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PUBLIC MEETING

A NEW ERA OF SMARTER FOOD SAFETY

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AGENDA

P R O C E E D I N G S

PLENARY SESSION

GREETING & HOUSEKEEPING/LOGISTICS

MS. BARRETT: Well, you guys are exceptionally compliant, thank you. Usually, it takes a few minutes, but I am going to take that as a great sign that everybody is eager and ready to go. So, I want to say good morning to everybody and welcome to today's public meeting. We are focused on a new era of smarter food safety. Today is really an exciting day for all of us to consider our collective food safety future together and it really is an exciting day, this meeting more than many that I have helped to moderate has a certain vibe about it bringing folks together. So, we're really looking forward to the day.

My name is Kari Barrett and I'm on the communications and public engagement team for the FDA Center for Food Safety and Applied Nutrition. I want to thank everybody. Again, I know there has been tremendous interest in this meeting. In fact, we are full house, full capacity both in the room and online. And it's always tough to not have the ability to accommodate everybody. But again, we are just really, really pleased with the turnout and your enthusiasm. So again, thank you to our large webcast audience that we have today as well. Before we start our meeting, there's always some housekeeping that needs to be done someone to go through that fairly quickly. But I do want to note a couple of things; all of the meeting that occurs in this room today will be webcast. For those who are webcasting when we talk about some of the materials that we have available in the packet you should also have access to that online.

For our breakout sessions we will have a couple in here. And again, this will be webcast, but the other breakout sessions will not be. There are a few things that we're going to do towards the end of the day and I just want to bring them to your attention. Before we close we will have some report outs from our breakout session facilitators and will also, of course, talk about some steps going forward. So be sure to stick around for that.

In your folders that you received at the registration desk, as I mentioned, there are a number of handouts and there are some that are really important for today and for the conversations that we're going to have. One is the list of questions that we're going to go through in the breakout sessions, the other is a document that we put together just called food for thought. And I really hope that all of you would have a chance to look at that. We've laid out some of our early thinking around many of the topics that we're going to talk about today. So, we want to be sure that you've had an opportunity to at least be familiar with that before you go into the breakout sessions. We also have a list of biographies in the packet so we're going to keep most of our introductions fairly short today. And there's some other information in there too about how to comment, which is very important. There is an opportunity after today to continue to share your thoughts on these topics. And so that piece of paper will give you all the information you need for submitting your comments to the docket.

I do want to note, if there's any media or press here, if you can let us know raise your hand media, press present, great. Okay, we have a couple of folks in the back who can assist you if you haven't had a chance to talk with them or check in Jennifer Dooren and Peter Cassell are in the back, do you want to just raise your hand, okay thank you. Also, too, for those who have signed up to give public comment, again, we are at capacity for that. So, we want that to go very smoothly. If you haven't had a chance to check in with Juanita Yates today and you're giving public comment this afternoon, please do, she can usually be found around the registration desk. She can give you little guidance and information about how we'll move through that session.

A couple other quick things, a Wi-Fi is not available in this room, but I understand it is available in the lobby area. We also wanted to thank the hotel for giving us the nice tea and coffee break this morning. And there is some information about

parking that you can get at the hotel desk, if you drove in today, you will want to talk to them about that. And then in regards to lunch, there is a buffet that's offered here in the restaurant that's to help sort of facilitate a quick lunch if that's something you're interested in.

Today, there's going to be a big theme around timing. We are going to be moving pretty quickly throughout the day because we have a lot of ground to cover. So, you might again want to consider that for your lunch option. Restrooms are right across the room. Always please check for the nearest exit just as a routine safety measure and then, of course, for your phones, if you will mute your phones that would be very much appreciated.

And then again, just for any general questions that anybody has if, you need any assistance throughout the day please check with the folks at the registration desk, they are more than happy to help you.

So with that now, we can get to really the start of our agenda. And it is my great pleasure to welcome Frank Yiannas up to the podium. Frank is a renowned food safety expert and he serves as the FDA Deputy Commissioner of our Office of Food Policy and Response. Frank?

OPENING REMARKS

MR. YIANNAS: Well, thank you Kari. And good morning, it's good to see each and every one of you. And thank you for joining us today, whether you are here in person or participating by webcast, we're delighted that you've decided to be part of this day. Together, we're going to build on the progress that we've made implementing the Food Safety Modernization Act also known as FSMA. Together, we're going to create a more digital, traceable and safer food system. And together, we're going to usher in a new era of smarter food safety. See the destination is the same that's safe food for our families, safe food for our children and our loved ones, safe food for pets and animals. What we're talking about today is how we get there, how do we get there more quickly, how do we get there more effectively using modern vehicles of change.

I believe this is going to be a great day. I am very excited about it. We will be joined soon by our Acting Commissioner Dr. Ned Sharpless who shortly after his arrival at the Agency lend his support to this new era theme largely because of his prestigious work as a cancer research, and seeing firsthand how new technologies, big data and new tools are enhancing what we know about cancer in saving lives.

We also have experts today with us from all over the country and for that matter all over the world as far away as Europe. We also have experts from all walks of life representing all stakeholder groups. In the public sector we have United States Department of Agriculture USDA, we have the Centers for Disease Control and Prevention the CDC, and the Association of Food and Drug Officials all with us here in the house. From the private sector we have experts from some of the world's most prestigious brands and companies dedicated to advancing food safety. And it's just not food companies, we've had a record turnout from tech firms from the tech sector, companies that are working on new technologies that are improving business processes and making our lives better. And from the nonprofit organizations, dedicated to public health, we have participation from Pew Charitable Trusts and Stop Foodborne Illness just as an example.

Now, I've always believed that the words we use are very important. So, before we go on with today's business I want to stop and talk about what is it exactly that we mean when we talk about a new era of smarter food safety, what is that? Well, I looked up a definition in the dictionary that I thought was very relevant for today's conversation. A new era is a memorable or important date or event especially one that begins a new period in our history, this is the new era. I don't think I have to spend a lot of time persuading you that the world around us is changing very rapidly, faster than it ever has. And that involves food too.

In fact, I believe that we are in the midst of a new food revolution. How many of you believe we're in the midst of a food revolution? Lots of hands going

up. Some believe that we're going to see more changes in the food system in the next 10 years than we've seen in the past 30 or 40. Listen to this: Products could be reformulated, new food sources of production approaches will be realized, and the food system will become increasingly digitized. And we believe that to succeed in these modern times we need more modern approaches. That's why Dr. Sharpless and I announced earlier this year that we plan to usher the FDA and the United States into this new era of smarter food safety.

Now, smarter food safety isn't a tagline or a slogan, I promise you that, instead it's a new approach to food safety, a new mindset if you will, one that recognizes and builds on the success of the past but incorporates the use of new and emerging technologies that are improving business sectors all around us whether it's distributed ledger technology often referred to as block chain, whether it sensors, the Internet of things IoT, whether it's machine learning, 5G and artificial intelligence and more.

But smarter food safety is more than technology. It's also about simpler, more effective methods. And I believe it's also about leadership creativity and culture. Smarter food safety is people led, FSMA based, and technology enabled. Let me repeat because I think that's really important smarter food safety is people led, it'll require people like the folks in this audience and listening by webcast to lead these efforts; it will continue to be FSMA based but it'll increasingly be technology enabled. But we want to capture the best ideas for this new era from within the boundaries and outside the boundaries of FDA. And that's why you're here today. To jumpstart today's meeting we've already been brainstorming at the Agency. And we've had some focus groups focusing on these four key themes. They are: tech enabled traceability and outbreak response, smarter tools and approaches for prevention, adapting to new business models and retail food safety modernization and food safety culture.

Each of these will be critical in fueling us to our final destination of making food as safe as it can be. A vision that Congress embodied in FSMA and

each of these is critical in bending the food borne illness curve. Because after all, at the end of the day that's what we're after right, less food-borne illnesses.

Let me briefly share some high-level thoughts on these four key themes before we move on, beginning with tech enabled traceability. If you pause to think about it I believe today's food system is pretty impressive. Think about it, you get to go into a grocery store and find tens of thousands of different food SKUs of a wide variety for foods, all available for a fraction of your hard-earned dollar that's impressive and it's usually safe. But I've also learned from our experiences that today's food system has one major Achilles ' heel and that's a lack of traceability and transparency in my view. And you don't have to look too far to see what a lack of better food traceability costs us and society. I don't think I have to spend a lot of time persuading you, whether it was the spinach outbreak of 2006, we knew there were E. coli illnesses linked to bagged spinach but we couldn't find the source and it took 2 weeks to find the source. Whether it was what I refer to as the summer of Salmonella in 2008, when we heard from health officials that there were illnesses due to Roma tomatoes and then maybe it's not the Roma tomatoes but the jalapeno peppers or maybe it's both a lack of traceability. Whether it was in 2009 PCA peanut butter illnesses and peanut paste; a company that manufactured a mere 2 percent of the peanut paste in this country resulting in hundreds and hundreds of recalls because that ingredient was in food products. And some of those recalls by the way coming in 3 months after the original outbreak was announced, a lack of traceability. Or more recently just last year, two outbreaks associated with romaine lettuce, one at the height of Thanksgiving holiday when Americans were sitting down to celebrate food worried about food safety, a lack of traceability.

In FSMA Congress anticipated the need for enhanced tracking and tracing of certain foods. And part of the work the FDA will do in modernizing food

traceability will come through rulemaking under the development that's required in this Section 204 of the law. It requires FDA to designate certain foods for which additional records are needed. We've been working very diligently already on Section 204 and we anticipate proposing a rule sometime next year. I also know there's a lot of good work going on by folks in this room in the industry to advance traceability. You see, food safety and traceability isn't just a priority for FDA it is a priority for many of you in the industry.

We'll be mindful of the food traceability work you have underway in both how we develop regulation and the broader work that we'll do to advance traceability in the new era. While the agency isn't currently planning to build our own technological platform, we do believe there's a role for FDA to work together with you on issues ranging from interoperability, encouraging participation along the entire food continuum. And by clarifying and harmonizing what are the key data elements that are needed from a public health perspective, we will do that together. We also believe there's a role for the public sector in creating incentives for these types of solutions to be adopted and for them to scale.

A second area of focus for us is smarter tools and approaches for prevention. Think about it, there is more food safety data being generated now than ever before, as modern food safety approaches generate new data streams and larger data streams and the tools for rapidly analyzing big data become available will explore their preventive value. For example, we've already publicly announced that we're conducting a pilot that will leverage artificial intelligence, and machine learning to explore ways the agency can review imported foods at ports of entry to ensure that those foods meet US food safety standards. And the ability to get better at predictive analytics is good for all of us. And it's applicable to everyone in the food system ranging from farms to new innovative products and food ingredients.

Another area we plan to address is, how to

protect foods as new business models emerge to change the needs of today's consumer. The evolution of how food gets from farm to home continues to evolve from around the corner to around the globe with the emergence of e-commerce, new delivery methods and the ever-changing last mile. This is interesting, research indicates that by 2025 online grocery will have a 20 percent share of consumer spending in the US. If you think about it a little differently, 1 out of every 5 dollars that consumer spend on food will be spent on online platforms. This means new methods of delivery packaging materials, new temperature control approaches and digital means of communication are needed. And we must identify the industry's best standard of care to ensure that these new food models are safe.

And remember I said we're passionate about bending the food borne illness curve, so looking at more traditional models we're exploring the best ways to ensure the safety of food sold at restaurants and other retail establishments. Because as many of you know studies have shown repeatedly that they tend to be a very common nexus of food borne outbreaks. And disturbingly the Addus compliance rates of the retail risk factors have not changed much decade after decade we've seen that through FDA baseline studies. And that's why we're committed to taking a fresh look at how we're going to address retail food safety by exploring new tools that might go beyond the traditional training and inspectional approaches that we've been using for decades.

And last but not least, food safety culture. Yes that's right, food safety culture. I've spent a great portion of my career talking about this subject as you know. And in fact, some of you might be thinking, I suspect, does culture really have a place or a central tenet in the new era of smarter food safety? And my answer is, absolutely yes.

There are many times over the course of the years that I've had people say, "Frank but we showed up today because we want to talk about technology and food science not culture. Culture is the soft stuff. We want to talk about the hard sciences and the hard

stuff." And my answer is always humble but direct - we have to talk about culture because I've learned over the years working for organizations that have tens of thousands to literally millions of employees that it's the soft stuff that's the hard stuff. I think you know I've seen it in my career you can have the best policies, written procedures, rules and laws on the books but if they're not put into practice by people, they are absolutely useless. Clearly, what we write what we think about food safety, what we know the sciences are important but they're not what matters most, what matters most is what people do with food safety.

In fact, my favorite definition of food safety isn't a fancy Codex definition. It's one that I use says, food safety equals behavior. It's impossible to advance food safety without influencing people's behavior. And food safety culture, in my view, is a prerequisite to food safety management. So, let's work together to foster support and strengthen food safety cultures beginning on farms and food production facilities and even in homes. And we won't make dramatic improvements unless we get better at influencing human behavior.

Now, we're talking new era today but FSMA is absolutely central to our work and our commitment to FSMA will be unabated. See, modernization isn't something you just do once a year or once a lifetime or once a decade let's say in 2011, it's about continuous improvement. And so we are going to continue to do work on the tasks at hand that remain for FSMA in building on this prevention-based food safety management system.

But a lot has changed since FSMA was passed into law in 2011, a lot has changed. And as an agency and food safety professionals we must adopt to the changing world around us to protect public health and facilitate innovation. To me, leveraging new technologies approaches, while we forge ahead with FMSA is akin to advances we've seen in food or in phone technology, in mapping devices, in music platforms. We're still communicating by phone right, the phones

are different, we're still asking for directions but we're not taking out paper maps, and we're still listening to music it's just no longer vinyl.

The new era of smarter food safety is a driver of FSMA, it's not going to be a diversion from FSMA. And so I ask that your questions today not be about what about and rear-view looking. Instead of what about let's ask what if. The operative word I want all of you to adopt for today, if you would entertain me, is this word imagine, yes imagine. Imagine, and while you are at your seat, visualize, this being the industry standard of care. Imagine scanning a bag of lettuce at the grocery store or if you are a health professional in a patient's refrigerator and being able to know where that lettuce came from with speed and precision. Food traceability at the speed of thought not days or weeks or you can never answer that question that's smarter food safety. Imagine receiving a text message on your smart device that says you've purchased a product that's been recalled as opposed to looking for a printed paper flyer somewhere in a grocery store that's smarter food safety. Imagine while you're at home watching TV, you hear something about a flour involving recall and use but you didn't quite catch it. And you walk over to your pantry open the door, pull a bag of flour off the shelf, scan it and you find out the bag of flour you have in your pantry is part of the recall that's smarter food safety. Or imagine, as you sit here today, you aren't worried because you are way from the office because you have confidence in the critical control points in your facility or critical points in your facility because you're monitoring them and you have access to, let's say, water quality parameters because they're being tracked by sensor technology and you have access to them in real time as you sit here through a smart device, that's smarter food safety.

We're not talking about things that can't be done. All of these things and more are actually being done today. What I am asking of you is the same thing I'm asking of everyone at FDA think, think about how to do your work differently. Now, in your packet of

materials, as you heard from Kari, you'll see a sampling of some of the ideas that our brainstorming groups came up with. We charged them with brainstorming and giving us ideas on these 4 areas. We asked them to develop their best ideas without considering the practicality of them getting done. That conversation will come but just not yet. And we offer these for food for thought as you think about your own ideas today.

In closing, we've received a record response as you've heard, and I can't tell you how grateful I am that so many people have turned out in person and on webcast. I can't tell you how grateful I am that you joining us today and more importantly that you committed to working with us on this journey.

We can and we will learn from each and every one of you and from each other. And we will use your insights and I promise to craft a blueprint that we plan to publish early in 2020 there's power in the new era and a new decade. I look forward to working with each and every one of you as we usher in this new era of smarter food safety together, thank you.

