. We'd also of course love your input on how best FDA can continue to support and foster industry efforts in this space.

So thank you for your engagement over the past years on food safety culture. We've learned a lot. We hope others have as well, and we look forward to continuing our food safety culture journey together. Thank you very much.

MS. FINNEGAN: Thank you, Chris. We will now take a break for lunch and when we return, we will begin our public comment session.

(Break)

MR. KAWCZYNSKI: All right. Good afternoon. We'll get started here shortly. So I welcome everyone to our "Data and Technology in the New Era of Smarter Food Safety" webinar. Again, we're just going to come

back from break, and we'll get started roughly in about a minute or so.

All right. Good afternoon, and welcome back from that break. I'm Mike Kawczynski, and this is the "Data and Technology in the New Era of Smarter Food Safety" webinar. At this time, I'd like to hand it off to my co-host, Lauren Finnegan. Lauren, if you're ready, take it away.

PANELIST INTRODUCTION

MS. FINNEGAN: Thank you, Michael. I hope you all had a great break. Now we'll get into our afternoon session, which will consist of comments from members of the public, followed by responses by our group of panelists. Before we hear from our public commentators, I'd like to introduce our panel members. From Core Element 1, we have Adam Friedlander. From Core Element 2, we have Mark Moorman, Ruth Timme and Vinetta Howard, and from Core Element 3, we have Laurie Farmer and Glenda Lewis.

And now we'll hear from our public commentators. Just a quick reminder before we get started, that the views expressed today don't

necessarily represent the views of FDA. First up we have Celina To.

MR. KAWCZYNSKI: Good afternoon, everybody. First we'd like to please introduce each one of our panel members. So let's go around with Core Element 1. Adam, would you please introduce yourself and tell us what element you're managing?

MR. FRIEDLANDER: Hi. Thanks, Mike. And thank you, Lauren, as well. My name is Adam Friedlander. I'm a policy analyst in FDA's coordinated outbreak response and evaluation network, also known as CORE. I'm also the co-lead for New Era of Smarter Food Safety Core Element 1, which is the tech-enabled traceability initiative, and I co-lead that core element we're Captain Kari Irvin, who is, CORE's deputy director. And I'm very happy that you all are here today. And I'm looking forward to your comments. Thank you.

MR. KAWCZYNSKI: I'm going to hand it back to Lauren, who can go around and introduce each one and allow them to give their opening remarks.

Lauren, you want to take it away?

MS. FINNEGAN: Yeah. So, Mark, would you like to introduce yourself?

DR. MOORMAN: I'd be happy to. My name is Mark Moorman. I'm the director of the Office of Food Safety. I've been with the Food and Drug Administration for five years, prior to that in the private sector. I have the privilege of leading the Office of Food Safety, where our team spends a lot of time thinking about when outbreaks happen, how do we prevent them? What are those levers of prevention that that we pull in that space of post response? within that, we do a lot of work on policy, research supporting our subject matter experts, support the Office of Compliance. And very importantly for today, I have the privilege of calling Core Element 2 with Vinetta. So, thank you so much for taking the time to be with us today. And look forward to hear from you.

MS. FINNEGAN: Thanks, Mark. Ruth, would you like to begin?

DR. TIMME: Yeah, sure. I'm really happy to be here today. My name is Ruth Timme. I'm a research microbiologist at the FDA within the Office of

Regulatory Science and I've been with the FDA going on 13 years now. And for most of that time, I've been really actively involved in FDA's initiative to use genomics for foodborne pathogen surveillance. We call this the GenomeTrakr program. And I'm the lead for that program. And within New Era, that program, the GenomeTrakr contributes to Critical Element Number 2, along with Mark Moorman. Thanks.

MS. FINNEGAN: Thanks, Ruth. Vinetta?

MS. HOWARD-KING: Hi, everyone. My name is Vinetta Howard-King. I am the director of the Office of Human and Animal Food East in FDA's Office of Regulatory Affairs, where I have executive oversight over inspections and investigations, sample collections and, for a while longer, compliance and enforcement activities, foreign and domestic. I'm also, as Mark mentioned, the co-lead for New Era of Smarter Food Safety Core Element 2. Specifically, I lead Elements 2.3, domestic mutual reliance, 2.4, inspection, training and compliance tools and 2.6, recall modernization.

MS. FINNEGAN: Thanks, Vinetta. Laurie?

MS. FARMER: Hi. So glad to be here. So I'm Laurie Farmer. I'm the director of the Office of State Cooperative Programs, and this team of subject matter experts work in the field in the areas of retail food protection, mollusk and shellfish, sanitation and Grade A milk safety. And I'm just so glad to be here. I co-chair the Core Element 3 with Andreas Keller. And I work very closely with Glenda Lewis, who is here today. So, looking forward to hearing from you. Thank you.

MS. FINNEGAN: And Glenda?

MS. LEWIS: Good afternoon, everyone, or good morning. So happy to be here today. I am the director for the retail food protection staff in CFSAN's Office of Food Safety, and I've been at FDA since 1996 in the retail program and I currently have responsibility for oversight of the retail policy component at FDA, and I work with a fantastic group of staff on a team developing national retail food policy and interstate travel program policy.

I co-lead the New Era 3.1 core element on e-commerce with Andreas Keller. So happy to hear from

everyone today. Thank you.

PUBLIC COMMENT

MS. FINNEGAN: Great. Thanks, Glenda, and thank you all for being here today. Now we'll go switch over to our public commentators, and we have Celina To first.

MS. TO: Thank you. Good afternoon. Thank you for this opportunity to provide feedback specifically, to align with the continued New Era work and WGS and ways to monitor and gather data. Oxford Nanopore Technologies has created greater access for labs to bring genomics and health due to capital free, scalable and real-time devices with end-to-end workflows like No-MISS, nanopore-only microbial isolate sequencing.

These simpler workflows can accelerate the implementation of GenomeTrakr across 50 states and internationally, similar to ongoing efforts with CDC PulseNet. Also, access to EPI2ME, a point and click solution with optional use of smaller robotics like TurBOT can potentially integrate Galaxy Tracker and FDA BAM pipelines, similar to our integration of 602

for salmonella serotyping. The intent is to streamline training of technicians, especially during a staff turnover.

This type of technology can become useful when responding to emerging pathogens like Cyclospora. Similarly, if we were to face another Cronobacter outbreak, we would be prepared with the ability of this technology to further shorten root cause analysis and response time. The real-time capability is pivotal not just for the FDA, but for all stakeholders in food safety.

I also hope the FDA will consider developing and validating quasimetagenomics, metabarcoding or targeted panel approach to update FDA BAM as a cost and time saving strategy and screening and confirmation. These tests can better align with private sector and current operations and may allow easier sharing of data anonymously by creating a safe haven through similar setup like the Food Industry Intelligence Network with Creme Global. Such a collaborative environment would improve our ability to predict an event day, build trust to encourage sharing

of WGS data, and exchange effective corrective actions ahead of FDA sampling assignment and before an outbreak occurs.

Thank you for considering these initiatives. I look forward to seeing the FDA lead in these innovative areas, setting a global standard for food safety and public health preparedness.

MS. FINNEGAN: Thank you, Celina. Now up next, we have John Bailey.

MR. BAILEY: Thank you, everyone. My name is John Bailey. I'm the executive director of Top 10 Produce LLC located in Salinas, California. We have growers in 25 states who utilize our low cost traceability system currently. For the past 14 years, we've been assigning globally unique GS1 global location numbers, commonly known as GLNs, to uniquely identify each of our growers nationwide.

Our growers use their global location numbers, which we have assigned to them, as the traceability lot code source reference. It is our position that this current ongoing practice is in compliance with the Food Safety Modernization Act 204

final rule. There are currently just under 2 million farms nationwide who are looking for clear and direct answers related to FSMA, the Food Safety Modernization Act.

So the most significant action the FDA could undertake to enable our independent growers to enhance traceability across the global supply chain would be for the FDA to confirm that the use of these unique GLNs as a traceability lot code source reference is in compliance with the FSMA 204 final rule. Thank you.

MS. FINNEGAN: Thank you, John. We appreciate those remarks. Next up we have Alexander Kashef.

MR. KASHEF: First, I would like to really thank FDA for this opportunity and also share my excitement and passion from New Era. My name is Alexander Kashef. I live in Los Angeles next to UCLA. I'm the owner and the president of the Food Safety and Geospatial Data Analysis Training Institute. It is basically two institutes all together. Now, in terms of my educational background, my degree is geology, astrogeology, environmental science, microbial

ecology.

And I also want to share with you, the first time I heard about HACCP was in the class of -- was astrogeology. That changed my whole life. So this is my beginnings in terms of getting involved in HACCP. I'm also a GIS specialist. I generally believe that if it is not mapped, it is not done. So, I'm basically, involved in mapping and teaching mapping in addition to being a (indiscernible) specialist.

I'm also lead instructor for 22 HACCP and FSMA classes. I teach human food, PCQI for human food, PCQI for animal food, for produce, imported food and food defense. I also have established and written for six different classes for the New Era. In addition to six New Era HACCP class that I teach already, and it's pretty much popular and also teach FSMA classes, but also teach another 11 HACCP classes that pretty much are regulated by FDA. Meat, poultry, package, dietary supplement. So pretty much whatever is regulated by FDA, my institute is teaching them.