MS. BARRETT: Super. Thank you so much. We are now going to go to our first panel. And I'll ask for Susan Mayne and the panelists for Visions of a New Era of Smarter Food Safety to come forward. Dr. Mayne will moderate this session, she is our director, Center for Food Safety and Applied Nutrition at FDA.

VISIONS FOR A NEW ERA OF SMARTER FOOD SAFETY

MS. MAYNE: Good morning, everyone. And thank you, Kari. I'm really excited to be part of this conversation as we bring in experts in food safety, innovation, data analytics, agricultural transformation and digital solutions to share what the new era of smarter food safety looks like from their perspective. Before I introduce each of our esteemed panelists, I'd like to share some thoughts about my own vision for this next chapter in FDA's efforts to provide global leadership in food safety.

My vision is of a collaboration including some new partners to the foods program and thus unlike any we've seen before. This has been a collaborative

endeavor right from the beginning as we enlisted brainstorming groups within FDA this summer to give us their best ideas on how this could work. We asked them to think big without being constrained by practical considerations for the time being. And they jumped into this with both feet. I'd like to share an anecdote. When we first started talking about the new era of smarter food safety, before the brainstorming participants were selected, I was stopped in the hallway by one of my staff members, as I often am during the course of my day. But this conversation was different because she had heard about this new initiative and was excited and energized about it. "There are so many exciting technologies out there and so many new things going on we have to be part of that," she told me and she's right. These are exciting times. And this initiative is recasting our thinking in a whole new light. It's not only generating excitement internally but among our stakeholders as well. This meeting itself is a great example. We filled our physical and virtual house to capacity. And if we had charged admission we likely would've sold out. This is a strong testament to the enthusiasm and energy around this work.

There are many questions and challenges. There was a whole set of new technologies and approaches that we live with every day digital technologies, large data mining, how do we leverage them to protect consumers all over the world from unsafe food? How do we leverage them to overcome obstacles that were seemingly insurmountable? Anyone who's lived through an outbreak investigation and trace back and knows how daunting it is to sift through boxes of paper records to find the source of contamination does not have to be convinced that traceability is something that has to happen. And how do we leverage new technologies and approaches in facing the new challenges that are coming at us every day?

What if a drone is delivering dinner to your doorstep? How do we make sure that your food has been kept at a temperature that makes your food delicious and not dangerous? Are there available technology

solutions to these types of problems? These are issues we struggle with. But today, we have the opportunity to take advantage of all the expertise and all the commitment that everyone within the sound of my voice has shown by being with us here today.

We want to hear your visions of what the new era of smarter food safety should look like because those visions will be the building blocks of the blueprint we will create together. What ideas do you have that we can galvanize around. The time is now because we need to get ahead of these challenges and not be in reactive mode. What tools can we take advantage of? How do we create concrete information? Our own data highlights the importance of strengthening the food safety culture across the system.

We know that certain time-tested practices known to prevent contamination are not always followed, how do we change that? The ideas we hear today and those submitted through the Federal Register will augment the input provided by our brainstorming groups. Those groups comprised of our FDA staffers will soon be meeting a second time to consider how to make their ideas a reality being informed by our important work here today.

Together, all of this and put will form the fabric of the blueprint that reflects that collective wisdom. And now it is my pleasure to introduce our panelists each of whom was specifically selected based upon the unique wisdom each possesses and that we will all benefit from hearing.

So, our first speaker this morning is Mary Wagner. Mary Wagner is the president of MK Wagner & Associates, a global food science management consulting firm. Before starting her own company she had leadership roles in Starbucks, Mars Inc., EMG Gallo winery and Taco Bell. Dedication to research, innovation and food safety is a hallmark of her distinguished career. Mary.

Perspective on a Changing Food System

MS. WAGNER: Thank you, Susan. So today, I get to run through some interesting facts on trends in

the consumer. And I'm going to talk a little bit as I talk 50 -- I only have a short amount time, 12 minutes -- but as I talk through I want to touch on who are we talking about when we talk about the consumer that's impacting us in trends today? So, I'll give you just a snippet of what I think is really driving a lot of it. And then we'll talk about a couple of specific things that you all are very involved with around meats and around plants. And then I'll give you I pulled some really current data on restaurant trends, so that you can see what other people are doing as well.

First slide, next slide, there we go. So I put this up, it might be a little hard to see but it's consumer preferences and really let just talk about the consumer for just a minute. There's two things driving work in industry today and in the food segment. First, it's this consumer group is asking for a higher risk performance from products, fewer additives, local sourcing, you know, minimized processing all those things are driving some of the things that we're all involved with in this room. And to add to that, on the right side you see elevated connectivity. So all these people, these consumers are very connected iwaspoisoned.com is a great example of that. Another thing is Food Bait, so when things get out there not vetted but they impact us in this room. So, we end up either reacting or trying to -- have a -- come up with a solution very rapidly.

Next slide, so that's a little bit about the consumer. But here, I put this up to show you the industry impact. So, what do we think about in our jobs? There's four main things that I want to touch on. On the lower left speed to market, it's important to be first, and to be first you have to be fast, and to be fast it's easy to skip steps. So, you have to be conscious of that in really driving the knowledge of why that's important not to do that, to senior leadership especially. So speed to market, and this is a great example, pumpkin spice you know we were first at Starbucks and then everybody is piling on, so it's a good example of how it happens. Up in the top left you see increased leadership scrutiny. So, this is

Chipotle stock price, when they had their situation over the last several months or actually couple years. And their stock actually fluctuated, it still fluctuates quite a bit like $100 in a month or a day but they had a 50 percent stock price drop and that got a lot of attention from a lot of senior leaders. How can we prevent this from ever happening to us? What do we need to do to assure our food is safe? So senior leadership is getting much more involved in what we mean with food safety. Up in the top right you'll see competitive cost pressures -- and there's two lines hard to read but the blue line is eating out and the red line is eating at home. So what you see here is, people are not eating out as much. I mean recent data I've seen in the last couple weeks I pulled some other data it seems to be creeping up a bit. But basically people don't go out as much. So, what's the impact? Well the impact on industry is that we still have to pay for labor. You still have to clean the store. You still have to run the lines, but you're not getting as many people coming through the store.

So, and then we have a crunch on labor to top it off. So that is really pushing the limit in some restaurants and in some factories. Just the, how often do you clean, do you try to squeeze as much as you can out of each session. So, those are things you need to pay attention to. And then the bottom right-hand corner, I put that in there to show you that even industries so connected now, it used to be that we could see how many people visited a store now we can tell how often they hit on our website and how many minutes they stay on it. So, all the companies are looking at same data so it's very, very competitive.

Next slide. Alright, let's talk about the consumer. And I wanted to put in Generation Z. Generation Z, who are these people? Well, just to give you an inkling, I have two of them at home. They are born between 1990 and 2010. So they compromise today a quarter of our population in the US. But in 2020 it's going to be 40 percent. So, just let that sink in for just a minute. It is a huge impact on who buys what and what we offer to these kids.

The other thing is they are digital natives they've never been without their smart device. Everything they do is related to the smart device. And that includes not just what they buy and how they shop. Because they love to eat, they love to eat and they go out to eat all the time. Food is entertainment for them. But they can't cook, so it's really interesting. The other thing about these kids, we all hire them so we know them quite well, but they go to YouTube and if they can't find it on YouTube they will make it up for YouTube. So, they're very familiar, they're not afraid, they're very conscious of truth, they will speak -- they could sniff it out, so if you are a food company and you think you're going to all of a sudden come off as small and not large they're going to know that and that means a lot to them. Also environmental things mean a lot to them.

Next page. I thought I'd show you one more thing on Generation Z and that is they are really global, they've never not lived in a world where they have Asian food, Hispanic food any kind of food and they are used to that. But they're also the most diverse. I mean they're the -- Generation Z is definitely the least white of all the generations and that's not going to change. So that's what we're facing, we're facing kids who really have an interest in food, they want to try new things, the earth means a lot to them. And so that's who we're going to pay attention to because they have a lot of money, they are inheriting trillions of dollars. So, these kids are going to be a big buying force.

Next page. So now, I am going to get into a couple of slides of data but I wanted to show you, you know everybody talks about meat. There's four kinds of meat today. There's meat from a cow, from an animal. Then there's something, the first point here is a blended meat/plant alternative. So those who don't want to go 100 percent plant but they're interested in eating more plants they like this option almost 35 percent of people said they are willing to eat that. So, the first one is meat and mushroom based burgers. The second one is what we all heard a lot about and

that's plant based burgers, the thing that looks like meat, tastes like meat that's really popular and becoming even more popular. So that's -- and that's also about 35 percent of people say, you know what, I definitely buy that. Or I'd eat that for sure. And then we have something coming up cell-based that's taking cells from an animal and growing them in tissue culture that's tough for people. That is still a yuck factor for people actually 55 percent said, "I'm not going to do that." But just get ready because it's going to come and what that means is and the reason it will is because you don't kill a cow and that really appeals to Generation Z. So, it's going to -- you're going to see this evolution very quickly. And so, I thought I'd point that out.

Next slide, I can't say enough about vertical farming, hydroponics anything to do with local sourcing it's actually really fascinating. So, the concept is that you can grow something and people actually think it's healthier if it's local -- that's local, more local and it's just grown in a building. You use less pesticide, you use less water, you have less issue with bacteria. I mean, it's not sterile you still have to do what you do best in terms of monitoring and making sure everything is done right. But this is big. I mean this is how you're going to get more plants into people, is doing things like this. So, pay attention to this I think that we are going to have to learn from the food safety perspective, how to monitor it? How to make sure that it is done correctly? How to work with these people who are doing this, who may not know a lot about food, they are hiring people who know about egg but they need some help, so that's a big callout.

Last slide. I thought you'd find this really interesting. This is a survey done by NRA, right out -- hot off the press as I say. It's done by chefs. They polled chefs around the country and it's pretty factual and true. So, this is the list of what they say are the most important concepts. So, I thought you'd like to see, I'm not talking about all these today but I could talk about all these. And number one of course is CBD and cannabis. So, you're going to

start to see more of this coming out. CBD in particular and I'm just predicting. And so, us in this room have to be ready for that. Because today it's almost something that nobody talks about.

The second one is zero waste cooking, when you start using the waste that you used to feed to pigs and start to convert it to people food I think this room has to be paying attention to that as well because Generation Z doesn't want to have any waste. So, how do we deal with sanitizers if they've been put in the product how do we deal with other items that might have happened to the product. Those are just real and we'll have to figure out how to give advice on those things.

Again hyper local, I just want to touch on that again. Today, restaurant tourists go and buy 43 percent of their meat locally, so that's not manufactured meat, it's manufactured locally but there's a lot of control that has to happen. Some of these are actually been purchased at farmers' markets. So farmers' markets two thirds of chefs shop at farmers' markets. Or they acquire their produce through other small manufacturers that may not be familiar with what food safety really is. So, I just wanted to point those out but you have these slides too and I'm happy to talk more about them later. Thank you.

MS. MAYNE: Great. Thank you, Mary, for kicking us off, looking at some of the trends coming at us as we think about the smarter era. Now, it's my pleasure to introduce our next speaker, Dirk Herdes. Dirk is the senior vice president at the Nielsen Company, where he leads Nielsen's Partnership with Walmart and Sam's Club and helps both to make faster and smarter data driven decisions. Today, Dirk is giving us the benefits of his expertise in the global retail, consumer goods and technology arenas. Dirk?

Navigating a Trust-Enabled Food System

MR. HERDES: Good morning. Excited to be here and get the chance to talk to you about this important topic. So, at Nielsen our clients demand of us increased smarter markets, how to provide smarter

markets that is through accurate and actionable insights. And they -- the heart of that is data. It's about having trusted data to make decisions. And I hope to show you through the next few minutes and through information how consumers are showing with their dollars and their investment the demand for the same thing for increased transparency and trust.

So, if you want to go on to the next slide. So trust, for the next few minutes you will hear me use the words trust, transparency and truth quite a bit. Why? Because today's hyper choice, hyper information, hyper complex world and increasing complexity for consumers it's trust that will determine the success of an organization. Trust is never optional. It's not something you can half do. I can't trust an organization Monday through Friday and then not show up on the weekends. It's not something you can afford to break and once broken it can be costly and take a long time to rebuild. And in this new environment where there's immense amounts of information and consumers are overwhelmed with information and oftentimes the misinformation. Especially, I would argue, in the food and beverage system, trust represents safety, quality and commitment on a much more personal level for consumers.

These are the product that I am -- bring into my home. I'm energizing the nutrients in my body as well as feeding and providing for my family. Trust must be earned and nurtured. So, if you want to proceed? So, why is it that brands and retails provide an experience as trust more important than ever? Why are products that represents truth whether in advertising, in ingredients, in product claims as well as in my supply chain process so important? Well, here's one big reason, 91 percent, if you were to look around at your most favored brands and assume that their most loyal customers were in fact disloyal you'd be correct, 91 percent of the time they're open to and considering alternatives.

In a world of this much information and this much overload the connection to consumer is no longer tied to just those brands that I know, brands that I

know from a generic trust or a legacy reputation in society. Consumers are much more empowered, much more knowledgeable, and it's much more intimate and personally relevant factors that go into the consideration set for the products that they choose. Given this personal relevance and consumer connection the market for transparency has a significant upside and opportunity. Products that can transparently speak about their ingredients, the way their products are made, the way their products are shipped to the market and how they are helpful for the consumer and the world around them will continue to succeed.

The World Health Organization estimates globally that 12.6 million people will die due to increased dangerous levels of air and water pollution. Now this may seem adjacent to food but actually I would argue it's at the epicenter. As this continues to increase the access to healthful foods, safety will continue to become more and more important for the consumers they serve.

Today, product options and information and access are plentiful and consumers are prone to disloyal actions. And when trust breaks down the fundamentals like food safety and quality are compromised it takes very little to sway my interests to pursue a newer, safer alternative.

If you want to move forward to the next slide? And that currency that is defined trust especially in food will continue to evolve. So, one essential way is to speak to consumers the same way that they speak, doing so with authenticity and honesty, simple recognizable ingredients that we know and trust are ways to show consumers a bit more about my cards, a peek behind the curtain as to the products that I make and how I make them. It helps to reassure them with confidence that they can make that decision as a product worth purchasing. When a product demonstrates this from the earth connection it inherently draws a dotted line to safety and quality with food. These are things that consumers know and trust and the food products perceived with comfort and natural known ingredients can really make a difference in adoption.

If you can go to the next? Further, when consumers understand exactly what's in their products, what makes them safe, healthy or environmentally friendly, trust can really fuel business growth. If you will look at this example I will just focus on the top. Products that come with high quality and safety standards are a big influence into consumer's purchasing behavior. They are showing us an increasing ability to pay a premium for these products. And we see this across the business and across the store.

There are many ways willing to pay more for these products that can hit the sweet spot of better for me and better for the world around me. Food products then simply and effectively can guarantee a certain level of quality and safety can differentiate themselves in the market. Now, on the flip side of this you will see a lot of retailers if you pay attention either through their own investments across the value chain or in their private label working aggressively to offer these same products at a much lower cost. To broaden the availability to the consumer set and meet this increasing demand.

Move forward, so, it's not just in the transparency what's in it -- sorry, if you can progress one. So it's not just limited to what's in the product but it is also across the entirety of the store. Ice cream is one example I will lean on today. So, ice cream is a category where the industry and the companies have met this need for consumers' diversity whether it be meeting the needs of FDA amounts of protein, using alcohol, sugars or meeting the needs of low glycemic diet consumers.

I think if you can go forward one more, I think they flipped that one. Well, there's a mix up in slides, I have a whole section on e-commerce so I am going to focus on that one first. So, it's not just in the products that are made and what's in the ingredients but it is also a change in how the products are getting to the store that demands an increased need by the industry and the retailers that provide them to earn and reassure that trust.