So I would like to concentrate on the six classes that I'm teaching and what basically I'm

learning from the business, the industry and the academia in terms of New Era.

Since New Era came, I pretty much spend most of my time developing class for New Era. I strongly believe that the New Era is a whole new paradigm that is going to change everything. But my focus is this, basically using DNA fingerprinting, spectral fingerprinting and geospatial data collaboratively bringing them all to handheld devices.

So the issues that I cover in all these classes are artificial intelligence. I would love to share with you the six classes that I teach related to food safety era. The number one is how to write a HACCP plan to this class for traceability. So I really go in detail talking about Section 204 and how to write them with the addition or how to map everything. If is not mapped, it is not done. I strongly believe that we have to introduce geospatial data, when 70 percent of the data has a geospatial component. Bring them to all aspects of food safety. So I introduce that to traceability class.

Now I also have developed four courses for

Core Number 2, and these are the following four courses. I'll just talk about number two. Number one, two-day class for the application of artificial intelligence into food safety. So basically upon completion of this class, pretty much everybody knows what is AI and how it is used in food safety, all the way from farm to table.

The second course related to the second core is basically called food safety omics. it's the only course on Earth that basically bring the whole issue of omics, genomics, proteomics and transcriptomics, other genomics, and teach them how to apply them in food safety to this class for basically using all kinds of omics in terms of in food safety.

And the third class is basically -- it started eight, nine years ago. In Europe, there's an consortium called Food Smartphone, and the address is www.foodsmartphone.eu. They give PhD in how to use a smartphone in food safety and with food quality. I have been following what they have been doing. But I have my own approach using NASA information and USGS and other a spectral databases. It's very crucial to

really bring --

MR. KAWCZYNSKI: Please wrap it up.

MR. KASHEF: -- signature in food safety. And the last one is basically food safety modernization, food retail modernization. Do I have any more time?

MS. FINNEGAN: No. That's it.

MR. KAWCZYNSKI: No.

MS. FINNEGAN: Thank you, Alexander. We appreciate it.

MR. KASHEF: Thank you so much.

MS. FINNEGAN: Next up we have Jim White.

MR. WHITE: Hello, everyone. My name is, Jim White. I'm president of ENSESO4Food. The FDA's FSMA 204 regulation requires traceability for specific foods. This means tracking them from farm to fork. ENSESO4Food is here to help companies comply by creating a system of traceability lot codes. These codes are essential for the FDA to quickly investigate outbreaks.

Primary source data collection from farms and fishing enterprises will be the first big

challenge. Cost effectively capturing source traceability lot codes has become one of our passions. We're experts in traceability. We won the FDA's low cost food traceability challenge and have experience managing billions of transactions globally. ENSESO4Food recognizes the importance of a diverse traceability ecosystem and is committed to working with other solution providers.

Our Trakkey system is one such solution proven to support complex traceability needs. Trakkey already manages billions of transactions in Europe and around the world for both tobacco and pharmaceutical serialization. Collaboration is key to success. ENSESO4Food is a strong supporter of standards like GS1 for standardization and interoperability. But true success requires collaboration beyond just standards. That's why we invite other technology vendors to call us to discuss how our systems can work together to seamlessly share data across the supply chain.

ENSESO4Food's solutions are designed for ease of use. We offer smartphone apps with

multilingual capability, ensuring a familiar and comfortable experience for everyone involved. But user friendliness goes beyond the interface. Our solutions can enforce and automate workflows, minimizing errors in manual data entry. They also integrate with existing systems like accounting systems, warehouse management systems, ERPs and MRPs. This eliminates the need for duplicate data entry and streamlines existing operations.

ENSESO4Food understands the challenges of a small farm. We are piloting a solution to get source traceability lot codes into the system easily and cost effectively. This pilot includes offering our device as a service, or DaaS model, as an option. DaaS can simplify adoption for farmers and fishing operations that are still transitioning to digital tools. It provides a bundled solution with hardware, software and support at an affordable monthly cost.

FSMA 204 is a starting point. ENSESO4Food's solutions go beyond just compliance. For example, we offer IoT sensors to monitor the cold chain. Traceability solutions also provide valuable data for

recordkeeping related to GAP or planting strategies. These tools can empower small businesses to improve their operational efficiency and productivity today. While predictive analytics, machine learning and AI hold exciting opportunities, the foundation for a robust food safety system rests on high quality source traceability data.

Accurate data allows for faster outbreak identification and targeted interventions minimizing risks and protecting consumers. ENSESO4Food is committed to a safer, more efficient and transparent food system. We believe that FSMA 204 is a catalyst for positive change. We are here to help businesses of all sizes thrive in this New Era of Food Safety. Thank you for your time.

MS. FINNEGAN: Thank you, Jim. Next up, we have Dr. Marcia Lee Herzberg.

DR. LEE: Hello. First of all, I'd like to say thank you for allowing me to be here and speak, looking at this data and technology in the New Era. I find it to be very exciting. I am a former regulator myself, having worked in the retail food segment,

manufactured food segment and also having worked in the public sector and working as an adjunct professor for Northeastern University for their master's program in regulatory affairs for food.

What I'd like to speak about is the data systems that have been spoken about previously. And I'd like to speak about it in regards and in relation to the retail food program. I did a study, "Inspection, Laws, Risk Factors and Foodborne Illness," and an important question that I posed was how the current regulatory system could uphold its responsibility to the public, enforcing the law and food safety without adequate funding, with an increasing number of food establishments, insufficient numbers of food inspectors, budget constraints for regulatory agencies and a pandemic of foodborne illness, particularly relating to the food segment, often managed by small county or small town boards of health responsible for the majority of foodborne illness and the only segment of the food system not in the Code of Federal Regulation, the CFR, whose regulations are voluntarily adopted from the FDA,

Model Food Code, which changes every four years.

They are supported by the FDA's retail food program, which provides tremendous tools and tremendous resources. But somehow there's a gap and I know that's one of the things that Laurie mentioned, that they're looking to try to find a way and assess how to best address that task that they have.

My data demonstrated frequency of inspections, had a high negative correlation relationship with foodborne illnesses, frequency of inspection increases or decreases, foodborne illness will travel in the opposite direction. Every year that the frequency of inspection rose in subject cities, the per capita foodborne illness rate decreased, and in the years where the frequency of inspection was stagnant, the foodborne illness rates were relatively unchanged.

Frequency of inspection and high risk factors had a high positive correlation relationship. The more frequent the inspections, the higher the incidence of high-risk factors was noted. Risk factors are used to reduce foodborne illness. They

are a preventive control.

By correcting these critical items, if properly reported, an establishment can theoretically prevent foodborne illness, and the high-risk factors had a high negative correlation with foodborne illness in the years that foodborne illness decreased, demonstrating its functions as a preventative control, the preventative control it is meant to be.

Risk factors were coded by assigned values by state law and under a common numbering system. It was designed to see if the food law changed the assignment of the risk factors. The coded controlled law and assigned law risk factors did demonstrate a significant difference of means in each year of the study, establishing that food law does influence risk factor assignment, demonstrating the need for a similar or the same standardized food code to be used throughout the country.

One of the leading drivers to the success of this study was the ability to access research material through databases. It took a tremendous amount of time and analysis. But from this study, I concluded

the retail food system would benefit from a study on a viable national electronic inspection platform, an information database system accessible across all states by multiple agencies and all retail food programs nationally.

The sharing of information in real time is key to identifying factors that can mitigate risk of foodborne illness effects, not only at the local level, but nationally. And it's through data sharing that we can create a dynamic food safety system that can impact foodborne illness, necessary policy change, and make the most of scarce resources in the public health sector. If we can create --

MR. KAWCZYNSKI: That's time.

DR. LEE: Okay. Well --

MR. KAWCZYNSKI: Just go ahead and wrap -- you have a few minutes. Wrap it up, and then stay on, please.

DR. LEE: Okay. So, I just wanted to state that good policy is always driven by good data and that this aligns with the harmonization of traceability again through data. And we can use the

same type of system to do tracebacks and trace forwards and to align with what we find in the retail food system. Thank you.

MS. FINNEGAN: Thank you, Doctor. Next up, we have Sharmeen Khan.

MS. KHAN: Good afternoon. My name is Sharmeen Khan, and I am the chief strategy officer of OpsSmart Global. We are also one of the winners of the tech-enabled traceability challenge that was referenced earlier. We at OpsSmart belief that the FDA must stop looking at food safety through a topic-based vision and start looking at it from a broader spectrum.

It will require us to combine tech-enabled traceability, predictive analytics and data sharing, ambient IoTs. As said earlier, we must think strategically and big. What I mean by that is that the most significant and overarching focus should be on interoperability. Until we move away from silo-based data systems, we will never be fully able to flex the muscle of data.

All companies, big or small, have some sort

of data in some sort of format. However, their inability to share that data within their own organizations and with their partners handicaps them, the FDA and the public.

My first recommendation is that as the FDA continues to harmonize the critical tracking events and key data elements, the FDA also needs to harmonize how data is shared. If you look at the seafood industry as an example, organizations such as Global Dialog of Seafood Traceability, MSC, AFC, et cetera, got together and devised one method of electronic data exchange. They created a system to authorize technology providers to implement that methodology of electronic data exchange. The FDA must investigate finding a similar path in order to create a unified path forward so there are standardized tools for gathering and sharing data from industry to government and the public.

My second recommendation is that the first steps taken by the FDA in FSMA 204 have been a game changer, but they are not enough. Telling people or the industry that they need electronic sortable

spreadsheets, then saying that they don't have to have a digital method of collecting their data, it's sending the industry a very confusing message that will hurt them in the long run. I believe the FDA needs to speak more clearly as to what is technologically expected of food growers and processors. We need the FDA to possibly find a method of subsidizing access to simple data collecting methodologies, such as Microsoft Word or Excel, Google Sheets or Docs, something. Let's make it easier for the food industry to meet FDA's requirements by becoming digitized.

Lastly, to answer Adam's questions, all of which were fabulous, is what other areas can tech-enabled traceability create value? My answer is sustainability. If we can trace products, how they're grown, where they're grown, how they're grown, we can also capture the amount of waste, how product is reutilized, how soil and water is reused, what type of packaging we're using. By collecting how much we reuse, how much we waste, we improve a company's sustainability posture, but we also improve our

national carbon footprint.

In conclusion, it is important to remember that we are a global food system and a product can exchange multiple hands before it ends up on our shelves. So adopting a data exchange-centric or interoperability-centric approach to food safety enhances visibility across the supply chain, which translates to a safer food system. Thank you so much.

MS. FINNEGAN: Thank you, Sharmeen. So just a general reminder to all of our public commentators, please stay on the line so our panel, if they have any questions for follow up, they can contact you again. Next up, we have Tom Ragsdale.

MR. RAGSDALE: Hello everyone. I'm Tom Ragsdale, I'm an app developer living here and in Henderson, Nevada. Now, last year I worked for a small company here in the Las Vegas area that sells Vegas-themed candy to a number of stores, mostly in casinos on the Strip. Their tracking paperwork was entered into a ledger by hand, both incoming and outgoing product.

And after I left the company, I happened to

cross the FDA requirements that go into effect, I guess, next January. And at first I started working on an app customized for the candy company, but then realized there are probably a lot of other mom and pop shops, as well as larger companies that would benefit from a more generic app that would meet the FDA law tracking and reporting requirements.

The app's nearing completion. It's fully menu driven and has four sections. I call it Lot Number Tracker. The first section, it allows the user to enter products, multiple ingredient products, manufacturers and suppliers of those products and customers that they send the product to. And then there's a section to be able to edit all that in case they make mistakes.

There's a section to input tracking data for both incoming and outgoing products. And then, there's a section allowing the printing of reports. In the event of a recall of a particular product or an ingredient in a product, with one click reports can be generated, all incoming product and any products that have been distributed to customers containing the

ingredient with the suspect lot number, one report for each customer that has received any of the product in question.

At this time, the reports are in a PDF format and not Excel format, but Excel can import from PDF files. I've done it this way because text files are more susceptible to accidental corruption. The app will be available on Apple products, Android products and Windows products and could in the future be available on servers.

Again, my name is Tom Ragsdale. I can be reached at tomragsdale@cox.net, and my mobile phone number is 702-704-9497. That's 702-704-9497 or tomragsdale@cox.net. Thank you for your time.

MS. FINNEGAN: Thank you, Tom. Next up, we have Mara Burr.

MS. BURR: Thank you very much. I appreciate the opportunity. My name is Mara Burr. I'm the vice president for clinical affairs at Consumer Brands Association, and I appreciate the FDA providing this opportunity to speak on the data and technology in the New Era of Smarter Food Safety.

The Consumer Brands Association champions the industry whose products Americans depend on every day, representing nearly 2,000 iconic brands, from household and personal care products to food and beverage products to consumer packaged goods (indiscernible) industry plays a vital role in powering the U.S. economy, contributing $2 trillion to the U.S. GDP and supporting more than 20 million American jobs.

We appreciate the FDA's blueprint for the future of a New Era of Smarter Food Safety, and the opportunity to provide input on how data, innovation and technology are utilized to produce better food safety outcomes. Each of the core elements require a strong, transparent and inclusive FDA that is delivering on its mission as the lead food safety regulatory agency in the United States.

Our members innovate on traceability, safety, nutrition, sustainability and other information to address consumer preferences. We created the Facts up Front program in collaboration with FDA, providing transparent information through

front of pack labeling so consumers can make informed choices about the products they purchase. Although this is not a technology, it is an innovation. And with respect to technology and data specifically, industry leaders from manufacturers and retailers came together to create SmartLabel, a transparency tool that has become the standard for sharing product information beyond what is on the label.

SmartLabel currently has over 1,000 brands and over 100,000 products, all participating voluntarily. Consumers can gain access to ingredient definitions, context run allergen statements, nutrition resources, safe handling instructions and more, all with just a simple QR code scan. More recently, it was employed to facilitate recall notifications to consumers at the tail end of 2023 and into early 2024. Hundreds of thousands of consumers benefited from SmartLabel.

The private sector will continue to innovate to improve food safety and increase transparency, and we would urge FDA to continue working with the industry to encourage and incentivize innovation. FDA

should continue to incentivize the creation of technological tools, including artificial intelligence to address food safety issues, increase predictive tools and allow for recall communication technology that is implementable for companies and is accessible to consumers.

We all have a role to play in fostering, supporting and strengthening a food safety culture. But at the center is a strong FDA playing a leading role in enforcing its core mission of food safety. State and local governments, private sector partners and consumers are looking for leadership from the FDA and for it to be a collaborative partner to develop data and technological innovations to support the New Era of Smarter Food Safety. Thank you very much.

MS. FINNEGAN: Thank you, Mara. Next up, we --

MS. BARR: Thank you.

MS. FINNEGAN: -- Katy Jones.

MS. JONES: Yes, thank you so much. Thank you for the opportunity to speak today. My name is Katy Jones, and I am the CEO of Trustwell, a nutrition

analysis, food labeling, traceability and recall software company. I speak before you today not just as the CEO of a food technology company, but as a mother whose child's life can be threatened by something as simple as a snack.

My son's severe tree nut allergy not only has reshaped our family's life, but has also galvanized my dedication to ensuring the safety of every item of food that reaches the consumer's hands. At Trustwell, we recognize that technology and data standards are not just tools for business efficiency or regulatory compliance. They are vital lifelines that can protect consumers and enhance the integrity of our food supply chain.

As everyone here knows, each year millions are affected by foodborne illnesses and one of the key areas preventing these incidents is traceability. With precise tracking, we can swiftly identify and address the source of contamination or mislabeled product, potentially saving lives. Technology plays a key part in this process, ensuring that in the event of a recall, we can quickly isolate the affected

products.

And as has been mentioned, it's also critical that we think about traceability technology beyond food safety as well. There are tremendous opportunities to leverage this data in other areas of the business for sustainability, real-time inventory management, supplier scorecarding, just to name a few. Data standards like GS1, the GTIN and the (indiscernible) that have been mentioned are the foundation that makes this possible.

Standardizing data across the industry ensures that every stakeholder across the supply chain speaks the same language, making the process of tracing products not just possible, but seamless. This uniformity also allows for the interoperability of systems. We've had many software providers here today. We all want to work together to have better traceability in the supply chain from those small farmers to large retailers.

The work we do at Trustwell, in partnership with our customers, is driven by the belief that technology can and should create a safer and more

transparent food industry. We are dedicated to developing and implementing systems that ensure traceability, compliance and quality across the supply chain. And with that goal of turning this belief into reality, our offerings across tech solutions, training, training and services represent our mission to change the food industry for the better.

Whether tracing and tracking with our product, FoodLogiQ, or creating accurate and consumer-focused nutrition labels with Genesis Foods, our software gives companies the tools they need to adhere to FDA regulations. We work with some of the best food companies in the world who stand with us as leaders and innovators, ready to go beyond compliance to remain always ahead, tech-connected and focused on safe food for all. In fact, we have tracked nearly 200 million critical tracking events, or CTEs, already around the world to date.

In closing, I urge the FDA to continue its commitment to advancing tech-enabled traceability through the execution of FSMA 204 and emphasizing recall technology as well in the food industry.

Together, we have the power to protect our nation's health and well-being, ensuring that no one has to face the unthinkable because of what's unknowingly in their food. Thank you again for the time, your attention and your commitment to the safety of our food.

MS. FINNEGAN: Thank you, Katy. Next in the lineup, we have Neil Wieselman

MR. WIESELMAN: Hi. My name's Neil Wieselman. I am the director of infection prevention for Intercon Chemical in St. Louis. And everybody's been having really great points and traceability and education and new technology are all really important. But the one thing that most people aren't talking about is hand hygiene. And the fact that alcohol-based hand sanitizers do not have norovirus efficacy.