Today, e-commerce is upwards of $435 billion

in the US alone. The CPG side of that are food and beverages is now up to -- 46 percent each of the last 2 years. In industries that I serve across retail and CPG it is now $70 billion that is driven by online sales alone. Now historically, fresh foods has been with a slower to adopt and harder to emerge or grasp online categories. But in fact today already 1 in 3 dollars of all e-commerce sales of food and beverages is now spent online. So, one of the biggest trends driving this is actually new and unique ways of delivering product. So, many of you have heard of Curbside or Click & Collect and how fast that is growing in the marketplace. It is now 11 percent of all food e-commerce sales that's up from only 4 percent a year ago. Retailers are also investing in new technology to address the last mile. Many have seen announcements of how they're pushing not only to bring the product to your home but actually bring the product in your house and in your fridge. Yeah, a little creepy but new technology will -- haven't quite adopted that approach just yet. Yeah, feed you as well. Now, it's not just how we get it to you but it's how we package the products. I think you know Mary referenced meal kits. So, looking at new and innovative ways to package the products, a lot of this started with upstart brands and delivery online. You now actually see it not only online but embraced in stores. Last year alone, $93 million of meal kits were sold in stores alone. The bottom line is retail is omni channel. And this introduces new demands on the industry to deliver for retailers but also on the regulators to monitor and maintain these new package materials, ingredients delivery methods to ensure the integrity and the quality of food safety.

So, if we progress one. So, as you think about the growth of understanding and a need to know what's in my product and a need to know how I am going to get there. And as consumers are showing their willingness to spend more it means that the heightened sense of breaking that trust is even more valuable.

In this example, we're looking at romaine lettuce, which had a tumultuous 2018. I know Frank had

mentioned a lot of the challenges in the industry as well. Sales in the next year were $140 billion less than the year before, as consumers shifted their behavior to try new lettuce types like arugula. And we still see the unit price per romaine still hasn't upticked to this day. So, it's not just a one-time impact of a recall on the industries that are impacted or the consumers that are affected it actually has long-ranging impacts on the industries as well as on actual customer behavior.

So, I'll wrap it up with, what are we recommending or what are we talking to industries about and how are retail -- if you want to proceed one -- and brand addressing this. So, there's five key actions. The first is, finding that link between that micro-consumer and macroeconomic wellness that better for you and better for the world I serve. The next is really digging deep and using the data to understand what is it that is the attribute that matters the most to my consumer. There is no more one ingredient that's going to drive consumers.

I was talking to a family with gluten-free and they mentioned that "I can look at ingredients and I can tell what products are good for my family but I don't know what the supply chain is for that product. So I simply can't make that choice confidently to buy that product until I know more." So, we got to tell them more about the products we have and how they're made. The next is optimizing across my entire portfolio against these trends from the things that I innovate to the way that I market my -- or get my products to market. I have to work with retailers in these evolving ways of delivering whether it's deliver myself, through meal kits, through online grocery to make sure that my better for you helpful products are available. And then lastly that I communicate with authenticity in a world with so much information how do I stand out and show that I can be trusted.

So, my view of this is that we owe this to consumers. Every day, consumers are telling us what they care about with every click, with every like, with every post, with every share. Consumers have never

been more informed but never more overwhelmed with the information. We owe it to them to continue to operate the industries we serve around food with integrity and quality.

There's a lot of talk in our industry about data being the new oil, or it's the fuel for how we make decisions. I would make the case that it's not data but it's trust. Trust is the new currency with which we will operate. And I think the organizations that understand how to take that advantage of that with trust and transparency will be those that succeed. Thanks.

MS. MAYNE: Thank you. So, already we are here hearing some common themes from our first two speakers; the themes about transparency and good for the globe and e-commerce and how we need to use technology.

So with that, we are going to move on to our third speaker. It's my pleasure to welcome Pradeep Prabhala. Pradeep is a partner in McKenzie & Company, working across the Middle-East, South Asia, South East Asia and Sub-Saharan Africa on agricultural transformation efforts. He has actively supported efforts to catalyze private investment for agricultural development. And he advises the World Economic Forum on its new vision for agricultural program. Please join me in welcoming Pradeep to the microphone.

Disruptive Technologies for a Safer Food System

MR. PRABHALA: Good morning. So we, at McKenzie, looked at the food system problems from a slightly different angle. About 2 years ago we stepped back and said, listen this food system doesn't seem to be working for anyone, right. There are 800 million people that are suffering from malnutrition and about 1 billion people that are affected by poverty from food systems. There are -- 70 percent of the water used by food systems -- I mean 70 percent of the total water used globally is by the food systems and agriculture contributes to about 30 percent of global emissions. And we know that despite this the farmers largely don't earn a daily wage living. There are -- consumers are

not happy with the nutrition. So what's really going on, right? Why is it that the food systems don't work for anyone?

It is interestingly when we sort of did a bit of soul searching we found that the real challenge is the industrialization of the food system, right. Let me say why, right. Pre-industrial era food systems were hyper local. You could actually get the food that you want to eat from a farmer that's next door because these were predominantly local systems. But the food system over a period of time has become industrialized that's because we had to meet the food security imperative, which meant that there was industrialization of production, there's massive usage of crop inputs that might or might not be good for environment because food security trumped everything. The supply chains were organized for efficiency but not for transparency that's because people actually cared about delivering the food at the least possible -- least possible price. And predominantly I think a lot of problems that we see in the food system today are driven by massive industrialization over the last 50 years.

So we said how do we change that? What could we do that fundamentally could alter the dynamics in the food system that allows us to link consumers to suppliers, in a way that's effective and deliver to consumers the food that they truly desire to eat in a way that's actually safe and transparent.

And my earlier speakers have actually mentioned that there are massive consumer changes that are going on right. Consumers are actually demanding experiences, they want to eat healthy, they want to buy healthy, they want to actually shift away from foods that are environmentally unsustainable. But unless you sort of figure out a way to link the supply to the demand, you really can't move the food system forward.

On the other hand, we found that technologies are rapidly changing in the world around us. I don't know how many of you realize that total processing capacity of computers in NASA in 1970 is equivalent to the processing capacity of a single iPhone today.

Right, so often I think technologies grow at a pace that it is exponential and I think, as humans, we always tend to underestimate change in the long term and overestimate change in the short-term. So therefore fundamentally, we think that technologies are interesting they would change the world in the next 1, 2 years but in reality I think these technologies are creating massive shifts in the way the world is operating and they actually present interesting opportunities for us to drive food system changes.

I am actually going to move a page ahead. Next one, yeah, and if you look at it what are the types of technologies that we are talking about that could fundamentally change the food system. There are a whole host of technologies that we call as digital building blocks, right. Whether it is new computing technologies, whether it is big data NAI, whether it's Internet of Things, these are in the digital sphere that actually are enabling new models in ways that could lower costs, right, and could increase effectiveness.

There are also massive advances in science that we see, which are things like new genomics, right. I think today for instance, there are people that can deliver food that is exactly suited to your metabolism rate right, where I could do a quick investigation of your genome and tell you that this is the type of food that you should be consuming to be performing optimally. There are also massive advances in technology that are creating new ways to store and deliver energy. And on the other hand, there are also technologies that are reforming the physical spaces whether it is robotics, which everyone knows about, whether it is additive manufacturing, whether it's advance materials or nanotechnologies.

So, we embarked on the journey to figure out, how can we use some of these technologies for the benefit of food system. Next page, please. So we went ahead and did a journey, where we said that, listen conceptually this all makes sense, right, everyone is going to say that there are massive technologies, there is a hype story the world is changing. But we said, is

there something that's going on in the food systems which tells us that the landscape is actually changing. So we went and investigated about 2,000 enterprises that are startups, large companies that are innovating using disruptive technologies for the benefit of the food system.

For the benefit of a food system that's not going to be industrialized, for the benefit of the food system that allows you to link consumers to supply in an effective way that delivers sort of nutrition sustainability et cetera. The good news is there were -- we found that there were about 190 use cases of things that companies are doing that could allow the food systems to operate more effectively.

Move to the next page, please. So, we found about 12 use cases that we think could hold tremendous promise for food systems, going forward. And because of this narrative that I told you about, which is that people underestimate change in the long term from technologies, we decided to size some of these use cases that technologies could present over a 10-year period and a 30-year period and we presented, sort of, this at the World Economic Forum. And I think what sort of, really important here is that there are technologies that could change every aspects of food system. I will take a few examples and talk about it. For instance, we see that alternative proteins could reduce freshwater withdrawal by about 7 to 12 percent globally, right? That's material, right? At 7 to 12 percent lower withdrawal rates, you actually could address the at risk water basins by about 30 percent, right? Fairly significant numbers. You could reduce food waste by about 5 to 10 percent, right, by using food sensing technologies. I mean, these food sensing technologies are things that you could use to drive material changes to how consumers could predict whether a particular food product has gone waste when it goes to the households.

And largely, I think blockchain and traceability could address food losses by 1 to 2 percent, but if you look -- take an economic impact angle of reduced incidences of food safety, the value

is just humongous.

Next page, please. So, I think as we said, we actually did a fairly detailed amount of work in figuring out, how can these technologies therefore be applied in the context of food system. Among the examples that I have here is to talk about three such technologies that could change the game in supply chains. For instance, I think blockchain or distributed ledger technology could fundamentally change the way in which you could ensure that there's a full end to end transparency and traceability in supply chains; or whether it is Internet of Things that could actually reduce the burden on data collection in food systems because sensors are moving fairly quickly and actually are reducing in price fairly rapidly. Or food sensing technologies could change the way in which consumers could respond to challenges with their food, right. Today, for instance, if you have good food sensing technologies at the retail level, you could actually look at a particular product and exactly know as to what is the level of nutrition, how bad has the product gone, and how many days of shelf life will be left on the product, instead of relying on labels that are hot -- labels that are standardized, which make it very hard for you to predict what's going on.

Next page, please. So, what is actually required to drive the adoption of these technologies in the food system? We think there are four broad areas. One is, I think we need massive changes in consumer behavior and farmer behavior and growing behavior. I think this talks to the point of culture that Frank spoke about earlier today. I think we need to change the way people are behaving in food systems in the adoption of these technologies.

The second thing that's actually fairly important as technology infrastructure. I think the technology infrastructure is largely broken, we need to sort of think through how do we build the technology infrastructure that allows you to solve for it. Take for instance blockchains alone, I think there are a whole bunch of operating complexities to implement even in a developed country like the U.S., transaction

speeds, latency issues, right? How do you sort of make sure that the kiddies are standardized across? So, I think we need to sort of think through how do you build a technology infrastructure that allows you to build these solutions on top of it.

The third one is what we call as delivery systems. We need players in the ecosystem to think about new business models and delivery models that allow you to bring these technologies to fruition. And the last one, which is probably the most important as a regulatory environment that actually could facilitate this and therefore, we're very excited that FDA has chosen to make this a big priority, and think about how can they steward the food system in the direction that's going to deliver these optimal outcomes?

Last page. So in short, I think -- we think there is a significant amount of work to be done to accelerate the technology agenda. I think as we discussed food system really calls for improved technologies and how technologies could -- and technologies could actually improve the outcomes fairly significantly. And we think that there is real opportunity for players to come together to solve some of these problems. Thank you.

MS. MAYNE: Thank you. And I do hope we have an opportunity later to hear some of your thoughts about legislation, policy incentives that we can take from the FDA. We'll get to that in a little bit later today in the program.

Alright, it's my pleasure now to introduce Julie Pierce. Julie Pierce is the director of Openness Data and Digital, at the Food Standards Agency in England, Wales and Northern Ireland. In her career, she has established an expertise in driving digital and data solutions to problems in the public and private sectors that include food safety and adulteration risk. So we look forward to hearing our speaker from across the pond. Julie, can you join us?

New Data Opportunities for Strategic Surveillance: A Regulator's Perspective

MS. PIERCE: Thank you very much indeed. And

good morning, and just to kick off by saying, what a fantastic opportunity and honor it is for me to be here today. So yes, I'm Julie from the U.K. And why am I here? Maybe my title gives you a bit of a clue, Director of Openness Data and Digital. So encompassed in that fantastic title of mine, words like transparency, traceability, smarter approaches.

So hopefully, I'll also give a little bit more explanation as to why I might justify having that title. And yes, thank you very much, me from the U.K. from Europe. Just to remind you about the global nature of the food system. We've been hearing a lot about how it's becoming maybe more and more local, but it is also truly a global food system. So everything that happens over here will impact what happens over in U.K. and Europe.

So, my topic for this morning is data opportunities, new data opportunities. And I'm going to talk about what those opportunities are and also give a real life example as to what we've been doing over in the U.K. So those opportunities, simply more data, more available data, more accessible data and we can do more with that data. So, we also need the algorithms, the clever pieces of software that allows us to make sense of the data and to derive insight. And also, we've heard from some of my fellow speakers this morning about technology advancements that has been absolutely critical.

It's not only the technology, it's also the cost has gone through the floor over the last decade or so. And also with that comes speed of deployment. And I think I would also add certainly from where I sit; having been in this sector for many, many years; is I now think that people really believe in the power of these technologies. It's not only geeks like me that have been banging on about this stuff. It's out there and not just in the food system. It's out there in the real wider world. So hopefully, that's where it's really going to start to move to.

So the FSA, we are the regulator for food safety and authenticity in the U.K. And we have developed a capability an evolving set of services for

surveillance. So, this is what we have done. Thank you. So, our approach has been to start with a business question. So, somebody within the FSA came and said, "I'm really not sure how we will trade post Brexit. Maybe, we should get a better idea of that and be able to predict what might be going to happen." Also, somebody came along and said, we got a big thing at the moment around allergens changing legislation, but really do we know what consumers think about allergens? Do we know what they're actually worried about?

So, we start with a real business problem. We didn't go and start building a great big thing, however much I might have been tempted to make a case to spend a fortune on a big new IT system.

We started with a business question. And we developed fast. We worked with our users sitting by our side and took a very agile approach. And every single one of our use cases is developed through a series of sprints. And the whole process takes a maximum of 10 weeks. 10 weeks from getting somebody to articulate a business problem through to delivering a service that will work. And sometimes we do it quicker. We also have a number of sprints that run in 5 weeks. So, speed is really, really important to us.

Why do we do that? We do that to keep the costs down. And we also do it to keep our users engaged. They will sit with us for 10 weeks. If I said, I had to go away and spend 10 months at this I would have lost their interest, lost their attention. And also I would have been less and less valid for the business problems they were trying to tackle.

We have found that whilst there's lots of data out there, what I've been really pleased about when I've gone to look is the sheer volume of open data. Globally, we view D.C. data. Thank you very much. We've used data from across Europe. We've used U.K. government data. When you go look, there's a vast amount of data that is out there. So again, it is there, open data, free data.

And also, we found open source algorithms. Again, we're not doing anything particularly special

here. We're not spending a lot of money on this. We are taking those open source algorithms, and we're deploying them in a way that will address our business problems. And our absolute focus is to deliver something that will add value in 10 weeks maximum.

So my users are really happy, they get a thing at the end of that, it works. It delivers real value. And also for me, at the end of that process, we're harvesting the knowledge, the learning, and we're taking that knowledge and learning and we're putting all of that together and developing a sustainable set of services that will take us forward to the next business challenge, business question.

But also, as I come through each of those sprints, I've got a set of users who are enthusiasts, they are now my advocates. I don't worry when I have to go and bid for funds now because they're all standing with me saying, "Yes, we need to do this. This is absolutely critical. This is how we work and how we want to work and how we will work in the future."

So, I've just chosen one example to illustrate what we've done. So, over here on the left hand side, somebody says, I've been worried for a while, we get a lot of -- what we call RASFFs Rapid Alert System in Food and Feed messages coming through about aflatoxin, which is carcinogenic caused by fungus, and we're seeing it in Turkish figs. That's -- that's a concern, it doesn't seem quite right. But we don't know what's going on. So, as soon as somebody expresses a business problem like that, I grab them literally and I put them in a room and I try to get them to really articulate what the question is and what the problem is.

So, out of all of this fantastic technology and everything else, sometimes we find the hardest thing for the data people is just to really understand what are you talking about? Can I make any sense of this whatsoever? So, that is absolutely critical, those conversations.