Most people I talked to are unaware of the fact that they don't have norovirus efficacy with their hand hygiene programs. And if everybody is aware, norovirus is the leading cause of foodborne outbreaks. So we have a hand hygiene program that doesn't kill the leading cause of foodborne outbreaks.

And it's been this way for years.

My company manufactures alcohol-based hand sanitizers, and we're going around trying to alert as many people as possible about the lack of efficacy so that they're aware of that at least. And until COVID, it was a major concern. Of course, COVID put everything into the backseat. So this actually made things worse because during COVID, first of all, norovirus is a non-enveloped virus where COVID, which was caused by SARS-CoV-2 is an envelope virus.

And actually alcohol hand sanitizers do have envelope viral efficacy like SARS. But they do not kill non-envelope viral organisms like norovirus. So during COVID, the CDC correctly was pushing alcohol hand sanitizer use and their recommendation increased the usage of alcohol hand sanitizers exponentially. And it's caused the dependance on alcohol hand sanitizers. And now that we're somewhat out of COVID and we're somewhat normal, everybody's dependent on alcohol hand sanitizers because for one, they're convenient and, two, the CDC pushed them like constantly, which was great for our business and they

actually worked for that.

But now the only thing that the CDC is saying right now, if you go and look at their norovirus prevention page, it says hand sanitizer does not work well against norovirus. It's not a substitute for washing your hands with warm -- with soap and water, which is great except for the fact that it doesn't really come out and say hand sanitizer does not kill norovirus, period.

I mean, except for the fact that I hate to use someone's name, but he was quoted in an article, Dr. Aron Hall, the former chief of viral gastroenterology for the CDC, actually was quoted in an article in Forbes last year saying alcohol gels won't kill the virus. Even if you were to use so much hand sanitizer on your hands that you felt like you were wearing hand sanitizer mittens, the live virus could still remain on your hands.

And that's the thing is, the CDC is not doing their job in making sure that everybody is aware of the problem, and the only thing they're telling people to do is wash your hands, which is great. And

hand washing is a very important aspect of hand hygiene. But hand washing doesn't kill norovirus.

You can remove it if you use the proper technique, but that's according to the USDA that's done less than 50 percent of the time. So if you've got a sick employee who has norovirus, or if you have contaminated food that comes in with the norovirus or if you have a customer coming into your food service place with norovirus and they start touching things, anyone that were to touch anything they touched is going to start spreading around norovirus and their hand hygiene isn't going to kill it.

So we have a major problem here with hand hygiene not killing norovirus is being the leading cause of foodborne outbreaks. And on top of that, alcohol-based hand sanitizers also can dissolve the lipid layer of your skin, which causes dermal damage, which causes the lipid barrier of your skin to no longer function properly, which allows --

MR. KAWCZYNSKI: Time --

MR. WIESELMAN: -- organisms into -- okay, I'll finish up -- which allows organisms to --

actually like norovirus actually to contaminate you easier. So something needs to be done. The UK and Europe use hypochlorous acid for hand hygiene and for surface hygiene. And so we need to follow what the UK and Europe do and switch everything to hypochlorous acid. But we need to make sure you use one that is safe for your hands, because some of them are not. There's a lot more to this, but apparently my time's up. So I'd be more than happy to continue on if anybody would like me to point out a few more things. So thank you.

MS. FINNEGAN: Thank you, Neil. Next up, we have Julie McGill.

MS. MCGILL: Thank you, and good afternoon. My name is Julie McGill, and I'm the vice president of supply chain strategy and insights at Trustwell. At Trustwell, we provide food companies with a connected platform managing food formulation, nutrition labeling, supplier compliance, traceability and recall management. And I thank you for the opportunity to provide comments today.

So I'd like to address a few questions for

consideration that were included in today's event material. First, what are the greatest challenges to creating a more digital, traceable global food supply? And how can the FDA and stakeholders work together to approach this in a manner that creates shared value for all participants?

So first I'd like to point out, change is hard, right? It just is. However, many companies don't realize that they do collect most of the information they need today for food safety and traceability recordkeeping. It may be in multiple systems that aren't connected. It might be on paper, but that data is available and we look to the FDA to continue organizing virtual meetings like this one, but also to provide other educational opportunities to engage all stakeholders.

Next, we need solutions for all. Industry partners are often surprised that solution providers do offer food safety solutions for companies of all sizes. To enable the industry, we must meet companies where they are but continue to educate on new tools and technologies. Today, many companies are using

tools such as RFID, IoT, API or might have a robust (indiscernible) but others are using barcodes to scan, maybe mobile apps or spreadsheet upload to share information.

What we want to recognize is that when we level the playing field, all companies can benefit, and value can be found in many areas, such as inventory management and freshness. And we've seen this in action with companies' timesheets and lot data information to their slotting systems. This allows them to move from FEFO, first expired, first out for their produce items, which provided better shelf life to the distributor and fresher products for their customers and consumers. But it also help reduce waste for both parties.

And with the advent of new technologies such as ambient IoT, we can seamlessly capture information beyond traceability data such as temperature and humidity, which can adversely affect produce items and other products as they move across supply chain. Helping companies to achieve accurate and precise lot level traceability is a reality today, and with new

technologies, we will continue to see improvements in read rate, data accuracy and enable connectivity with more systems than ever before.

Looking ahead, we need to pilot these solutions and much of the pilot work today has been focused on data capture, and we need the FDA's help to conduct more pilots that are focused on data exchange. GS1 US, IoT, GDSG, they also have helped traceability pilots to demonstrate how using standards can help achieve interoperability across diverse tracing systems that leverages blockchain and cloud technologies. More pilots such as these are needed with various stakeholders solutions and product scenarios. And with the FDA's direction and partnership, we can get these pilots underway.

So I'll wrap up with technology, which is, as we know, outpacing industry, and the time is now to engage and demonstrate how we can enable digital food safety and traceability, adding value for all industry stakeholders. Thank you.

MS. FINNEGAN: Thank you, Julie. Stepping up to the spotlight next is Erik Lieberman.

MR. LIEBERMAN: Hello. Can you hear me?

MS. FINNEGAN: Yes, we can hear you. Go ahead.

MR. LIEBERMAN: Okay, great. Okay, great. I'm Erik Lieberman, president of U.S. Food Imports. I'd like to thank FDA today for the opportunity to speak and hosting this meeting and just generally thanking the agency for really fostering public participation in all of these FSMA rulemaking. So I've been involved with them since the beginning, you know, over ten years ago.

So we are a company that provides food regulatory compliance software and services. We have a platform that's called FSMA Cloud, which is utilized by supermarket chains, wholesalers, manufacturers and trading companies for compliance with FSMA regulations. We built a module for compliance with Section 204 with the aim of automating compliance to the greatest extent possible and minimizing burdens on food industry firms.

I'm going to address today some of the questions that the agency had posed to the public as

topics for consideration, starting with the tech-enabled traceability, Number 2, how can FDA promote collaboration and information sharing between tech providers and food supply chain entities to support low or no cost traceability?

I'd just caution the agency there's no such thing as a no cost traceability solution. And many of these costs get passed down the supply chain, ultimately to consumers. Given the high cost of food, minimizing compliance costs should be a top consideration for FDA as it continues to work to implement Section 204.

What are the greatest challenges in creating a more digital and traceable food supply chain, and where can FDA help? I would say FDA support of a global standard and recognition of it is critical and I envision this much the way that FDA did with certain GFSI schemes, in the context of the produce safety rule and the preventive controls for human food rule. FDA recognized certain GFSI schemes as being aligned with those, and that -- those regulations, and that gives industry confidence that they can rely on those

schemes for purposes of supporting compliance with FDA requirements.

And we want to invest as a -- you know, as a provider of compliance solutions, we want to invest and develop standards that support FDA's mission of strengthening food safety throughout the supply chain. We want to create a system that helps FDA do its job. So I think, you know, making sure that the expectations of the agency on what records need to be kept and how they should be provided to the agency or perhaps, you know, the agency's preferences and getting that data, that should be absolutely made clear so we can start working on that now as opposed to reacting after, you know, this regulation starts getting enforced.

Beyond food safety, where can tech-enabled traceability create value? Absolutely in prevention of food fraud. We've just seen the U.S. Department of Agriculture put into place the strengthening organic enforcement regulation, went into effect last month and it requires traceability. So industry efforts on traceability would support compliance with this rule

and efforts to combat food fraud. There was recently a report that FDA released, I believe, about, sampling imported honey and now 10 percent of imported honey was found to be adulterated for economic purposes. So, you know, traceability can go a long way in combating those food fraud issues.

Now, obstacles on sharing data with the agency, of course, ensuring confidentiality, protecting data from FOIA requests. And what kind of incentives can FDA give for sharing data? Fewer inspections is a consideration for businesses that share data voluntarily. Also, reduced penalties is something the agency should consider if a firm is found in violation. And also, a safe harbor for sharing data in certain circumstances.

How should FDA share data with industry and technology providers? I can tell you from a software developers perspective, API is very helpful. And that would be our preference. In terms of e-commerce, obviously that's a that's a growing area. It's an area that regulations are working to catch up with and obviously FDA is contemplating that by posing these

questions to the public. One of the challenges with e-commerce is that we have lots of -- from the import side is we have a lot of small value shipments that fall under the de minimis standards for importation. It's section -- they're coming in under a Type 86 entry, Section 321. FDA doesn't get all the data that they would for a shipment with larger value.