We did manage to understand the question, and what we did was we built a model using historical data about the aflatoxin problem. And we could see that it

was a function of the weather. And it was the weather in Turkey affecting those figs. So we can use weather, weather data is easily accessible, and we created a model. We then used machine learning to predict incidents of aflatoxin in figs in Turkey. And we then thought, well figs don't just come from Turkey, is this a Turkish problem? No. It applies to all figs across all geographies, where they have similar climate and weather. Then we realized that aflatoxin doesn't only affect figs, it affects many commodities. So, we now have a model that predicts aflatoxin in many, many commodities from around the world.

And one nice example for us is, Brazil nuts. Brazil nuts have been regulated for import into the U.K. for a while now. So importers are pretty, pretty canny. They moved to Bolivia and started importing Bolivian Brazil nuts. But that's not regulated, but it has the same aflatoxin risk. So, we are stopping Brazil nuts from Brazil and allowing them through from Bolivia. What was the point of that?

So, we then could start to predict and see how the trade would move around and not only what action we needed to take, but start to see the impact of any action we, as a regulator would be taking. And we tested our model, and we sampled imports at ports, U.K. ports, and we found across all of these commodities, we were getting positive results back, so the model is working.

So, at the end of this we've got a model where we can predict climate that's simple. We can see weather that's pretty simple. And we can see the aflatoxin risk and we now have enough time before those products leave that country of origin to make a change in how they're regulated or what the action is as they come through the U.K. ports.

So, this was a real life example. We did all of this in 10 weeks. And what would I say? We've got technology developments going on here. We've got big data. We've been talking about DLT technology this morning. We've been talking about AI. But what I'm saying is, yeah, that's all great. And we do need to be bold, and we need to roll forward and imagine that

future world. But at the same time, today, we have small data, we have open data, it's accessible. Just go do, it's in your hands, we can do all of this stuff now. And I see no reason for waiting until all this big fancy stuff comes along. We need to start doing this stuff now. We need to learn. We need to practice. We need to see what works and what doesn't work.

So, please, my message to you is be bold, but just start doing it and doing it now. Thank you very much indeed.

MS. MAYNE: Okay. Is this mic -- mic on, good. Okay. So, you've heard some really wonderful remarks from our first set of speakers. And now, I'm going to have -- as the chair of the group, I get the opportunity to ask a question, and I'd like each one of our speakers to try to -- try to address it. The question I'd like to hear from you is, knowing what you know, and sharing what you have shared with us. What are the most critical steps that FDA can take now and in their near future, to accelerate innovation with respect to food safety? So from your perspective, what actionable critical steps should we be taking? So, we'll start with Mary and go down, go down the line.

MS. WAGNER: I think -- I think, the one of the most critical thing is to continue having the exchange and getting the diverse group together. I think it's a benefit to everybody. It'll save time, it'll develop tools, faster for training. It'll get buy in at senior levels faster. Because I think the speed comes out of everything I've heard this morning, speed is of the utmost importance right now, and getting the right players in the room. I would pull someone in from tech, like you have today, and someone with all the things that we bring to the table, but definitely, make it a group effort, and it'll go faster.

MR. HERDES: Yeah. I think the thing is, as you think about consumers are evolving to continue to push organizations to make that investment back in the food supply chain and in the system. By -- we've seen organizations, Julie has some great examples of

technologies changing very quickly. And we can mine massive sets of data, there's algorithms that are available. But it all depends upon having the right data available to actually make those decisions. So helping organizations understand why it is so important to invest in technology to go all the way back through and trace the supply chain, because once we have that data, I think it'll become very clear, how to communicate that, how to get more buy in, and to get organizations to really draft around that. So for me, that would be the most exciting area.

MR. PRABHALA: I think there are two priorities. One is how can we leverage technologies and innovation to change the way we do business, right? I think, for instance, I think Frank mentioned about doing a pilot on import data to understand the challenges. So, I think there's a whole bunch of things that you could innovate on within the four walls of FDA. And I think the first question is thinking through, what are the specific use cases that we could pilot? And how do we do that? And I love Julie's example on, sort of, using an agile method to do that.

A second question is how do you actually incentivize players in the ecosystem through to adopt new technologies, which I think is harder. And obviously, I agree that, I think, building a coalition is really important and getting feedback. But also, it's really helpful to think about, in each of those solutions that you're trying to catalyze, what is the role that you wish to play? Right? Would you actually be a part of -- active participant in some of the solutions or would you be a regulator and set standards? I think it's really important to have that clarity for us to, sort of, move forward.

MS. PIERCE: Thanks very much. Yes, I think I'm going to build on the comments my colleagues have made. Absolutely, the conversation of which today is just part of that. Regulators, I include myself in that, we can help convene and have those conversations. Then make it real, make it relevant. And do it yet again, just do it. And also, I would ask that this sort of stuff shouldn't just be for the big

organizations, I think the opportunity that we are seeing now. And again, it comes from the, the evolution of the technology generally. It's much more available than it ever has been to small organizations, smaller, poorer countries. So I think we've got an opportunity to level the playing field and let everybody in and play.

MS. MAYNE: Okay. Thank you. My next question is, we heard a lot about how consumer desires, things are driving a lot of what we're seeing in the food system today. And one of my questions is we heard about things like performance nutrition, organic and natural. How much are improvements in food safety being a concern for consumers as they're looking for transparency and what can you share about that? And what do consumers see as the government's responsibility in terms of food safety and traceability? Whoever wants to jump in on that, maybe Nielsen?

MR. HERDES: Yeah, I would say from a consumer demand standpoint, and I'll probably let someone else address a bit of the government's responsibility. We see as new claims and things they can have confidence in, are labeled and clear, adoption goes up quickly. They're willing to receive -- pay a premium for that as well, but, and I think that's when you talk about incentives, you see organizations now really rally around those ideas, and work hard to make them available. 46 percent of consumers have said they're willing to pay a premium for a product that's better for them. I think they often equate better for me with safety. But I think they struggle to understand what does safety mean? So for example, grass-fed beef is a -- proteins is a big claim that's growing really fast. You would think that's pretty straightforward and simple, but in reality over what we've measured of 1 billion dollars in sales of items that have grass-fed claims on it, only 25 percent actually are 100 percent grass-fed. So I think it's that increased transparency that will be the key there. They're adopting to it, but I think those that truly stand out and that's where government can provide clarity, it'll grow faster.

MS. PIERCE: Yes. From the U.K., we do ask our consumers on a regular basis what, what concerns them, what was interesting for them. And I'm not so sure about the premium of food safety. Most of our consumers just assume that it is safe and they assume that businesses made it safe and they just assume we, the regulator, somehow has just made it safe. So that's, that's a given. And then, we then head into sometimes very complex conversations around animal welfare, authenticity, all of these other consumer interests and that's becomes quite a complex conversation. I think we need to keep the conversation going. But when we're talking about safety, it's just assumed to be there.

MR. PRABHALA: Two comments. We did a survey about 3 years ago that looked at how consumers are buying their food and what are their preferences. And for the first time in the U.S. history people are making food decisions not based on taste, price and convenience, but on other factors and I think safety experience, matter a lot to consumers. But having said that, I think the other big learning was that there's just a lot of noise that consumers find it really hard to discern from grass-fed beef versus organically grown beef, GMO free versus organic, people don't really understand what are the differences. So therefore, I really think that there's a massive opportunity here to drive consumer behavior change and cultural change. How do you actually educate consumers to be more informed in the way they're making their food choices? I think there's a huge opportunity.

Ms. WAGNER: There's a couple of slides, I didn't bring, but one shows when you ask consumers about what is most important in food safety to them. It repeatedly -- food micro comes out on top. I don't think they totally understand, as we get into things like buying your meat in a farmers' market, what the implications are. So we have some education to do. It's almost like extension in the 60s and 70s is coming back to help, help people figure out what they need to do. And then the other thing, there's another piece of data that shows that confidence in the FDA and USDA is

the highest over family, over farmers, over a lot of the other trusted brands, brands that we look at in the past. So that's a good position to be in, that's a position of strength to come out and stand for something and make change. It's a good place to be when you're number one.

MS. MAYNE: I think we have time maybe for one more round of questions for our panelists. We've heard a lot about the global nature of the food supply. And that was a fantastic analogy talking about how you're using weather data to predict potential contamination from mycotoxins. And so the question I have is, how can the global regulatory bodies work together? A lot of these data analytics are using global weather data, as you highlighted, you guys, have been analyzing data from Turkey. How do we form partnerships regulatory with our regulatory counterparts so that we can all be on this journey to use the best analytic information to improve food safety? So, we'd appreciate your thoughts on that.

MS. PIERCE: Absolutely. We are spending increasing amount of time to have these conversations and build these relationships. And I spend a lot of my time talking about data standards and maybe somewhat dry topics like that. And those underpinning data standards are really important to share this information. And again, at the end of the day, though, it's about those relationships and having those conversations and having those trusted relationships across the regulatory community, and also bringing businesses on board as well. This isn't something that the regulators should go away in a huddle and work in glorious isolation. It -- again, it has to become real. It has to be implementable for all of the businesses because it's the businesses that provide the food. It's not us. And it's the business that remains responsible for ensuring that food is safe. And I think it's an ongoing set of conversations.

MR. PRABHALA: My mind, full priorities from a regulatory perspective. One is, I think, there are some quick wins like standardizing on Codex, right, and ensuring that we have labeling standards that cut

across.

The second one is, I think -- as I agree, interoperability of data is really important. Interoperability of systems and how do we sort of set the right conversations between regulatory agencies is sort of important.

The third is actually I think, which is often underleveraged is getting multinational companies to be a part of the dialogue. I think most of them have global supply chains. And I think this radius chart right, because obviously a lot of supply chains are very complex that cut across geographies. Could you partner with a select set of actors to start piloting solutions that can transcend individual markets and what would it look like? And as FSMA already sets a few guidelines on how do you sort of predict by ensuring that the things -- the products that are coming into the market are regulated at border. But I think more could be done in partnerships with private companies.

And the fourth one is there needs to be a bigger forum for regulators to have conversations more regularly, right? And then, I think, we need to sort of think about what are those opportunities that are presented rarely, like for instance, if you look at the big events like the platforms like the World Economic Forum, or the UN, they often don't tend to be very tailored platforms for regulators to have conversations around food. So I think there's a real need in the world to think about how do we do that.

MS. PIERCE: Yes, I mean, GFSI is a great opportunity, Codex as well again; so those four are there. And I think it's beholden on us to make sure that they are actually alive and having the right conversations. And so we need to really engage with them on that.

MS. MAYNE: Okay. I think we are right on schedule. It's high 10:00 o'clock. And so we're going to move on to the next part of our program. Thank you to all of our panelists.

MS. BARRETT: Yes, thank you very much to our panel. We are now taking some time in the agenda to

hear from our FDA acting commissioner. We have Dr. Steve Solomon, who is our director for Center for Food Veterinary Medicine, who will be joining the acting commissioner and will introduce him. So, if the two can come up?

MR. SOLOMON: Good morning. Let me join my colleagues in welcoming you to today's public meeting. I'm delighted to see so many people at capacity here and on the webcast. You just had an opportunity to hear a very stimulating panel offering visions for our new era. We're fortunate to have as our next speaker, Dr. Ned Sharpless, the acting commissioner of the Food and Drug Administration. He started in April 2019. He previously served as the 15th director of the National Cancer Institute.

Prior to the National Cancer Institute appointment, Dr. Sharpless served as the director of the University of North Carolina Lineberger Comprehensive Cancer Center, a position he held since January 2014. Dr. Sharpless was a Morehead scholar at the UNC–Chapel Hill and received his undergraduate degree in mathematics.

He went on to pursue his medical degree from the UNC School of Medicine, graduating with honors and distinctions in 1993. He then completed his internal medicine residency at the Massachusetts General Hospital in hematology oncology fellowship at Dana-Farber/Partners CancerCare, both at Harvard Medical School in Boston. After 2 years on the faculty at Harvard Medical School, he joined the faculty at the UNC School of Medicine in the Department of Medicine and Genetics in 2002. And he became the Wellcome Professor of Cancer Research at UNC in 2012.

His career has focused on innovation and promoting research into promising new therapies and guiding FDA towards a new era of food safety is right in his wheelhouse. It's my honor and privilege to welcome Dr. Sharpless.

FDA MOVES FORWARD INTO A NEW ERA

DR. SHARPLESS: Thank you, Steve, for that introduction. Good morning, everyone. I'm delighted to join you here for this important meeting to gather

public input on our proposal for a new era of smarter food safety. And I think, you know, the great turnout for the meeting, both here and online and also the excitement in the era, I think, really underscores why this topic is a top priority for the FDA presently.

As a doctor, I've long appreciated the importance of nutrition and diet and the role it plays in health and disease. As many of you know, obesity is a leading cause of cancer in the United States and so I was very interested in the topic of nutrition given that I was a cancer doctor and been exposed to this a lot when I was directing the National Cancer Institute. And I was also aware that the research in this area could be better having a co-chair of the Trans-NIH working group addressing nutrition priorities for the NIH.

But food safety specifically, the issue of how to prevent food-borne illness was frankly not something I had thought much about since medical school. I remember like listeria and salmonella that was like board questions from 20 years ago. And I don't think I was very good at it back then. So it was -- when I was coming to the FDA, this topic actually provided some cause for trepidation. You know, what would I be able to do on this topic. But I have to say I found the topic of food safety really fascinating. And the FDA's work in this area is particularly rewarding.

And you know what, after long conversations with Frank and Susan and others, I realized the topic is really not that foreign to me as I thought it might be. Some of the epidemiologic approaches I knew well from studying cancer clusters, as a NCI director and cancer doctor, are not dissimilar to approaches used in studying food outbreaks. The timescale is different but the need for great data, the analytical tools, the -- you know, many of the same issues are related. And that experience taught me the power -- and the critical need for really, really strong data and data analysis.

That research is very dependent on how we can collect high quality data and how we analyze those data using the most cutting edge novel analytical tools. And these issues are very familiar to a cancer

researcher and not dissimilar at all from what I used to think about all the time at NCI and as a Cancer Center director. And I've realized I'm very excited about our opportunity to support the modernization of our system to help prevent and ensure more timely responses of food-borne illness outbreaks.

Food safety is a critical public health responsibility that this agency takes very seriously. We have oversight of approximately 80 percent of foods Americans eat including -- and I have a list here, so I won't mess it up -- seafood, fresh fruits, vegetables, milk and dairy products, baby food, infant formula; frozen, canned, packaged and snack foods; juice, soft drinks, and much, much more. And in short, the FDA's responsibility in this area touches every American every day and all of our lives.

So one of the first things I did, when I learned I was coming to FDA, was commit myself and FDA to advancing this vision of a new era of smarter food safety. And this began as I was transitioning to FDA, I learned early on about the FDA's plans that were being developed. And immediately I appreciated what an opportunity this is to make an impact in this area.

Last spring, immediately after arriving at FDA, I was pleased to join with Frank Yiannas to announce the steps we plan to take to usher the FDA and the United States into this new era of smarter food safety. As you're aware, our proposal is a dynamic initiative, with enormous potential to make a difference in the lives of all Americans.

As mentioned, several of the issues this initiative focuses on include strengthening predictive capabilities, accelerating prevention, speeding response and using and analyzing data are things I really understand from my time as an NCI director working on cancer treatment and cancer prevention. I've been a strong proponent of leveraging new and emerging technologies and of developing novel analytical tools in the service of saving lives throughout my career. So doing this for food safety just makes perfect sense to me.

Harnessing computer power and applying state

of the art data storage and computing to support new initiatives are approaches I fully believe in and play a key role in the new era of smart food safety. We'll employ such approaches to mine new types and sources of data and we will develop new ways to share those data, allowing us to work together across public and private sector boundaries in the development of new possibilities and solutions for food safety.

So I welcome the opportunity to work on food safety. Employing the full range of the most modern and effective scientific and technological resources to strengthen the FDA's work in this area. Improving food safety is a big challenge and it's a target that's been constantly in motion for years now. That's because the world of food supply and demand has been dramatically transformed. The food we eat -- the foods we eat are increasingly grown and manufactured in countries other than our own, and we heard a lot about this in the prior session. Other countries now supply more than 50 percent of fresh fruit, almost 30 percent of vegetables, over 90 percent of spices, and an estimated 95 percent of seafood eaten by U.S. consumers.