But, you know, these consolidated shipments are very important for entrepreneurs that are using the third-party fulfillment services. So, you know, it would be requiring food to be sent in larger quantities would certainly pose challenges for a number of importers. But, you know, FDA could look at requiring importers to keep more data that FDA could audit at a later time. That would be, you know, something that they could consider.

Ambiguity in e-commerce. What are the responsibilities of third-party fulfillment providers? That's something that the courts --

MR. KAWCZYNSKI: Time.

MR. LIEBERMAN: Okay. Can I -- should I finish this one thing?

MR. KAWCZYNSKI: Yeah. Finish your thought.

MR. LIEBERMAN: So yeah, the courts, that's one thing the courts are grappling with now. They don't own, import or sell the product, but they are providing a way for entrepreneurs to get the product into, you know, the U.S. marketplace. And they're very important for small businesses. So I would just urge the agency to allow these platforms to continue to innovate because it's very important for small businesses in selling food products in the United States. Thank you.

MS. FINNEGAN: Thank you, Eric. And finally, our last public commentator of the day is Steven Mandernach.

MR. MANDERNACH: Thank you to Deputy Commissioner Jones and the FDA for holding this public meeting. The Association of Food and Drug Official, or AFDO, is a regulatory organization that connects food and medical product safety stakeholders and impacts the regulatory environment by shaping sound science-based rules, laws and regulations, and sharing best practices that protect public health. Founded in

1896, AFDO is an international professional organization consisting of state, federal and local regulatory officials as members. AFDO and its members were among the early advocates working with Dr. Harvey Wiley for the adoption of the nation's first food safety laws, including the Pure Food and Drug Act in 1906.

Today we'll focus on four topics: data, recall food safety, traceability and recalls, and public-private partnerships. First, we at AFDO have been very engaged in data work, which currently we support over 25 state agencies and their regulatory data systems. We have also been bringing together larger data sets, including a retail inspections database of about 900,000 inspections from nine states.

We then use this data to look at improving inspection outcomes and improving inspections overall. We have partnered with another group of states to bring together a similar (indiscernible) in the manufactured food space. Lastly, we are currently building the system for agriculture, food, health, e-

inspections and registration, or SAFHER, a regulatory data system for states and local governments with financial support from FDA and states. We are beginning to understand the data available and use it to improve regulatory programs. We have far more we can accomplish using this data.

In retail food safety, the second area, much of the work that is in retail food safety has been funded and supported partially through the FDA Retail Food Safety Regulatory Association Collaborative. This first of its kind program partners FDA, CDC, AFDO, ASTHO, CFP, NACCHO and NEHA to set programmatic goals and develop action plan today, leveraging the each group's strength and focusing all on the same objectives: reducing foodborne illness, implementing risk based inspections, assisting and promoting food code adoption and implementing program standards. This small amount of FDA funding is essential in accelerating this work in retail food safety, the area with the greatest opportunity to reduce foodborne illness and bend the illness curve.

We also believe a comprehensive review of

the retail food safety program is needed. We believe this review is fundamental for the retail food safety (indiscernible) to be timely and to keep up with the innovation of industry. This review must engage all stakeholders and help ensure that we have an FDA retail food safety program that meets the needs and the current needs of industry, state and local regulators and the American consumers.

With traceability and recalls, we strongly support a traceability rule, but also recognize some challenges of the rule and its implementation. Currently, there is a lack of clear enforcement strategy and implementation strategy with restaurants and grocery stores, nearly all of which fall under federal food safety regulation for the first time with traceability. We urge the FDA to work more proactively with these areas that will be new to federal regulation and the state and local agencies that typically regulate them.

We also urge FDA to be open and flexible with the rule to these unique industry segment challenges. No one is favorably impacted if the rule

goes into effect in portions cannot be successfully implemented. Further, we hope FDA can move toward using and coalescing around current industry best practices such as the GS1 standard, which is widely adopted and used with all products and barcodes.

We see enormous opportunity for FDA to modernize and embrace technology and improve communication with recalls. In September 2023, FDA had a public meeting on recalls, and it was clear there was a desire to modernize food recalls through both technology and improved communication to consumers based on good risk communication practices. We hope the FDA human food program continues to prioritize this effort. We continue to observe ineffective recalls resulting in unnecessary illnesses and exposures, including in the most -- in the recent applesauce recall.

Lastly, we continue to work on public-private partnerships in bringing together all areas of the human food program. We see a game-changing opportunity to work with industry to jointly use shared data to improve regulatory outcomes and more

efficiently use regulatory resources.

Some very practical methods could be sharing regulatory inspections, third-party audit information, and industry and regulatory samples for use by both industry and regulatory agencies. We also see ways to improve access to regulatory information to consumers. The technology exists. The challenge today relates to trust and willingness to embrace change.

Together, we do believe FDA, state and local governments and industry can use data to improve regulatory and food safety outcomes. We would urge FDA and state and local regulatory agencies to promote and allow this safe space and to move forward to a New Era of Food Safety that is focusing on preventing foodborne illness and improving outcomes, and less on building a case for compliance and enforcement. Thank you for the opportunity to comment today on behalf of the boots on the ground state and local regulatory programs.

PANEL DISCUSSION

MS. FINNEGAN: Thank you, Steve. And before we bring the panel back to respond to those, I just

wanted to thank all of our speakers today for offering your thoughts and ideas. So now we will have our panel respond to those comments. Adam, we'll start off with you first.

MR. FRIEDLANDER: Hi. Well, I'm Adam Friedlander. I'm the co-lead for Core Element 1, tech-enabled traceability. And I also just want to echo Lauren's comments and thank everyone for providing their expertise, their feedback. And I really enjoyed listening to everyone's comments today. And I certainly encourage people to respond in writing to the docket questions as well.

There were many common themes that I heard around tech-enabled traceability. And I just want to just go a little bit into some of the common themes that I wrote down today. There is an incredible amount of effort being put into complying with the traceability rule. And although I cannot comment on FDA's compliance efforts about the rule, we heard themes about going above and beyond the rule's requirements to improve traceability, and how there were other themes that can improve food traceability

that extends beyond food safety, such as improving sustainability efforts, reducing food waste, preventing food fraud, and just to name a few. And I really appreciated those insights.

There were also conversations about how FDA can continue to support the harmonization of data that's used for traceability and the importance of interoperability, and I certainly agree that FDA can continue to support those industry-led efforts and to help everyone speak that same food traceability language.

We also heard about some of the challenges that are currently present in today's food traceability system. And one comment mentioned that there is data that is currently available to advance food traceability today, but it may be in separate IT systems. And I found that fascinating.

So although I can't comment on the rule, I just want to point people towards the FSMA technical assistance network on FDA's website if they have any specific questions about the food traceability rule and our compliance efforts. I certainly encourage

people to ask those questions, so you can get an official response. And I encourage people to be as specific as you can in those questions so that way you can get the best response that that you can get.

So with that, I just again wanted to thank everyone for providing the comments today. And I'll turn it to my colleagues over at Core Element 2. Thank you.

MS. FINNEGAN: Thank you, Adam. Mark, would you like to begin?

DR. MOORMAN: I am more than happy to. Yes. I heard some interesting things that were brought up that I'll comment on first. One of the speakers mentioned WGS expansion and the -- I think you get a flavor from the FDA, we're very interested in the expansion of that technology. You know, we all have a lot to learn about these strains and attribution and very importantly, ecology of these strains. So a lot of shared ground between what the first person on the group spoke to and the FDA.

One of the other things that was said I captured was, how the FDA can encourage, incentivize,

incentivize data sharing. And, you know, certainly we can do sessions like we're doing today to encourage it. But the word incentivize is a very interesting word. And I think it's an important one. And I'll talk this out, as we've spent a lot of time thinking about this topic.

You know, if you if you read the Reagan-Udall report on the FDA, they acknowledged there's a lot of work being done in the agency and we've all determined that one of the things we have to do a better job of is identifying and discerning $5 problems from five cent problems. My words, not the FDA's. And it's true, if everything's a priority, nothing's a priority. And one of the incentives to think about in this space, I'll reflect on this, is that if we can work with those that have data to better understand hazards and to characterize those hazards, the more that we can be informed as to what we think are the $5 problems and what are not.

A good example of this is what is being done with our toxic elements group and close to zero. We've clearly signaled a desire to have groups provide

us with data so that we can better understand what levels can be achieved. So that's the second thing that that jumped out at me.

And then the third I think is a really important question that we should all struggle with, which is what are the greatest challenges to digitization? And I'll reflect on that, that, you know, when our group started thinking a lot about data, data trusts and building those, of course we spent a lot of time thinking about the first part of that, data. But I've come around to realizing that a very important point that we don't talk enough about is trust.

There's a there's a great quote I heard a long time ago that progress in life happens at the speed of trust. And there is a reticence to share data. And I think we've got to find a way to build trust and to talk about how we can do that better, both across the stakeholders and even with the FDA. So I would submit trust is an important one that we have to spend time thinking about and what can be done to build that trust.

And then number two, I think we need good stories to tell, you know, where have we had some wins in data sharing? I just think that that's a really important one, if we can. You know, one of the things I like a lot about the traceability challenges is it showed some good examples of where traceability could be done. And it doesn't have to cost $30 million in capital. There are some simple tools that are out there. And I think of those as good stories to tell. And I think in the data sharing, data trust, predictive analytics space, we all need to do a better job of telling stories and what works. So my thoughts. Over to Ruth or Vinetta. Thank you.

MS. FINNEGAN: Thanks, Mark. Ruth, you're up next.

DR. TIMME: Yeah. Thanks for all the comments. I really enjoyed listening to all the different perspectives as well (indiscernible) food safety. I wanted to first mention the commenter who talked about pathogen and genomic surveillance, Celina To, and just respond specifically to her inquiry on the validation of new technologies such as Oxford

Nanopore.

And I just -- I want to asssure both Celina and the general public that GenomeTrakr is committed to really thorough testing of all new technologies and chemistries, including OIT and we really prioritize the accuracy and reliability in our methods. We've been fairly stable over the past decade. But as new technologies come up, we evaluate them intensively. We work alongside our other U.S. agency partners to ensure that new data types that are generated for public health response are validated and can be seamlessly integrated. They're all interoperable, right, with our huge, large historical databases of genomic data for testing. So, thank you for bringing up that important topic (indiscernible).

There were a couple other questions that were that were submitted asking -- surrounding GenomeTrakr, and I thought I'd chat about the one about how important it is to make data public, since Mark talked about it so eloquently. One of the biggest strengths of our GenomeTrakr program, and its database, is that we make all the whole genome

sequence data public immediately after the data are collected. And this really benefits all the stakeholders collaborating to create a safer food system in the U.S., including industry, and this kind of transparency allows industry to independently monitor this public database, these pathogen genomes coming in every day for signals. And they can respond to those signals without any direct communication with the FDA.

And so this strength of really standard data, really current data being publicly -- being made publicly available to stakeholders is really what I think New Era is all about, and I think New Era can even -- it's so important for GenomeTrakr in that our missions really align perfectly (indiscernible) New Era really has the capacity to potentially integrate GenomeTrakr's genomic information with other digital food system databases.

You've heard a lot of these today, including the supply chain, tech-enable traceability. So as we go into the future, you know, GenomeTrakr is well integrated with these other efforts at the FDA for

digital data and improving (indiscernible) technology. So with that, I will close my remarks and thank everyone again for all the comments. I really enjoyed it. Thank you.

MS. FINNEGAN: Thank you so much for those thoughts, Ruth. Next, we'll move on to Vinetta.

MS. HOWARD-KING: Hi. Yeah. So, you know, first I want to thank all of the FDA and industry stakeholders who took the opportunity to join us today for this extremely important public meeting. A special thanks to those who provided comments today on how FDA can work with our stakeholders to leverage data and technology.

I heard a few comments that sort of resonated with me. The need to maybe look at some handheld tools and other data innovation and technology platforms to provide real-time recall notifications to consumers. I would also be interested in handheld tools for inspectional purposes. So thank you for that. We definitely will be looking into that more.

Like, Mark said, the need to incentivize has

really, you know, struck me, to incentivize data sharing. Like, fewer inspections, I find this could be a better way to manage everyone's very limited resources, from the regulator side and industry side. So it's really a topic that we need to look at carefully.

And in order to really embrace data sharing, I agree with Mark. I agree with Steve Mandernach. There is a need for a trusted and safe place for all involved. So that that's an area that we that we need to work on, all of us, we need to work on. We can't do this alone. No one can do this in a bottle.

I also wanted to take this opportunity to address a few questions on data sharing that was submitted prior to the public meeting. There was a question regarding data connectivity with FDA's reportable food registry. I want to mention that FDA has been working on various projects to allow and enhance connectivity with the RFR; for example, activities to make RFR filings more user friendly. We believe that enhanced data connectivity with FDA databases would be in line with how we're looking at

leveraging existing data to advance food safety outcomes. So that's one area.

There was also a question on how FDA is going to work with -- I'm sorry, how FDA is going to work with state level regulators to improve access to and acceptance of new technology. So, I want to first acknowledge the very important partnership that FDA has with our state and public health regulators, our state regulators and our public health partners. This this can't be understated. We can't do this without them.

And so our ability to work with our partners is extremely important. So, one example of this partnership is the work FDA is doing with the Association of Food and Drug Officials, or AFDO, under a cooperative agreement with AFDO is working -- there's work being done to update, as Steve mentioned, the regulatory program management system for states called SAFHER (System for Agriculture, Food, Health, E-Inspections, and Registration).

This effort actually would allow for a system-to-system integrated data sharing with our FDA applications. So, I mean, these are just a few

examples of how FDA is actually working with our stakeholders to leverage data and technology.

So again, thank you. I heard a lot of great ideas. And we are actually taking this all in, and we are also going to utilize this information with information and comment that we got from the recall public -- recall modernization public meeting. And so you'll be hearing from us soon. Thank you.

MS. FINNEGAN: Thank you, Vinetta. And now to start off for Core Element 3, Glenda Lewis.

MS. LEWIS: Hi everyone. I just really enjoyed hearing so much of the comments that have come in and been made. I'm like Vinetta. We're taking it in. I heard about just, you know, that we want other engagement opportunities and the virtual meetings and great. And, and we actually had a question that came in with registration around how are we going to interact with industry stakeholders and continue to modernize and prepare for food delivery. And I'm here speaking on behalf of three, Core Element 3, industry (indiscernible) space related to that e-commerce. And in that area, we do plan further engagement together.

We've been working with regulatory partners, industry partners, consumers and we just want to continue that outreach. We really want to continue the (indiscernible) protection on their guidance document. And we just know the regulatory landscape is of interest to that group, and it can be daunting. And so lots of stakeholders have questions. What is it like in my lane? What's your lane look like? How do we drive this this car together?

So, as we further explore challenges and barriers faced by regulatory partners, we want to bring folks together. We want to bring them to the table. We want to have a dialog, hear concerns, gain ideas and really work together to address barriers as we proceed. As we continue to do this, we know (indiscernible) and education, and that's really going to be the focus. We have to work together, as many of my colleagues have already said, so that we can avoid foodborne illnesses happening.

So we do anticipate and envision stakeholder meetings, webinars for these dialogs and engaging in different sessions with that. We have already

addressed some issues with consumers by providing educational materials. We have fact sheets. We have a video out and infographics around that and our focus is going to be on that regulatory framework and (indiscernible) and what data speaks (indiscernible) as we close out, about what data pieces may be, could be involved in that was the question.

But I also heard many comments around we need to meet companies where they are, and that's what we want to do in the 3.1 New Era space and to have that level playing field. So, as we look at the regulatory scope of e-commerce, we'll keep that in mind. And I like the idea of raising the challenge to the company so that we can move forward into the future.

And I really found interesting the comment by Marcia, Dr. Lee Herzberg. I'd like to hear more of your study that you're doing. So we may reach back to you on to learn more about your study.

And lastly, I guess I wanted to compliment AFDO and its work with state partners and the work that that we have been doing and the interest there

that they're capturing in terms of the data and looking at the reporting, you said over 25 state agencies (indiscernible).

I think all of that can help us strengthen what the technological system will look like going into the future in this New Era of Food Safety, the idea of having someone else, having uniformity in the system is what we need (indiscernible) and I think that's key. And that will be key across all of the core elements. So, I really appreciate the comments today and looking forward to hearing more. And I'll turn it over to Laurie. She's going to talk a little bit more about the broader scope of retail food and retail food (indiscernible). Laurie?

MS. FARMER: Great. Thanks, Glenda. I appreciate that. So, I'm Laurie Farmer. Glad to see all of you today. Thank you for taking the time to be here. I know this is a long webinar and just so happy that you're here. Happy for the engagement and want to thank you for the comments.

You know, I heard an overall desire for collaboration and a desire for a transparent food

system. And I especially appreciate Katy Jones putting a face on food safety issues to really bring it. You know, I wrote in the chat, oh, I got a chill. This kind of storytelling, a way to communicate the need for an organization's food safety culture is critical for all of us. I just really appreciated that.

And I really want to also thank the speaker recognizing the leading cause of foodborne illness in the retail industry is norovirus, and how we need to take approaches to reduce foodborne illness in the industry. I am co-leading with the CDC the AFDO Healthy People Norovirus workgroup, and we are working with regulators and industry to develop an employee health toolkit to get employees not to come to work sick.

I mean, this includes an employee health assessment tool that is being piloted that can be used by both regulators and industry. And we also look at the use of sanitation and disinfectants on surfaces to reduce the norovirus load, and we're doing that with the lead of NoroCORE, Lee-Ann Jaykus, who is on this

team. So all of us who are familiar with foodborne illness risk factors, we also know the great benefits of handwashing, and other things that I've heard that relate to the retail food safety sector for the Core Element 3, which is, you know, one is retail is a team sport.