Foods are also being produced and delivered differently. For example, consumers are increasingly ordering products online, taking advantage of new delivery, packaging and communications. And I for one am looking forward to the day when the drones deliver my groceries. So this -- there's a big change in demand. Consumers want different foods too, they want reasons for health and nutrition. Sometimes they just want them because they like them because that's what they want to eat. So, each of these changes in choices can have benefits particularly, when they support improved health and nutrition. But each can also prevent potential new or changed risks relating to the safety of the foods.

It's up to the FDA to make sure we have the tools and expertise to effectively evaluate these changes to ensure that food safety remains secure while not stifling innovation or choice. As Frank has stated, we're in the midst of a new revolution in food technology, the advances in science and technology and

a change in trajectory in so many areas of public health, including cancer are also having an enormous impact on food safety and nutrition. This further smooth, safety plan embraces many of these developments. By employing new technologies and gathering more rigorous data and applying it in new ways, this plan will help us to develop new and more effective tools to find more solutions to the challenges we face. This includes accelerating our response time in crises, improving our effectiveness in detecting and preventing outbreaks, and ultimately helping more people and saving more lives.

I should point out that the best available science is not a new approach for the FDA. Since the earliest days of the agency's food safety oversight authority, we've seen advances in science and technology as an important part of what we do. And as a science focused organization we've always embraced and relied on these advances to inform our decisions and fulfill our mission to promote the public health.

To give one example, I call attention to the case of Burton J. Howard, a micro analyst who joined what was then called the Bureau of Chemistry in 1901, a precursor to the FDA. One of the primary goals in the bureau at that time was the use of regulatory science to develop evidence that would hold up in court. Dr. Howard devised a quantifiable method to detect mold in ketchup. And this relied on the cutting edge new technology, back then, of a good tabletop microscope. And thanks to his scientific prowess, the government soon was able to invoke his mold count, to establish consistently, in court, of a products' decomposition and therefore its level of contamination. So it's a big deal, science to make a regulatory decision.

As an agency and as food safety professionals, we will continue to apply scientific diligence and creativity to help determine the most effective ways to apply the most modern technologies and the best tools to protect the public health and facilitate innovation. Fast forward now to the new era smarter food safety, which once again sees the agency applying today's most cutting edge science and technology to this topic, this

is an idea whose time has frankly come. Our foods and veterinary program have already made enormous strides in strengthening food safety protections through the implementation of the landmark FDA Food Safety Modernization Act or FSMA.

And the new era builds on that foundation established by FSMA, and takes the next important steps to address the safety issues involved in our changing world of food production and delivery.

Today's meeting is a critical step in that process. Your presence is super important to those efforts and I want to thank you all for being here. This is how the FDA gets input and learns and becomes a stronger agency. Your ideas will inform and shape this blueprint in the development of smarter food safety tools and processes. I thank you for your engagement and I look forward to your input and have a great meeting.

INTRODUCTION TO BREAKOUT SESSIONS

MS. BARRETT: Wonderful, thank you so much. Alright. So now, we're going to change the dynamic of the meeting. Fairly soon, we're going to move into the active participation phase. As noted in the agenda, after our break, we're going to have four concurrent breakout sessions. They are going to start directly after the break, on time. And they will also be repeated the same for this afternoon. So, you'll essentially have a choice of two of the four to participate in.

Again, the purpose of the breakout sessions is to solicit your input and your ideas. And the four topics is noted and has been discussed, we have the tech-enabled traceability and food borne outbreak response; smarter tools and approaches for prevention; new business models and retail monetization; and food safety culture.

And again, as noted in the meeting materials, today's breakout session dialogue is going to further inform the FDA new era of smarter food safety blueprint that Frank talked about. And really, it's meant to outline the critical steps to protect public health and keep pace with the ever changing global food supply

chain.

So in the breakout sessions, FDA staff, volunteers, subject matter experts, they're going to facilitate the conversation around the specific questions that the agency posts in the Federal Register notice and again, are included in your meeting materials. We've also shared with you, as has been discussed, the food for thought document. So feel free to raise up and expand on ideas that you see in that document. But we also want you to know you're not constrained by those ideas. These are really breakout sessions. It's an opportunity to brainstorm, as Frank said, it's an opportunity to imagine the possibilities.

So please, when you go into those breakouts, give your energy to them, have that conversation, it's rare that we set aside time to do something like this. So, we really hope you'll take advantage of that opportunity.

The time in those breakouts is limited. So our facilitators will help you move through the conversations. And again, the ideas that you hear, we hope that you will expand on those when you submit comments to the docket as well.

All of the information and logistics about the breakout rooms are again in your folder. If you need any assistance, please do see the folks at the registration desk. And as noted, we are going to keep to our schedule. Just to let you know what's coming up, we have the break, then the breakout sessions. Then we have lunch and then we will come back as a group into this room following lunch. We also, as noted, will have sessions in this room and those will be webcast.

So again, thank you for your active engagement. We look forward to the conversation and we will go ahead and take our break now.

BREAK

MS. BARRETT: Ready for a great afternoon. I see folks coming in. If people can hear me in the hall please do come in. As noted, we want to stay on time. And really excited to have our afternoon session begin. So we are going to jump in. And I think we're right at

12:30. And it's really my great pleasure to welcome Mindy Brashears to the podium.

Mindy serves as the USDA deputy under secretary for Food Safety. And she is going to offer some brief remarks on smart and modern food safety policy. So welcome, Mindy.

FOOD SAFETY POLICIES: SMART AND MODERN

MS. BRASHEARS: Oh, is there a clicker or, okay.

MS. BARRETT: You can say advance slides.

MS. BRASHEARS: Okay. There we go. No wait. Okay, there we go. Oh, they're right here, sorry. Alright, thank you so much for the introduction. And I definitely want to thank Deputy Commissioner Frankie Yiannas for inviting me here to participate in this public meeting. It is so important for us to share ideas on science and technology and innovation. I have known Frank for many years professionally and now it's wonderful to get to work with him in the public sector on food safety. We may have two food safety agencies, but Frank and are committed to working together in building the relationship between USDA and FDA.

So who are we? We -- and I just wanted to touch on this, to distinguish USDA from FDA. USDA in the food safety inspection service is the public health agency responsible for the inspection of meat, poultry and processed egg products. And we do this under several statutes that are listed here. For the sake of time I'm not going to go over all of those, but we oversee meat, poultry and eggs and then FDA overseas basically all the other food products.

So I want dive into really what we have at the heart of the matter, which I called in the title, "Smart in modern policies". I'm using the term smart from Frank's initiative. I appreciate his direction in going in a new era of smart food safety. And we both have modern policies and practices that both agencies are moving toward in order to keep our food supply safe.

I am a scientist. I have spent my entire career in academia. Over 20 years I have been a professor of food safety and public health at Texas

Tech University. And I've studied food safety microbiology. When someone puts data before me I have a very high standard of what I would like to see.

We want sound science and methods and then we have to make wise decisions. And in just a couple minutes I'm going to follow up with that. Earlier today, Frank said, how do we get there using modern vehicles of change? And I think our modern vehicles of change are research, technology and innovation and across our two agencies we're using that.

I want to touch quickly on the -- some of our major policies at the food safety inspection service. We are moving towards modernized inspection, performance standards and consumer education. And I will touch on these quickly. FSIS is rolling out modernized food inspection efforts. The meat -- Federal Meat Inspection Act was enacted in 1906. This morning, Dr. Sharpless mentioned the Bureau of Chemistry back in 1901, where they utilized a microscope to look at molds. Great technology for 1901 visualizing molds and looking at things, but we have moved ahead and as science and technology moves forward we have to move -- allow our policies to move forward as well in order to keep our consumer safe.

So on -- the modernized side in 2014, we implemented modernized poultry inspection. About a month ago, we announced a modernized pork inspection. It will go into effect the first week of December.

These systems are based on 20 years of data and science and I have spent a lot of time reviewing all of the data and science that have informed these policies. I just wanted to mention that we will still have 100 percent ante-mortem and postmortem inspection of all carcasses. And USDA, FSIS will be conducting all the inspection activities. None of that will be conducted in the plant. It will all be done by USDA.

However, we will be focusing resources on HUSB (ph), sanitation, food safety and are different public health measures that actually impact pathogen prevalence.

Another area where we're moving is towards performance standards. Our performance standards have

a tremendous amount of data driving those. We have a baseline prevalence data in all of our species. Currently, we have this for poultry. We will be rolling out beef and pork performance standards soon. And those will be out for public comment, so please comment and give your input on those. The public comment is a very important part of what we do.

And the -- after we establish a baseline, we tie this back to public health goals. So as we change the prevalence of our pathogens in our product, this should be correlated back to the prevalence of illnesses. And we want to see that reduce in line with our Healthy People 2020 soon to be 2030 goals.

And then the third area, and I call this smarter consumer education. To keep in line with our theme today, I'm -- Frank and I are working closely together with FDA and FSIS on the consumer education side. Both of us are very dedicated on the industry side and making sure that what reaches the consumer is as safe as it possibly can be. But we have to empower our consumer to have the knowledge that they need to have to keep their family safe.

Now, USDA has been conducting many research studies and we have found that really our messages are kind of falling flat and we're not getting a behavior change. Earlier today, Frank spoke about that and we actually want educational methods that cause a behavior change. We are partnering with different industries, different media outlets and looking at new and innovative ways to convey the consumer message so that will actually result in a behavior change.

Now, I want to just touch on one last point. And that's applying wisdom to our science and technology and anything that we're given. And being in this role, I have many people that come to me and they'll say, "I have some research" or "I have some data" and it might be a sentence of a result. Well, I'm always going to want the methods to see, if it's really science, if it's really data and research.

We have to make sure we use our minds to make these decisions. So I'm going to use some of our data as a poor example. So this quote up here, please read

the whole slot. This is not a quote. This is not what I'm really saying I want to make that very clear. But what we could say, based on some of the data, that we worked with RTI and NC State University to do this research, we could say and it would be accurate that FSIS funded a study where they use of a video intervention, improved hand washing behavior in research subjects who were preparing raw poultry. That is an accurate statement based on our data.

But this is where we have to be wise and look at the actual data. Here's the actual data. If you'll see, column number one, 1 percent of the participants properly washed their hands. Column number two is our treatment group. A statistically different -- a statistical difference, 5 percent of our participants washed their hands. Now, I could -- we could put this message out and say we did this great research study, taught people how to wash their hands and there is a significant difference, but is this practical? Do we really only want 5 percent of the people washing their hands?

So we have to look at the data and make sure that the one lines -- liners in the information that you're given is actually accurate and then that can correlate into accurate policies in things that make a difference.

There is another thing I want to point out about the -- in the slide. It if you'll notice, in one grade 26 percent did not wash their hands and in the other 32 percent. Well, hand washing I really don't see this as a new innovative technology. It is a basic foundation of public health. We need to get that message out and we need to find new and innovative ways to tell people to wash their hands, because it's very important.

And with that again, I want to thank FDA for having me here. We owe it to our family members, our friends and our colleagues and all consumers to make sure our food is safe. I am a scientist, I'm very passionate about science and data and research. But I'm also a mother and I am a public health educator and I want to make sure that there is safe food on every

plate. Thank you very much.

MS. BARRETT: Okay. Great remarks. Thank you so much. We are now going to move on to our afternoon panel, which is, perspectives on a new era of smarter food safety. So, I want to welcome Melinda Plaisier, who will moderate the panel, as well as all the panelists. So please do come on up.

Melinda is the associate commissioner for Regulatory Affairs in the Office of Regulatory Affairs at FDA. I am going to go ahead and turn this over to you.

PERSPECTIVES ON A NEW ERA OF SMARTER FOOD SAFETY

MS. PLAISIER: Thank you, Kari. And I'm just going to go ahead and get started, while our panel gets settled.

Good afternoon, everyone. I hope you all had a nice lunch and are ready for another round this afternoon. I thought this morning's plenary session was just terrific. And I know that the morning breakout sessions, I sat in on the traceability session, but I'm sure the others were equally interesting and robust.

I think we have started an important public dialogue about the future of food safety and started to identify some common threads of either challenges or opportunities. I always prefer to look at them as opportunities. And the things that I have heard this morning are the importance of transparency and effective communication, the critical importance of trust, better use of data, better use of technology and artificial intelligence or machine learning, the importance of the concept of harmonization or compatibility of technology. And that is -- that is affordable, which I thought was a really interesting comment that came out in the traceability session that it is affordable throughout the food system that is already quite complex. And then lastly, I heard the importance of investing in food culture. And I know that there are other key points, but those were the most salient to me.

You know, I think the success of effectively defining the new era of smarter food safety rests on

our collective ability to truly engage at all points of the food safety system literally from farm facility to table. The members of this panel represent a diverse landscape of stakeholders, government partners, public health advocates and private industry that Frank mentioned this morning. Each panelist brings unique perspectives to what the new era of smarter food safety should encompass and each one of the groups our panelists represent will be critical to our collective success in defining the future state.

On behalf of the FDA's Office of Regulatory Affairs I can say that we are all very excited to be a part of this important initiative. We see this as a natural progression from FDA's program alignment initiative of a few years ago that among other things resulted in the most significant realignment of FDA's field operations in our over 100 year history, where we established exclusive program specialization for operations. We enhanced integration with the programs and across the agency. That effort has truly positioned ORA to be more nimble, adaptable and ready for the future.

When we consider the why of the new era of smarter food safety, it really mirrors the why of program alignment. We realigned in part, to better address as an agency the challenges created by the continuing evolution of science, technology, innovation and globalization. And we realigned knowing that we had FSMA mandates for our food safety work that would be better served by the -- by that reorganization. It has now been over 8 years since FSMA was signed into law in January of 2011. Science, technology, innovation and globalization have continued to evolve. So it's just about time for us to think about how do we evolve along with them so that we stay evergreen and work to stay ahead of the challenges that always come with changing times.

There is another way in which this process is following that, that we used in program alignment and that is adopting the tenet of inclusion. We have to ensure that the people who will live and work through the change are helping to actually design and drive the

change.

The diversity of participants in the food sectors represented here today is impressive. And it is actually quite critical for the collective us to have an effective inclusion and diversity of this process. You heard from Susan this morning that the FDA brainstorming groups, we really worked hard to make those groups diverse. They have expertise in produce science, epidemiology, food law, food policy, outbreak response, informatics, consumer education, data analytics, microbiology, chemistry, regulatory compliance and enforcement and criminal law enforcement. And I'm sure I forgot a few, but they were selected to ensure a rich representation of disciplines across the agency.

And that is what we see here today in the people in this room and those who registered for the webcast. It's also important to note, and I do think Frank mentioned this, this morning, but we are not building this out of whole cloth. We are building on efforts that preceded this effort, FSMA for example, program alignment and the very long and rich history of working on an integrated food safety system.

But now we are going to look at these efforts through a new lens of how emerging technologies and new approaches can enhance our success, reaching our goals more efficiently and doing more to protect public health by harnessing new knowledge. We recognize that food safety is a shared responsibility so we're particularly grateful to this panel of stakeholders. Each of you are leaders in various aspects of the food safety system so we want to hear from you on two overarching themes.

One, what are your thoughts on the critical areas of focus for the new era of smarter food safety? And related to this, what activities do you or others already have underway that represent the direction that we should be heading or what can we learn from your ongoing work? So let's get started. I'll introduce each of you and give you a few minutes to provide some thoughts. And as I introduce you, I'm also going to ask you to cover perhaps another specific point on

these two overarching themes.

So, we're going to start with Dr. Ian Williams. Ian is the Chief Outbreak Response and Prevention branch director of the Division of Foodborne, Waterborne and Environmental Diseases at the National Center for Emerging and Zoonotic Infectious Diseases at the Centers for Disease Control and Prevention. That's a mouthful, Ian.

SPEAKER: That doesn't fit --

MS. PLAISIER: Yeah, exactly. Ian helps coordinate the national network of epidemiologists and other public health officials, who investigate outbreaks of food borne, water borne and other enteric illnesses in the United States. Ian and his colleagues at the CDC work closely with FDA in responding to outbreaks of food borne illness. So Ian, in addition to the two questions, what do you see as being critical to the new era? In particular, how do you see leveraging new and emerging technologies, including work that CDC is already doing, as being helpful to advancing the outbreak response work as part of this initiative? Let me turn this over.

MR. WILLIAMS: Good afternoon and thank you for the invitation to talk to you today. Can I have the next slide, please? So rapid coordinated response to multistate food borne disease, outbreaks can prevent illness and save lives. Such responses require close collaboration, communication and data sharing among local, state and federal agencies. This includes both public health and regulatory officials, who do things like the DNA fingerprinting of specimens from ill persons. Interviewing persons who are part of the outbreak and then tracing back and testing the food that those ill people ate. And then inspecting the establishments and farms where the suspect foods came from.

During a multistate outbreak investigation it's not unusual to have 50 or more state, local and federal agencies involved. Successfully solving these outbreaks requires close collaboration among all of these groups.

Next slide, please. An important gap in

multistate outbreak investigations is the need for an electronic system to integrate information and facilitate communication among partners. This type of systems need to be able to integrate laboratory information and data about the ill persons to generate information like case counts and other descriptive data relating to describing the outbreak in both person, place and time. This information is incredibly critical to generate a hypothesis about the likely source of this outbreak, then to test the hypothesis and then to try to reconstruct how and where contamination is likely to occur in order to prevent it from happening again. These processes have historically been done by e-mail, phone, fax and with databases and spreadsheets that cannot share data among partners.

Next slide, please. Since 2011, CDC has worked with a private sector partner to develop a commercial, off the shelf, secure, web-based system to streamline and coordinate outbreak investigations. This system, managed by CDC is called SEDRIC or the System for Enteric Disease Response, Investigation and Coordination.

SEDRIC focuses on four core capabilities. First, integrating multiple surveillance data sources in real time for investigators. Then visualizing outbreak data rapidly in one place. Providing a secure platform for partner collaboration and managing and serving as a repository for historic surveillance and outbreak data. A short description of SEDRIC can actually be found on the CDC website by using your favorite search engine and typing in SEDRIC with an S as shown on the slide up here and then CDC. So, if you want to know more you can type that in and there's a nice sort of two pager that describes sort of how the system works.

Next slide. But in brief the way this system works is that SEDRIC provides tools that integrate again multiple data streams in real time. These data streams include, PulseNet, which is the national subtyping network of public health and food regulatory agency laboratories, which is coordinated by CDC, the

national antimicrobial resistance monitoring system and the national outbreak reporting system. These data systems are then combined in real time with investigation data from laboratories, epidemiologists, environmental health and regulatory agencies from state, local and federal partners.

Shown on the right side of the slide here, SEDRIC provides outbreak dashboards to view summary data for outbreaks, including demographics of when and where illnesses occurred, maps to visualize the geographic spread of illnesses, including capabilities to view illness distribution over time. And lineless to create and edit list of information about each ill person in an outbreak, including relevant demographic, clinical, laboratory and exposure data.

SEDRIC has successfully managed outbreak investigations with hundreds of cases. It promoted collaboration among investigation partners and helped us quickly to collect the knots to help solve complex outbreak investigations involving contaminated foods from cucumbers to romaine lettuce.

The SEDRIC platform is also providing a model for data integration for systems for other groups at CDC involved in outbreak response and is currently being implemented for the multistate outbreak of lung injury associated with the use of e-cigarettes or vaping.

So going back to Mel's question of what do I think one of the major limitations with a lot of this outbreak investigations really comes down to? We're only as good as the data we have to do the investigation. And one of the challenges, I would say currently, is one of the major focuses of this meeting is traceability continues to be a problem. If -- from the epidemiologist's side, if we suspect that romaine lettuce is causing an outbreak, we need to be able to figure out what romaine lettuce, from where. And in the current traceability system we've been having trouble getting to that, because we want to provide the most precise information to the public so that they can take action to protect their health.

We -- no one in the public health agencies

wants to make a broad-scale recommendation like, don't eat romaine lettuce in the United States. However, unless we have traceability to get us to a point, where we can help protect the public's health in real time, then we're going to be left with having to make those broad-scale recommendations.

So I think some of this is, from my perspective, is giving us the right data so that we can integrate it across all of these other data feeds. So, we can quickly get, when a problem happens, get to what the source is, find that product, get it off the market. But also, figure out what happened so we can keep it from happening again. So with that, I will stop.

MS. PLAISIER: Thank you, Ian. That was terrific and SEDRIC sounds incredibly interesting. I heard loud and clear, sort of, the complexity of outbreak response, the important use of technology, the important use of data, but the quality of data and the importance of the quality of data to essentially have effective traceability.

Next up, is Steve Mandernach. He is the executive director of the Association of Food and Drug Officials, or we fondly refer to it as AFDO, since we love to talk about acronyms.

Steve and AFDO are really critical partners to FDA in our work to implement FSMA and so many other shared public health goals that we work together on. Steve, in addition to the two questions I posed, as we move forward what conversations are taking place at the state and local level that relate to the priorities in the new era of smarter food safety and what do state and local partners see as the critical areas of focus.

MR. MANDERNACH: Well, thank you very much for the opportunity to present on behalf of our state and local partners and the Association of Food and Drug Officials. We're embarking on a very exciting time as partners in the -- in food safety. All of us are partners, not just the regulatory agencies, but industry and consumers, who are represented here on this panel as well. And we've got a lot of exciting things that we can do to enhance on food safety and

make it smarter and better.

I'm going to start with kind of the -- what I almost think is the low hanging fruit here, which is the retail sector. Retail sector is close to the hearts of all of us at the state and local level, because we're the primary custodians of that area. We're primarily the regulators in retail.

The first thing that I want to mention a little bit is outbreak investigations of retail outbreaks. Most recent CDC data from 2017 shows over 50 percent of the outbreaks identified are food service based. That is an area we have to do better at. One example, where AFDO and CDC and I believe nine state partners have been actively working on is taking what we've learned in environmental sampling for manufactured foods, but taking that to the retail level.

When we have a retail outbreak seldom do we have the food available, but we can often truly link that outbreak with the environmental samples. We have to get that skill set in the routines toolbox for our state and local regulators.

Another thing that is absolutely going to be changing in the world of state and local regulators is with the Culture-Independent Diagnostic Tests and whole genome sequencing we are going to find more outbreaks at that level. Often what was considered background will no longer be background, but will be identified as outbreaks. So we have to get our abilities at the state and local level even better when it comes to investigating those.

The second thing I would say is we have a wealth of information across this country from inspectional findings of these agencies. There are probably some people in this room that have access to 80, 90 or near 100 percent of the inspectional findings across the country. Imagine if we use that data to identify the common challenges? We might see brand A has this problem, why aren't we identifying that and working on correcting that potential food borne illness risk factor? Just imagine how much impact we could have, if we could use some of that data that's already

currently available. So that's something I would say from a technological perspective we need to start thinking about.

Lastly in the retail sector, we need to rethink the dividing lines. Retail has changed a great deal. Perhaps our traditional dividing lines between manufactured foods and retail foods are no longer appropriate and our regulatory scheme hasn't quite caught up to that concept. So we need to take another look and think about that.

I'm going to move on to a couple other highlight areas that I just want us to think about as we go forward. The first thing is we need to be more prepared to address issues more quickly. It used to be we'd see something start perhaps on the East or West Coast and five to seven years later we would see it in the Midwest. That is no longer the case. Think back to when you first heard about CBD and when you first saw it in your convenience store or where -- or anywhere else, that time frame has greatly shrunk. We as regulators have to figure out a way to address these emerging potential public health issues in a quick fashion, so that they don't, you know, grow outside what we could ever possibly regulate again. So that's a challenge for us to look -- to think about and I think CBD and kratom are just two examples to be thinking about as we go forward.

The other challenge we face is things no longer fit in the traditional boxes. Things aren't necessarily food. They aren't necessarily drugs. They aren't necessarily dietary supplements. They'd crossed the lines all the time now. We have to be more careful about what that looks like and be willing to respond to that in a quick manner even though it might not necessarily be in the right box and it's unclear who has authority. We have to do the right thing for public health.

The last thing I would want to talk a little bit about is how we can be better at inspections and compliance? The first thing is I want to do a shout out to Pew Charitable Trusts on this. They did some amazing work on root cause analysis a few years ago.

And that is one of the things we have to teach our inspectors and investigators in the field, how to be effective at. But that requires a complete retooling of our system. Our investigators have been taught to be fact finders. They have been taught to see something. They observe something, otherwise they can't be on a report.

Root cause analysis is not that. You have to have professional judgment and come to some conclusions that are not necessarily always the fact in front of you. So it's a new set of skills we have to teach our investigators and inspectors in the field.

The other thing, I'm going to just hit on a little bit just very quickly, is, we have to be able to follow up quicker. When we identify a potential problem in a facility, whether it'd be a retailer, a restaurant or a groceries -- a restaurant, grocery store, manufacturer, we have to shorten that follow-up time.

Traditionally at retail, there has been a standard of in many cases two weeks or sometimes a day. Manufactured foods, a lot of times, the standard was 6 months. When we have a known issue in a facility that may cause food borne illness, 6 months is not fast enough. We have to be back and be back quickly.

Another opportunity is recalls. And I talked a lot about recalls. Some of you might have heard a few comments about this. But in these emergency situations of outbreaks and recalls our federal and state agencies need to be aligned. There is no reason that we should approach recalls differently. When we have so many jurisdiction facilities out there, why do we need to confuse them in this emergency situation and have them rethink the system, when we're in that terrible time. That only makes it more difficult for them to respond to this public health crisis at that point. We have to get closer. Traceability follows right along that. If we don't do it at the same we're probably going to have limited success. So we have to get to that point.

The last thing I'm going to hit on is metrics. Traditionally, our inspectional system and I was --

I'll tell you when I built the metrics and performance measures for my state program, I did this too, it was based on inspections. Inspections don't necessarily achieve the public health outcome. What do we need to do in a new era of metrics, and I'm going to argue performance measures that are built into people's performance plans that really promotes this concept of a food safety culture and reducing food borne illness. If we can do that, we can really improve our effectiveness.

Ultimately, all of us are public health advocates. We want to produce safe food for the nation and the world. If we do that well, we have been successful and we will accomplish our goal of having a smarter era of food safety.

(Applause)

MS. PLAISIER: Thank you so much, Steve. So many things that you said really resonated with me from, you know, starting with this regulatory infrastructure still the right one to, you know, how do we think about the definition of food as new things sort of come into whatever, the marketplace that aren't really traditional foods. How do we how do we deal with those. Two, of course, operational efficiency, which is near and dear to my heart and that we have been working very hard on in ORA and I'm seeing Michael Rogers over there nodding, who heads our field operations. You know, it's something that we spend a lot of time on, you know, are we as operationally efficient as we could be, how do we develop those new approaches and then of course the importance of metrics and accountability. So thank you very much for those great comments.

Next, I'd like to invite Sandra Eskin up. She's the Director of the safe food project at the PEW Charitable Trusts. Sandy directs PEW's work on food and dietary supplement safety. And these initiatives engage the federal government, industry leaders and other stakeholders in efforts to reduce health risks from contaminated foods and unsafe supplement products including those that illegally contain pharmaceutical ingredients. Sandy and the PEW Charitable Trusts are

dedicated to protecting public health and had been very important advocates for a more prevention focused food system. So Sandy, in addition to the two questions, what do you see as critical considerations as we continue on the journey that began with FSMA and to now look to enhance our food safety work with the New Era tools and approaches?

MS. ESKIN: Good afternoon. Again, I want to thank the agency for having this meeting, for the thinking they've done, the thinking they're doing now and the thinking they're going to be doing in the future on how to have a more effective food safety oversight system and if -- and food industry. I want to just take the obvious, which is what does smarter mean in this context. And I think it means more effective, that we're doing a better job, all of us in reducing contamination and in reducing the burden of food borne illness. That may involve some shiny new technologies and it may just involve probably some lower tech, but no less important tools.

So I'm going focus on those in my remarks. I wrote them as I was reading the food for thought document. I think everybody has that in their materials. So I would put, sorry, as number one, food safety culture. It wasn't put first in the document. It doesn't mean it isn't important, we have one of the world's experts on the subject here and at FDA, I think that underpins everything and I think our ability to use an expert, take advantage of an expert like Frank and also to consult with other experts. I urge the agency to do that. I think Dr. Brashears talked about communication and messaging. I think that it is so critical that any messages that are directed to consumers in particular, are tested on consumers because I think many of us, myself included, who've worked in the area, it's not my expertise, but I think I've learned a lot. But there's a lot I always learn when I talked to experts.

And let's go back to messaging for the people who grow our food and manufacture our food. I'm going to point to a tool that I think has been very effective and I hope everyone will go look at the Leafy Green's

marketing agreement website. They did a video, a training video with two victims, a young woman and a younger girl who had been sickened by contaminated greens and talk about motivating, talk about incentivizing, when you see real people who've been hurt, it's very, very powerful.

So two, smarter tools and approaches. Root cause analysis, I'll mention it. Thank you Steve for the shout out. My colleague, Karin Hoelzer, who has led our effort at PEW, we are putting together a guide for hopefully anybody who wants to do root cause analysis in the food industry, government, private, whatever, can find it helpful and useful. Obviously if you're a smaller entity, it may be more of a challenge. But I hope the agency thinks about ways that they can encourage and reach out to and help smaller and midsized companies that want to do the right thing. They figure out if there's an outbreak working with the public health authorities, what made people sick. But the next question is the one that does have a huge impact for prevention. How did that particular product get contaminated? Sometimes it's pretty straightforward and a lot of times it's not, but this is the kind of tool that can really, really lead to significant improvement in terms of food safety.

The document, the food for thought document talks about third party audits as a tool. And we know not only in the food industry, but many industries use them in lieu of government regulation to complement regulation. And I guess my view has always been that anything that can help improve food safety, I want to support. From a consumer public health advocate view, the thing that makes me pause here is that the whole industry is built on private contracts. That's not a bad thing. It just means that there's no accountability to individual consumers. And there's really no transparency. At the very least, if FDA wants to use these third party audits in their oversight, and I've said this at numerous FSMA hearings, they need to figure out a way to make them at least as transparent as an inspection that they do.

And the other thing, there is a conversation

in the food for thought document about inspections and component inspections and how can we change inspections. Inspection and always been a foundational consumer protection. Whatever the agency does in terms of modifying or changing inspection, I think it's critical and many agree with me that product testing, environmental testing has to be increased, amplified in a way that presents a picture that can tell us what's going on in a field, in a facility.

Okay. Obviously traceability is critical, and it's a real gap in our current system. And I know that the agency is very focused on the consent agreement that requires them to develop the high risk food list and enhanced record keeping. I believe and many people as well believe that they need to do something now. And that something is provide guidance to the industry. What are those key data elements? Frank mentioned that this morning, what are best practices? Obviously, there are legal limitations, but I also like to think there are legal authorities. A guidance document would be hugely helpful. We had a meeting last year with a broad range of stakeholders on traceability, the need for some guidance on key data elements was the key piece of information that people wanted. And I don't think FDA has to wait for this because of this separate proceeding, doesn't need to finish, it can be done now.

And then, finally, I want to note back to my beginning and talking about lower tech solutions, lower tech tools is that we developed with a number of stakeholders something called the supply chain consultative process. That's what we called it. And what that was that we were at a meeting to talk about how to improve outbreak response, how to kind of get things moving and there was an identification that a lot of times CDC doesn't communicate with experts in the food industry, be it produce, be it manufactured foods and that that information early on in an investigation when they have multiple hypotheses, they're not quite sure what the -- which food it is. Information about distribution change, about growing seasons can really make a difference. And it's a process obviously, but we tried to set it up as a model

of how that could work. And that's a great example of perhaps something that's more low tech.