This is something that we're going to have to do together, we're going to do together and we continue to do together with states, locals, tribes, territories, industries and academia. Glenda talked about the conference for food protection and that is one place where we all come together. The recognition for the heavy lift that state and local regulators have in conducting retail food inspections and the need to focus on risk factors and the relationships with food laws and standardization.

And the point about policy is driven by good data, so I really appreciated that from Dr. Marcia Lee Herzberg. So thank you for that. And there is already happening, and Vinetta pointed to this, the electronic gathering of regulatory inspection findings. This information can be used for

improvement of inspections and public health outcomes. So, one of the questions that we received --- you were able to, in your registration submit questions and you'll also be able to ask questions in the docket and provide additional information. So, I encourage you to do that.

But one of the questions that came in was, how can we address the diversity of data systems and low data literacy across local food inspection agencies? And wanted to make sure that you heard the talking point that I actually also heard Steve Mandernach talk about from AFDO, and he talked about a pilot that FDA is funding around regulatory data sharing, and it is the SAFHER system, S-A-F-H-E-R (System for Agriculture, Food, Health, E-Inspections, and Registration), and this is an example of how data can be shared across systems. And it's starting with a relatively small number of jurisdictions. But it also includes not only manufactured foods, but retail food safety. The goal is to have all regulatory jurisdictions on a interoperable platform where inspectional data is transparent to regulators and holistic interoperability of data systems was something that a

speaker touched on today from a broad perspective, and that's a need.

The vision here is all regulatory jurisdictions have access to the data. There is reciprocal data from states and FDA. We are going to be able to trend analysis. What could be done to inform interventions such as training? You heard Mark talking about trend analysis and how that's so important with our learning for the future. FDA wants to encourage progress on data sharing and improving data literacy and technology use, while still meeting jurisdictions wherever they currently are so nobody gets left behind.

Other things that I've heard also are I heard the ask for the agency to keep an item that was in the original New Era blueprint, which is prioritizing the comprehensive review of the national retail food safety system in this country and how FDA supports it. I heard the importance of, and the need for the agency to continue to prioritize and support the FDA retail food regulatory association, that it's really a force. It's a force of four regulatory

associations, FDA and CDC working together towards targeted objectives in the retail sector.

And again in the retail and restaurant food sector, FDA does not have regulatory authority but provides support to states and local jurisdictions. I heard the concern for implementing the traceability rule as it relates to any enforcement strategy and the implementation with restaurants and grocery stores, and I heard that Adam recognizes that as well.

So, I want to thank you for the time today, for you coming, and I really am looking forward to more engagement. This is the beginning of a lot of conversation that is already been talked about today. So I will, at this point, pass it back to Lauren.

CLOSING REMARKS

MS. FINNEGAN: Thank you, Laurie, for those remarks. Now I'd like to open the floor to all of the panelists for closing remarks. Adam, we'll start with you.

MR. FRIEDLANDER: Thank you, Lauren. And I just wanted to reiterate my huge thanks to everyone today for joining this conversation. As Laurie

mentioned, this is just one of many conversations that we're looking forward to having in the future. I want to thank the commenters today. I want to thank you in advance for submitting your questions or your written comments into the docket.

And while this panel is up here, you know, we're just a small subset of many people behind the scenes who are working on this New Era Initiative, and it is incredibly important for us to always look toward the future. How can we make progress in our food safety system? How can we better protect consumers? How do we leverage data and technology at the intersection of all of our core elements with traceability, whole genome sequencing, recall modernization, e-commerce modernization, and retail modernization as well, as well as safety culture. We all intersect with one another, and we all have a role to play along with you, the public, the industry, consumer groups, other regulatory agencies, academia, solution providers. We're all part of the same team. And I'm just excited to continue these efforts with each of you. And I strongly encourage people to

submit their thoughts, ideas into the docket and always feel free to reach out to because we want to help. So thank you.

MS. FINNEGAN: All right. Now let's move on to Mark.

DR. MOORMAN: Yeah. I will join my fellow panelists in saying a big thanks for the questions, the comments that we received today. There were some that came in that I thought I would briefly touch on in the limited time that I have.

One of them spoke to can artificial intelligence help us in navigating the potential problem based on past history and product risk Assessment. I think it's a really important question, the way that it was phrased in navigating, because, well, indeed, we do have to navigate these challenges. You know, the way that I think about problems in food safety is sometimes it's based upon something the firm or individual did. And sometimes these hazards in the food supply are just there. Mother Nature put them there or it's an artifact of human behavior from a long, long time ago.

Artificial intelligence and machine learning gives us an opportunity to step back and to look at all of the data that might be out there that can help us color the drivers of those hazards and, you know, things like the production region, the size of the firms, the history of the firms, seasonality, climatic drivers, all of those factors can help us, to give an example, an understanding, as I said in the opening comments, what containers do we sample when they come to the United States. Artificial intelligence and applying that to machine learning gives us the ability to tap into all of that information and better understand what can be the best signals, the best, drivers so that we know what to do.

There was another question that I thought was really important and it is will FDA consider research in data collection and sharing platform technologies funded by public-private collaborations to inform future policies. And the answer that is a big fat yes, flat out. We are very interested in understanding what information is out there. If I can just reflect on this, you know, one of the things that

I have learned in life is you can't solve a problem you don't understand. And, you know, we're in a discipline, particularly in the food microbiology that's about 300 years old. There's so much that we don't understand about these microorganisms. So, we look at genomics now and we've gone from detection to sequencing. We look at massive data sources. These are two things that fundamentally change the way we go about doing food safety.

We're interested in canvasing to get what information is out there. Now one of the things that I think has to be called out is why would a firm or why would anybody share information with the Food and Drug Administration. And I want to just tell you that I think it's a really important one to speak to and it does involve trust.

The FDA wears many different hats. We do have -- you know, Congress has given us the regulatory hat that we have to wear, the compliance hat, if you will, that we have to wear. But as I talked about earlier, there are many of us that spend all of our time thinking about prevention, and when we talk about

data sharing, I have my prevention hat on. I have my hat on to say how do we work together to build data sets so that we can all make better decisions. I don't have that compliance hat on. I understand many people will question then how does how does that happen, and I will tell you that we've got some people that have given a lot of thought. I'll call out Dr. Stacy Wig and Dr. Nate Anderson from our team that has spent a lot of time thinking about how information can be provided to us and be protected so that it doesn't impact the firms.

We're getting really good at this. You're all going to hear about longitudinal studies that are coming out from the Yuma, Arizona region, later next month. Those studies were conducted because we got really good at understanding how do we collect data and not put firms at risk. And so I want to say that, yes, the FDA would very much like to have a seat at the table. But when we look at this New Era effort, it isn't all about FDA. We want to encourage firms to share amongst one of us with each other. That's very important.

And then the final point that I'll make is a question came in, gosh, I would like to work with other companies and share data, but how do we do that? And I want to point out that I think the data sharing is actually topic two. Topic one is the question. You know, I often get asked can we share coliform data. Can we share fecal coliform play count data with the FDA? And I think sure. But that's the easy part. The question is what's the question. What's the problem that we're trying to solve? And if you really focus on that, it brings out creativity and thinking of if we aggregated data, how could we answer some problems. From a food manufacturing standpoint, I always wonder how our plant environmental results compared to other companies. That's a really good question. I always wondered with pathogen detection that we would find is it seasonal. I was wondering about toxic elements and is it regional. Companies have the opportunity, stakeholders have the opportunity to compile that data and to answer those really important questions. So how could you go about sharing that information? I'll tell you these four

areas. Number one, we have firms, groups that work directly with us. Number two, we have others that work directly with platforms like Creme Global that we've contracted with. We have -- they don't provide data to us. They provide it to Creme Global and they work to make sure that it's presented in a way that protects all parties. I think the trade associations are very central to answering category problems, and they can serve to compile data. Number four, we have law firms that work with us directly to provide that information.

And then, one of the questions asked, well, how do I do this? Well, if you want to learn more, there's a simple email. And I'm sure it's out there on our websites. It's foodsafetydatasharingplatform@fda.gov. And we are more than happy. We watch that. And we're very happy to talk more with anybody about what information can be shared. So with that, I thank you.

MS. FINNEGAN: Thanks, Mark. Appreciate it. Ruth, would you like to go next?

DR. TIMME: Yeah. Sure. I just have a

couple closing comments. Again, thank you all for your comments. It's been a good discussion. I thought I'd just dovetail on something that Mark mentioned. And, you know, that is the recognition that, you know, there's Mother Nature out there. Foodborne pathogens kind of grow and exist and are quite happy in kind of the food facility and environmental spaces all across the country and across the world. And one of our goals in GenomeTrakr is to try to sample that space to get an idea about what are these pathogens doing out there and how are they intersecting with our food supply, And so this just goes to address one of the questions that came in, in the registration, about why, why we're monitoring, you know, why we're sequencing pathogens for food in environmental spaces.

You know, you don't usually think about this for other pathogens like COVID or avian flu. Those are -- you know, those pathogens transmit from animal to animal or human to human. But foodborne pathogens are quite different. You know, those contamination events come in from an environmental source and then

spread out from there.

And so, yeah, so with that, I think I'll just hit on that common theme that has come up about data sharing. The GenomeTrakr program, you know, in conjunction with New Era, is a really good example of us sharing data as soon as it's generated. And I think this really helps the entire collaborative stakeholders that are trying to make food supply safer in the U.S. And so with that, I will thank you and turn it to the next person.

MS. FINNEGAN: Thanks, Ruth. Vinetta, go ahead.

MS. HOWARD-KING: Hi. So in closing, I again just want to thank all of the stakeholders and, of course, my FDA colleagues for joining us today. Another reminder that the docket is open. So please don't hesitate to send in your comments and your ideas. I want to say that we're always looking for sensible and meaningful ways to leverage with our stakeholders. We're never closed to that. And we should never be closed to that. That's just a necessity in order for us all to continue to develop

and grow.

One area that I heard was the interoperability of IT systems to leverage data. I can tell you now that FDA, we're actually working on trying to do that our very self internally. And that's not easy because anything dealing with IT, you need funding and you need resources. And so we know that that's limited for everyone. So how do we do this with the resources that we have? But that that is something that we're working on internally as well.

We hear the need to harmonize data that's shared so that we have a unified data sharing tool. That goes without saying. We're working with our state and local public health regulators on that that effort. And we want to be making sure -- we want to make sure that we're working with industry partners as well. We know that no one, no one entity, be it federal, state, local, territorial, tribal, industry or academia, none of us can do this alone. You know, none of us can ensure food safety by ourselves. We just can't.

And so, you know, it's going to take a

collaborative, integrated partnership and a relationship, a trusted relationship. And that's going to come with a culture change as well, not only internally with FDA, but with some of our stakeholders and some of our partners. There is a culture change that needs to happen across the board in order for us to all be on the same playing field.

So, we're at the table. We're going to stay at the table. We know you're at the table. And so, you know, let's start talking. Let's look at what each one can bring to the table and let's help consumers. And so, you know, I just want you to please continue to share your ideas, please. And thank you again for talking with us today.

MS. FINNEGAN: Thanks, Vinetta. Glenda, you're up next.

MS. LEWIS: I just -- all I can say is, wow, this has been really great. I am so honored to sit here with my FDA colleagues, with colleagues on the phone, with the attendees to the meeting today and just have this conversation and hear the ideas that folks are bringing to the table and just taking notes

on, you know, so much is going on and so many ideas that you've given to us to reach back and to engage with you even further.

I think about it I guess in two ways, coming from retail, everything ends up at retail. So all the food, all the food safety information and controls and things that are in place, that my colleagues have mentioned, I'm happy to hear that, and Laurie and I are committed to, at the retail level, you know, making sure with our state and local partners, our industry partners, that when it gets to the consumer that it's safe and whether that's by e-commerce or other ways. Probably some of us on this call today are going to order lunch or order dinner to be delivered this evening. And so we know that -- talking about that e-commerce section of it, that it's so entrenched in our environment now and in the way we live. And so leveraging that data and technology for a strong infrastructure, we want to continue conversations around that and to any data usage.

So again, for the docket as well, there were several questions, three questions that were in there,

24, 25 and 26 where we talk about utilizing technologies in ways that can help strengthen the program. So I encourage you to review that. And when you look at those questions, I did just want to say a little bit sort of frame up of why we asked some of those questions. Right? The first question was, and these are ways to use technology to monitor and gather data.

And we asked, how can FDA, industry and our state, local, tribal and regulatory partners use technology to monitor and gather data on sales of food through e-commerce. So, we're interested there on whether and how data on e-commerce products and sales can inform the regulatory landscape. Remember when we' looking at what lanes do we survey? How can we drive food safety and what types of technologies and data sources can help us to inform future implementations and perhaps any enforcement efforts?

And then, we had a second question. We asked what data and research can be collected in partnership with stakeholders to help assess the existing regulatory framework in place domestically and

internationally for the (indiscernible). Some things that we are looking for there, you know, what policies or rules are in place currently? What impact does it have -- has it had or could it have or maybe that it did not have, alternatives that could be modeled at a national level, you know? Is that an approach we should take? Why or why not? So that's something to think about and just look at Question 25.

And I think Question 26, it asks -- we asked are there current ambiguities related to sales of food through e-commerce that could pose a risk to the consumer. So, we know it's happening everywhere. It's on the Internet. But the advent of cottage food (indiscernible) in states, there are social media, we have Facebook Marketplace and other similar platforms that may not necessarily have regulatory oversight. So it's very convenient for the general public, but does it pose a risk or can it pose a risk to consumers that we may not be aware of. So we're mindful of that food safety (indiscernible).

And we're thinking about too what actions could FDA and partners take. So this one's kind of a

tough one. It could be perceived as an infringement on rights to do business or to earn money, that type of thing. But we're approaching it more in a different context of being able to sell or serve safe food. And we want to ensure that there's a level playing field. I heard that in the comments. Make sure we all have a level playing field that's there for anyone who steps into that platform (indiscernible).

And we do define the e-commerce space as a retail space. And just encourage folks to take a look at those. Thank you again for joining us today, and we look forward to continued conversations around data and technology in e-commerce. So with that, I'll turn it back to Lauren, over to Laurie.

MS. FINNEGAN: Thanks, Glenda, and I'll turn it over to Laurie.

MS. FARMER: All right. Well, again, I want to thank you. I want to thank my fellow panelists and all those that put this event together. It is a lot to put one of these things together. So thank you. And we're here representing a much larger workforce of

collaborators. And as we consider the future of the FDA human foods program, please know that we want to take food safety to the next level, and we want to do that with stakeholders. Please think about the ideas posed today. What areas would you like to see FDA prioritize and invest in? Please be specific in your feedback to the docket. Your input is essential for us to have an effective human foods program.

At the point of food safety as a system, we're talking about connections in the system. Within retail food protection, we're making transformational changes that will impact our strategic goal of reducing foodborne illness in the industry. FDA has a variety of ways we currently support data and technology with regulatory jurisdictions. Retail regulatory food programs, our program standards, this is where we lift regulatory programs up to performing, top performing organizations. And one example of how we support that is our food shield risk factor study database. As an enrolled jurisdiction, you can request access to the same data collection and analysis program that the FDA uses for our national

study. The risk factor study database provides cloud storage for your data as well as customizable data collection forms. The database is built and quality assuranced -- has built-in quality assurance checks, and it's really a saving time mechanism for you. And it'll decrease errors. And the system provides several reporting options, including some that do the heavy lift for your analysis. So FDA is sharing the same tool we utilized for our national risk factor study.

FDA has made a large investment in retail regulatory jurisdictions working towards conformance with our program standards. Between 2022 and 2024 this year, we've been able to fund $22.8 million to an average of 237 jurisdictions each year, for a total of 1,487 retail program standards projects to date. Some of these funds were used to support data and technology initiatives.

As has already been said, we can't do this New Era transformational work alone. This is a journey with stakeholders. We've identified areas to work in partnership that will have significant impact

in the retail sector. They are food code adoption, leveling the playing field across the country, risk-based inspections and intervention strategies, having a uniform assessment of risk and providing interventions and measuring effects (indiscernible) retail regulatory program standards, increased work towards conformance of a quality improvement framework for a regulatory program, outbreak investigations improving the use of existing resources and identifying areas for improvement, food safety management systems.

Our goal is to increase active managerial control in the retail restaurant setting. We need your help in validating these existing partnerships and identifying new ones, identifying groups that we need to work closely with. Tell us what you want us to prioritize in this space.

Some questions in the docket targeted to retail food protection are the following. What can FDA do to have the biggest impact to meet our retail food program strategic goal and take it to the next level? What can FDA do, working in partnership with

regulatory, industry and academic partners to impact the reduction of foodborne illness in retail food safety environment?

Are there specific collaborations between FDA and industry that will help to ensure the safety of retail food? What benefits will be gained by conducting an audit of the traditional retail food safety systems' effectiveness and how FDA supports that system?

And food safety culture is also a very important aspect of food safety, so please feel free to post additional feedback beyond the questions posed in the docket. Other areas to consider are what food safety challenges you're facing that could be addressed by data sharing. Are there public-private partnerships that could help move the needle on the reduction of foodborne illness in the industry? We look forward to seeing your comments and future stakeholder engagement. Thank you all and I will pass it back to Lauren.

MS. FINNEGAN: Thank you, Laurie, and thank you for all the panelists today for all your thoughts

and expertise.

Now, before we adjourn today's meeting, I'd like to encourage you all to submit comments to the docket by June 24, 2024. The link to the docket can be found if you scroll down to the "More Info" section underneath the stream, and you can also enter the number up on the screen on regulations.gov.

A recording of the public meeting will be posted on the FDA's public meetings webpage shortly. The meeting transcript will also be posted within a few weeks, as well as a summary of themes shared through the listening session.

Thank you for your time today, especially to everybody watching at home, all of our public commentators and, again, our panelists and everybody who made this possible. We hope you have a great rest of your day. Thank you.

(Whereupon, the proceeding was concluded.)

CERTIFICATE OF TRANSCRIBER

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

SONYA LEDANSKI HYDE

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