I'm going to close with a cartoon. If you could go to the next slide, please. I know the size of the computer screen shows you its rather dated, but I believe the message is quite clear. We know that humans aren't perfect. But we also have to remember that whatever technology we use, it's not perfect either. So thank you.

(Applause)

MS. PLAISIER: Thank you so much, Sandy. You raise so many good points. So one of my big takeaways was how do we turn effective outbreak response, having the data through root cause analysis into prevention, effective prevention activities, I mean, you had many other really good points, but that one really resonated with me.

Next, I'd like to invite Carletta Ooton to this -- to the podium. She is the Vice President for Safety, Sustainability, Security & Compliance at Amazon. Carletta oversees Amazon's food safety, trade services, product safety and recalls, customer packaging experience, social responsibility, energy and environment, sustainability, science and global security teams worldwide, you've got a huge portfolio. Her responsibilities include establishing global standards and policies, managing emerging issues, developing and deploying global programs and ensuring effective risk identification and mitigation worldwide. She has been actively involved with industry and government collaboration across many of her areas of responsibility.

So Carletta same two questions to you. I know that you're on the front lines of change at Amazon, you're selling, you know, more food products every day, both online and in grocery stores. Could you share your perspectives on the New Era, including what new tools that Amazon is using to address concerns about food safety and inform risk management?

MS. OOTON: Thank you very much. We're super excited at Amazon to be here, to be part of the New Era of smarter food safety. And hopefully, Mel, I'll get

to the questions.

MS. PLAISIER: Sure.

MS. OOTON: With the slides I'm going to cover. Can you switch to slide one, please? Okay. At a high level, I would say what my teams do is very similar to what other teams in industry do. We develop policies and assessment programs. We risk categorize products looking for high risk particularly. And we put in place proactive mechanisms so that we can actually mitigate the risks. So I think that's pretty standard.

For us, though, when we think about the mechanisms, we actually think about our mechanisms in four buckets. And you'll see them across the bottom of the slide. First, detection and identification of both customer signals and regulatory notifications, investigation and continuous monitoring, remediation and enforcement such as recalls execution and in supply chain processes including traceability. Specifically today though, I want to cover something that we call CFM, Customer Feedback Monitoring, which for us is an issue detection mechanism and something that we think is critically important as it provides the training data for our state-of-the-art machine learning models that we use at Amazon.

So let's take a look at the next slide. So I'm going to walk you through this and when I get through how it works, then I'm going to try to share some numbers to kind of bring it to life for you. So in the backdrop of customer feedback monitoring at Amazon, you need to understand sort of the size of what we're working with. On average in a given week, we get 22 million pieces of customer feedback. A couple of examples of customer feedback that we get would be, if you call and talk to a customer service agent for example. But hopefully some of you are Amazon customers here in the audience, have any of you written a product review ever or read them, right? Okay. That would be another source of customer feedback and part of that universe of 22 million pieces of feedback we get.

So we do a couple of different things as we

dig into that data and those 22 million pieces of information. First of all, we use some keyword based rules classification. Some of you probably do something very similar. We have subject matter experts that identify words that we use and we run against this feedback. So a super simple example would be vomiting, right? Or maybe the word sick, and I'll explain why I used the word sick here in just a minute. But in addition to keyword based rules, we actually have some machine learning models that we run. And so I want to dig into those a little bit more. We use natural language processing, and we use it to actually dig into the context of what we are learning in the feedback. Things like sentiment, right? Things like sentence structure. And it's really important because if we use the example sick, a customer might say, this product made me feel sick, right? I want to know that. But the customer also might tell me, hey, this product is sick. That could be my teenage daughter. But that would mean the product is really cool, right? And I don't want to push that, I don't want to send that to an investigation. But that kind of ability to detect sentiment and get into the, what the customer is really telling us is vitally important, particularly again against that backdrop of 22 million pieces of feedback.

What we're able to do is make a determination with the machines, if there's a potential safety issue or a non-safety issue, right, and we're able to do some very early manual reviews. Behind our machines are hundreds of food safety experts around the world working 24X7, interesting, the machines are working 24X7 too, but our people are because they're all around the world working different time zones. And they're able to further delineate whether or not we have an issue or a non-issue, which then drives us to something I think many of you would understand, which is really the true investigation process, where we have deep subject matter experts that are pulling and looking at documents, talking to manufacturers and really digging into understand what's going on. Here what is interesting is that because we're using the machines and we're doing this rapid manual review with humans in

the middle, we're able to compress the time from identification or potential identification to actual investigation down to below a day in some cases. So very, very rapid.

The other thing that's interesting is we're able to do this across multiple languages. Right now we're using our ML models at a localized form in nine different languages. And then for about 11 other languages, taking us up to a total of 20, we're able to translate back to English and run those against our English based models. The interesting thing about translation in this case is it isn't big deal like it is for readability. It really does inform the ML model and allow us to find these types of issues because of stem words.

So back to the numbers, 22 million coming in. Since we've been running these models, we've identified a potential of 250,000 safety issues of which about 120,000 of those are food -- were food safety issues. We were able to drive that down further using manual review to get to a place where we were investigating at a core level 20,000 cases. But remember what I said early and that was that that information from those investigations and the -- what wasn't investigated is really important because it feeds and fuels our training models, making them much more probable of finding the issues because they become more smart. We've been able to identify 16,000 products and take them down off of our side, where we had never had a single customer comment or review about them. But that's the power of ML and the power of the models to help us find things, predict issues and take rapid actions on behalf of the customers before the customer has to experience an issue.

So again, a little bit of a use case hopefully addressing the question about how to use technology or how at least Amazon's using technology. Thank you.

(Applause)

MS. PLAISIER: Thank you so much, Carletta. My head is spinning thinking about all we could learn from that customer feedback monitoring and, you know, the use of AI and really helping to mitigate risks. So

thank you very much for that.

Our last, certainly last, but not least speaker on our panel is Natalie Dyenson, she is the Vice President of Food Safety & Quality at the Dole Food Company and is also in the vanguard of change with Dole's early embrace of traceability of foods. Natalie's based at the Dole Nutrition Institute Campus in Kannapolis, North Carolina. And has responsibility for food safety and quality programs globally. Before joining Dole, she spent 8 years at Walmart most recently leading food safety across 6,500 retail stores, 48 company-owned manufacturing facilities, 48 -- I already said 48, and 220 fresh distribution centers in 26 countries for Walmart's international division.

So as you've heard earlier today, traceability is certainly one of our key areas of focus for this initiative. So Natalie, for you as well, in addition to the questions, what are your thoughts on the New Era of smarter food safety? And in particular, could you help us gain some insights on how Dole decided to commit to investing in these tools? And what lessons you have learned from advancing a system of traceability right down to the farm level?

MS. DYENSON: Thank you, Mel. Thank you to Deputy Commissioner Yiannas allowing me to be here. And we've heard a lot of things about romaine this morning. So I kind of feel I'm coming up here with the target on me. But, Sharon, I know you've got my back, right? So I just want to talk to you a little bit about kind of the journey that we've been on. In July of 2017, Dole started its blockchain journey by becoming part of a group of about 10 multinational companies that were brought together to really evaluate and define how blockchain could be used for the food industry. We recognized the transformative potential of this technology and we felt it important to step up as a leader in the food industry to see what this potential transformation could be and how traceability and that transparency could actually help us drive improvement in our processes, but more importantly, protect consumers and protect our customer's brands and protect our brands.

Blockchain is a journey. There's no one provider that will be the silver bullet for the industry. But over the last two years, we've learned that there really is a lot of potential that is in the system and I'll talk a little bit about that in a little bit. We have a significant number of retailers that are on the system now. We are fully live to the blockchain with information going every single day, multiple times a day. We have end to end traceability now. We've always had traceability all the way back to the farm, to the grower, to the lot in the farm, where the product was harvested. But instead of us taking hours or days to get out that information, we can now do it in a matter of seconds. It takes a little bit longer than 2.2 seconds, Frank, because we have a lot more data to go through. But it is still less than 10 seconds, which is important. We now have end to end, as I mentioned, with those customers that have implemented blockchain. But even for those customers who haven't, we still have a lot more access to the information a lot faster than we did even before. So even for those companies who choose not to take that down to the retail level, we can still get out the data faster, and they actually benefit from it as well.

We have -- I can't see without my glasses on. Oh, we also have, you know, the ability not just to trace product and where it came from. But one of the things that's complicated when you look at bagged salads and kits, there's a lot of different ingredient components that are in there. And we can actually now with this system, if we identify that there's a particular lot in question, we can very easily and just as fast, go ahead and trace forward and look at all of those other products that that material may have been in. And that's important because when -- as an epidemiologist myself, and in talking with Ian, the faster you can get the product off the shelf, the better it is. And I really think that this technology does a lot to help advance public health. So Deputy Commission -- I can't say that, I'm sorry, Frank. I worked for him for a little while, so.

So Frank mentioned 2018 was a tough year for

the romaine industry. And there are estimates that the advisories people call them recalls, I always correct that -- that the advisories actually cost the produce industry upwards of 100 million dollars and probably more. There were millions, if not billions, of pounds of perfectly good product that was sent to the landfill and went to waste. So not only is that a food waste problem, but that now becomes an environmental sustainability problem because all that decaying lettuce creates greenhouse gases.

One of the things that we also found is that every grower, processor, shipper, everybody was considered guilty until proven innocent. And that as the produce industry, we either succeed together or we fail together. And I speak with a lot of my peers and colleagues in the industry on a regular basis. And we all recognize that there is a need to do whatever we can do to help begin to repair consumer trust. Because estimates or there's research that has shown that even today bagged salads and salad, romaine, lettuce sales aren't exactly where they were before the two incidents in 2018.

So this solution is something that did require investment by Dole, but I think the investment required was negligible compared to the benefit that we're getting from the system. And someone mentioned earlier that you can't measure prevention and that's absolutely right. And we've actually approached this as a system that is an insurance policy, it's not going to guarantee that we won't have an issue, but it will guarantee, if we do have an issue, we can get it at the source as quickly as possible and mitigate the damage, not just to our brand, but to the industry's brand and most importantly protect consumers. The business ROI, in addition, has gone well beyond just the food safety aspect of it.

In fact it's interesting to see how it has evolved within the company because as we started compiling this data and digitizing it, so we had access to all the data in one place. Our business leaders started to see, oh, wow, there are inefficiencies here or there might be issues within our supply chain that

they then could address to make us a more efficient and nimble company. And that snowball keeps getting bigger and bigger and bigger.

The last thing I think I'll mention is that interoperability is going to be key and we've heard several comments on that. And I can't stress that enough. Sharon Wood actually from HEB mentioned earlier that her suppliers are faced with having to use multiple systems. She's absolutely right. Right now my team has to upload the same food safety audit into 23 different systems. That's a huge resource drain. That's an issue where my team can't spend time doing root cause analysis and other things that they should be doing because they're doing clerical work. Now don't get me wrong. We do all of that, but they just work longer hours.

So the interoperability is going to be key. This hasn't cost our growers anything. We've leveraged the PTI labels. So the PTI labels that all of them implemented almost a decade ago are what we used to collect the information. So our growers haven't seen an impact from this. And we feel that if we continue to use global standards like that, and we create this interoperability where systems can talk together, we should be able to then increase the transparency, help contribute to the smarter era food safety and most of all protect consumer health.

(Applause)

MS. PLAISIER: Thank you so much, Natalie. I wish we could all learn a lot from the best practices and how you built up to a fully live blockchain and end-to-end traceability. I hope we have time to carry for at least one. Okay. So -- thank you so much. One question I'd like to pose to the panel. So many great ideas and there're so many questions I want to ask you, but I'm going to just do one and it was something that Julie Pierce said this morning that really resonated with me. And that was sort of your charge Julie to how do we start now by using what you termed small data, I interpreted that as like the wealth of data that we already have at our fingertips. And we certainly heard from many of our panelists in their remarks about sort

of pockets of data that are already in existence that we could be making better use of. So, you know, whoever wants to go first, but I'd love to hear from you. How can we start now by better using the data that we already have?

MR. MANDERNACH: I'm going to give a real world example. So when I was running the state program in Iowa, we got to the point where we could do brand analysis. So we could look across the various brands in the retail sector and see where we saw commonality. We found that one of the brands had changed their preparation method of ground beef product. And all of the sudden we kept seeing cooking issues, temperature issues were coming. And we saw this across this very short period of time, 6 months, we could just see this spike, something that happened, we didn't exactly know what. We sat down with the brand and they realized, oh, we apparently had a training gap here when we did this new thing and we didn't teach well enough.

Now think of undercooking brown beef and all of the people that were eating that and the potential for illness there. That's one example of where if we had used the data across the country, we probably would have identified it in days or weeks versus six months for me to have enough data to realize this upward spiral had happened. Those are real things that we can do in a quick, relatively real time basis today that we couldn't have done 5 years ago.

MS. OOTON: Yeah, one thing I would suggest that we think about is the current reporting. A lot of us provide a lot of information. I'm not convinced that we use all that information because we have no way to consume it. One of the things I would think would be super helpful is by a small investment in machine learning science, very different than software development engineering, which is consuming and you have to have, you know, sometimes 10s, 20, 100s, a couple of machine learning science to kind of actually go at a problem like that, and help consume and parse data to a point that we can use the data more effectively. And if we're collecting data and we're not using it, it's not helping anybody. And so I would

collect less, but collect the right stuff and put some real smart folks at how do we then take actions on it. That would just be a super simple answer.

MS. DYENSON: Yeah, and I'll build on that. Because I think when you said collect the right data is really important. And I think this is where industry and regulatory can work together to define what are those key data elements that everybody should be collecting so that as we move forward and work on interoperability and exchange of data, work, you know, exchanging and comparing apples to apples instead of apples to bananas.

MR. WILLIAMS: So maybe a comment for me is you have to start. I think that's what we've learned I think with our system is we've been at this for a while and you can't let perfect be the enemy of good, you have to start and start collecting data and figure out where the gaps are in the system and really build a system. And I think that we have a lot of the good pieces in place, a lot of its stitching it together, figuring out where the gaps are and then again pushing it. And I think going back to some of the comments and traceability is, we've heard this over and over again. We do a pretty good job in the middle, we don't do a very good job actually at the terminally or what I call the last mile because that's where I start, that's you interview a person that said, I hated at this grocery store. Okay. What came out of that grocery store, being able to trace that back, if you can get back to the distribution center, it generally works beautiful. But it's again figuring out how to stitch those pieces together and really taking a systems approach is a lot of this. And you can't wait to have the perfect system. You've got to start and then figure out where the gaps are in the system and then improve that as you go. And I think we can build a really great system. We have a good system, but we can make much better.

MS. ESKIN: I was going to add one point to that. I don't know right now what the status is, is there a group of people at FDA that are specifically looking at all the data that's collected kind of like an audit, figure out what's there. And then they could

be doing this already. So that's a good thing or more do pilots, you know, sort of try to figure out, kind of get started, you know, and then take the training wheels off once you get riding. It seems like again, if the assumption is they've got a lot of data, let's see what they can do.

MS. PLAISIER: Thank you so much to the entire panel. I wish we had, you know, another half an hour. I've got so many questions I'd like to ask all of you. But let me just say, on behalf of the agency, thank you so very much for taking the time to participate in this incredibly important dialogue that is only going to continue and get better. Thanks, everyone.

(Applause)

MS. BARRETT: Alright. Well, I'm really here just to announce the break, but I can see many of you have already started. So that's great. We are going to have a 10-minute break till 1:45 and then please go directly to your breakout session. And we'll meet back in this room promptly at 2:30. So thank you and have a great conversation and the next round of breakouts.

BREAK

MS. BARRETT: Again, I know with our really tight schedule, it has been hard to maneuver everybody. But I do want to welcome you back.

And while we're still getting settled, I did want to address one thing that somebody had mentioned to me and I think it's worth just speaking about quickly. There was a question of for the breakout dialogue, would that be used by the FDA staff as they consider the development of the blueprint? And of course it will be. We are and have transcribed all of the breakout conversations for that purpose so that our staff can go through that and to look at those ideas and spend time on that. So please be assured that everything that you've shared today will be considered as we move forward.

The other thing is, I just want to say too, it has really been impressive, the amount of conversation heard. I know we went really quickly. So again, just to encourage people, if you didn't have the opportunity to share what you wanted today in the breakout session,

please do get those comments into the docket by November 20th.

OPEN PUBLIC COMMENT

MS. BARRETT: So with that we're going to jump into our public comment portion of the afternoon. This is where folks have signed up to offer their comments in advance. And I'll talk about the process in just a moment. But I do want to note, the FDA panel who was sitting here to listen to the public comment. I think many of you have seen these folks. They've been really busy being facilitators in most part. But we do have Michael Rogers, he's our Assistant Commissioner for Human and Animal Food Operations, Office of Regulatory Affairs. They want to welcome your participation here, Michael. Glenda Lewis, Director Retail Food Protection Staff at CFSAN. Kari Irvin, Deputy Director, Coordinated Outbreak Response and Evaluation (CORE) Network at CFSAN. Sharon Mayl, our Senior Advisor for Policy, Office of Food Policy and Response. And Chris Waldrop, our Senior Public Health Educator, Division of Public Health, Informatics and Analytics at CFSAN. So thank you for your time today as we listen --

(Applause)

MS. BARRETT: -- to the comment that's offered.

So we do have a large number of folks who are signed up to give public comment today. And each one has been allocated 3 minutes. I know that's not a lot of time. But we are going to ask you to stick to those 3 minutes. We do have someone here on our staff to assist; Larry, if you'll just raise your hand. Larry is sitting next to the podium where public comment will be offered. And if we're at 3 minutes, he's going to just sort of gently flash you a sign of wrap up. So again, you know, really it is so that we can get everybody the opportunity, you know, to give their comment and just appreciate that in advance that you'll be mindful of that.

When you do come to the podium, and what I'll do is I'll work through the list that I have with those who have signed up. It may be a little different than the list that you've seen, sometimes we have changes

during the day. So I'll work with what's given to me as most current. I'll call your name and if you'll come to the podium. And then if you will repeat your name and affiliation for the official record, that would be appreciated. And we'll go from there.

Also if you can please be in a seat if you're giving comment where it's sort of easy for you to get in and out, that's also appreciated. But I know it's a full house and that may be a little bit more challenging today.

So with that we are going to begin, and our first speaker is Sarah Sorscher. She's with the Center for Science in the Public Interest, Sarah.

MS. SORSCHER: Alright. Thank you. So I'm Sarah Sorscher, I'm Center for Science in the Public Interest. We are America's food and health watchdog. We represent the interests of consumers and ensuring a safe and healthy food system. And I have no financial conflicts of interest to declare.

We really appreciate today's meeting and the opportunity to think big and considering New Era of food safety. A key question that we have for this effort is how can the FDA using its existing authorities and potential new regulatory tools to promote progress on smarter food safety.

And while the Food Safety Modernization Act is now more than 8 years old, the agency is still generating new strategies and approaches to implementing that authority under the Act. For example, we were encouraged this year to see the agency issue its first warning letters under the Foreign Supplier Verification Rule including a letter threatening debarment for one importer that had refused, not only refused to conduct a requested recall, but also had a repeated pattern of importing adulterated food. You know, we talked a lot about food safety culture today. And I can't think of a better way to promote food safety culture than by making an example of a company that doesn't have that culture. So these are encouraging steps.

At the same time, FDA has yet to deploy additional authorities under FSMA, key among these are

the long delayed water testing requirements of the Produce Safety rule. CSPI has encouraged the agency to press forward with these provisions without additional delay. Yet compliance with the water testing standards should not create a false sense of security for produce growers. This is because as we saw from the romaine outbreak in Yuma, water may meet the testing standard, yet still pose serious safety risks. And so we think it's FDA's duty to think more deeply about this and consider additional steps that could be used to ensure that produce growers are assessing and controlling risks, particularly serious risks that are related to untreated surface water which has caused, posed repeated problems.

The agency should also develop and deploy regulations for traceability under FSMA. We are living in a data driven age and yet many businesses are still failing to invest in recordkeeping systems, to collect and retain data that's already available throughout the supply chain. This leads to dangerous delays and outbreak tracing, which has tremendous costs for both industry and consumers. We're heartened to see the agency's commitment to moving forward with section 204 and encourage FDA to provide also guidance for industry in the meantime, so that they can begin investing in modernized record keeping systems. At the same time we're concerned that the existing law fails to provide sufficient authority for the agency to require true farm to fork traceability. And so we believe Congress should expand the agency's authority so that FDA can require tracing of high priority foods from the point of sale back to the point of origin.

Finally, we also want to encourage the agency to look beyond FSMA and think creatively about applying some of its classic regulatory tools to new food safety problems. Congress long ago charged FDA with approving new food additives. And CSPI has urged FDA to use that authority to give adequate pre-market review and define conditions of use for CBD products.

So we appreciate this opportunity for comment. And before Larry pushes me off, we hope this meeting leads to a good framework. Thanks.

MS. BARRETT: Okay. Thank you very much for your comments. Our next speaker is Betsy Booren, the Grocery Manufacturers Association.

MS. BOOREN: Good afternoon. I'm Betsy Booren, I represent GMA which represents the world's leading consumer packaged goods companies. The CPG industry plays a unique role as a single largest U.S. manufacturer employment sector delivering good -- products that are vital to the wellbeing of people's lives every day.

GMA advocates for rational and form uniform regulatory frameworks that are based in risk-based science, promote choice and builds consumer trust across the sectors we represent from household products to food and beverage. GMA has been a long supporter of FSMA, and continues to work with FDA and stakeholders to implement the law. We support updating federal regulatory frameworks that permit new products that consumers demand and trust while protecting public health.

We are pleased today to understand that the concepts being discussed today will complement these ongoing FSMA efforts. We want to go and say that we support ardently that FDA is granted the resources both from staff and infrastructure necessary to ensure that all of the seven foundational FSMA laws as can be practically implemented as well as other activities like the ones discussed today that are critical to meeting FDA's public health mission. In addition, we support FDA strengthening its predictive capabilities and preparing for the technology advancements that industry is already working on while also addressing the evolving business market.

A food safety system built on risk-based principles for efficient and effective product traceability can always be improved. Our industry is constantly bettering the mechanism for rapidly removing adulterated products from the marketplace, investing in innovative technologies to assist in their ability to produce safe and wholesome products. But we recognize the need for the speed of outbreak response and make existing processes more effective and efficient is

critically needed in these areas. And we can give you one simple recommendation that we brought earlier in one of our groups of how to do this. And that would be to have FDA increase the frequency in which they update stakeholders on ongoing food borne watches and investigations. These forms can provide vital information when the agency captures signals of potential emerging issues. And this may help expedite both industry and regulators' response to these food safety events.

We will be developing written comments following this meeting, including discussing the flexibility of using digital disclosure platforms and providing information to consumers on the type of information they want about products. We thank you for this opportunity. We applaud you for holding this public meeting as a first step of a transparent process. It's only with this transparent process that effective and durable regulation frameworks will be developed. Thank you.

MS. BARRETT: Okay. Thank you very much. Jaydee Hanson, Center for Food Safety.

MR. HANSON: I'm Jaydee Hanson. I'm Policy Director at Center for Food Safety, the nonprofit one, not the one connected to the FDA. I have no financial conflict of interest to report.

Some of this is as Yogi Berra once said, deja vu all over again. The basic food safety stuff is really things we've heard for a while. Our organization has long argued that there needs to be one food safety agency, not a drug agency that does food or an animal protection agency that does food safety on the side. So we see that there are aspects of things that USDA regulates that needs to be better tied into what you all regulate.

There are 1500 CAFOs, Concentrated Agricultural Feeding Operations, in the U.S. There are 800 slaughterhouses in the U.S. These are huge sources of pathogens that are of concern to you all. In the produce area, just saying, don't locate your produce operation near one of these facilities is next to impossible. So we've got to stop it in the CAFO.

We've got it stop it in the meatpacking plant.

And one of the places we'll get advanced notice is through the work of another agency that's not here, the Labor Department. The workers are the first to get sick. In the Central Valley of California where I'm from, the workers speak Arabic, Haitian Creole, varieties of Spanish, Mayan. We need to understand that those workers we talked today in one of the talks about Gen X being people of color. Those workers already are almost all people of color. And so it is a kind of institutionalized racism that they're getting sick and we're not doing enough about it. I'll stop there on that point.

In the new stuff, today we gave the FDA letters asking you to take action on companies that are -- groceries that are selling the impossible burger. We had filed a challenge to the FDA's approval of that. And it is our opinion that the soy heme that's genetically engineered is an illegal food colorant until our questions to the agency have been resolved. And thank you all very much.

MS. BARRETT: Okay. Thank you for your comment. Our next speaker is Angela Fernandez, GS1.

MS. FERNANDEZ: Good afternoon, Angela Fernandez with GS1 U.S. Thank you for the opportunity to provide comments here today, talking about the New Era of Smarter Food Safety. GS1 is a neutral Global Identification Standards Organization that enables the digital and physical flow of data across food, food service and retail supply networks for almost 50 years in 150 different countries. We work with industry to develop and implement globally recognized and operable standards that are consistent with OMB circular A-119. If this is your first time to hear about our organization, be rest assured, if you're just in your local grocery store at checkout with our very first standard, the UPC barcode.

I'm here to inform you that traceability is possible today by leveraging GS1 standards. It requires thinking and acting more purposefully. It requires effectively leveraging data and technologies to reduce food safety incidences. And it requires a

culture of food safety developed from the top down. It requires new business models that are focused on collaboration and efficiencies. GS1 standards enable key data elements, products locations, lab batch, serials numbers, vital product dates that link customers, suppliers, retailers and consumers for farm to fork traceability. In essence GS1 is already at work with many organizations in this room today as well as the agency.

Our standards are highlighting the IFT report funded by the agency under FSMA, as well as other traceability efforts that were mentioned earlier today. The Produce Traceability initiative, the Global Dialogue on Seafood for Traceability and of course, GS1 U.S. member programs that we have inside of our retail and food service. And there's been a lot of talk around ROI. And there is ROI that can be found in the use of global identification and data standards. Some of them that have been realized is Frontera Produce, who reduced the scope of a recall from 100 to 12 percent. IPC Subway was able to reduce 9300 hours of label -- labor, excuse me, and prevented 11 food quality incidences in a single year. And Beaver Street Fisheries reduced product shipping errors from 27 to 1 percent, just to name a few. Like many of you, GS1 has seen these transformations on the horizon and working with the industry developed a global standard for food traceability. This standard has been used in the United States and globally for over a decade.

It incorporates key data elements that we've been discussing today, is based upon the Codex, the guidelines for hygiene, HASP and food traceability and is based upon ISO Standards for Food Safety Management System.

In closing, Smarter Food Safety requires a common language and a common standard, the ability to move forward collectively and to reduce marketplace redundancies and leverage our investments to extend the use of global standards to enhance processes and utilize new technologies. That language is GS1, the global language of business and we're leading the way with industry. Thank you.

MS. BARRETT: Thank you for your remarks. Our next speaker is Maria Palombini, IEEE Standards Association. Maria? Okay. We'll move on. Darin Detwiler, Northeastern University.

MR. DETWILER: Thank you. I'm Dr. Darin Detwiler from Northeastern University. As a professor of food policy, I now teach graduate students who are born after the landmark 1993 Jack in the Box E. coli outbreak. They're very much the Generation Z described by Dr. Wagner earlier this morning. In the era since then, the food industry has embraced a food safety culture, Described BY some as a change in the farm to fork beliefs, practices and values behind combating food borne illness. Food safety regulations are still being modernized, while new technologies offer promises for enhanced traceability and transparency.

During the same time, however, consumers have been continuously bombarded with evidence of the seemingly uninterrupted cycle of crisis and reform. They -- we witnessed the growing variety of contaminated foods, new ways in which foods become contaminated, unpredicted causes for failures in food safety mitigation and the addition of thousands of families each year who will live with a chair forever empty at their dinner tables. Unlike most of us, my graduate students grew up with words and phrases such as E. coli, food borne pathogen, multistate outbreak and recall as part of their social media feeds, Instagram posts, viral videos and even memes. They develop skill sets and confidence with digital tools and technology platforms that we are only now exploring for use in the food industry.

What should we call these future food leaders and -- food industry workers and leaders? The most useful definition I have found for them is food safety cultures next generation. As they are native speakers of the culture having been born into the modern era of legal, economic, political, technological and social aspects of food safety. So what does that make the rest of us who were not born into this culture of food safety? As it came about, at some point later in our lives and careers, perhaps we are food safety cultures

founders. The important of this distinction is this. The food safety cultures founders may not share the fluency of digital tools like artificial intelligence, blockchain and predictive analytics that this first -- that this next generation has acquired through their years of interaction and practice. However, in an industry bursting with big data, members of this next generation stand to benefit from the founder's knowledge and experience of the true burden of disease as well as compliance challenges before and throughout the previous era of change in food safety. With all the discussion of artificial intelligence in this new FDA blueprint, failure to incorporate ethics and a better understanding of the human condition will not support the effective and sustained efforts to promote food safety culture throughout the food system.

As a father who lost his son to E. coli during that landmark 1993 outbreak, I have high expectations for any and all errors of Smarter Food Safety. My son and too many others are part of food safety's last generation. Thank you.

MS. BARRETT: Thank you, Darin. Thank you for being here today. Our next speaker is Karin Hoelzer, the PEW Charitable Trust. Thank you.

MS. HOELZER: Thank you. My name is Karin Hoelzer, I'm with the PEW Charitable Trust. It's a great pleasure to be here today. I really appreciate all the work that has gone into this meeting and in the months and months leading up to it, putting together all the materials. And I really appreciate the conversations that we had today. I think they've been very fruitful. It has given me certainly a lot of food for thought. And I'm looking forward to continuing these conversations over the months to come.

We've already heard from my colleague, Sandra Eskin, earlier today. So I will just very quickly touch on one particular area related to the New Era of food safety. And that's around the use of root cause analysis.

I do see that it is in this plan, which I very much appreciate. However, I'm here because I think it should not be on page 3. It should be on page 1

because it's really underlines the foundation of a preventative food safety system. I really appreciate some of the points that I made in here about the value of root cause analysis, about it being, as I said, a foundation of a function-based food system and being one of those areas that are really ripe for tech innovation.

And I really appreciate the focus on partnership. We've heard a lot about that today as well as the value and standardization, whether that's in approaches or in communications. And I think that's another theme that we've heard loud and clear over and over today in the conversations. As well as the focus on better readiness, understanding that if a food borne outbreak occurs, data can be lost very quickly. So for FDA to be -- to stand ready to be able to go out to the field or the plant or wherever FDA has to go is very important.

So I really appreciate the focus on better readiness, as well as the focus on finding best practices. We at PEW actually have worked for more than 2 years with FDA, CDC, FSIS, state and local partners industry to develop some of these best practices. And we hope to have a guide that outlines some of these best practices come out in the next couple of months. Some of the areas that I wish would have been focused on a bit more in the document, my first, as I said before, elevating it because I think if we don't learn from food borne outbreak, we are just doomed to repeat them. So they -- we really have to focus on root cause analysis.

Then effective root cause analysis, in particular, in other areas, other industries that we at PEW have studied as part of our research, really not only look at what happened and why, but also how to fix it. How can the system be redesigned to avoid recurrence? And I would love to see stronger focus on that part of the root cause analysis. How can we redesign systems so that we don't see the same issue reoccur? And then third, funding, understanding, doing root cause analysis is time and resource intensive. And we want to make sure that there are sufficient

resources available to conduct root cause analysis whenever they are necessary.

Our goal for root cause analysis is to build a resilient food safety system where we can really learn from outbreaks as well as near misses. And I think there's a great opportunity to get there. And today's meeting is certainly an important step in that direction. Thank you.

MS. BARRETT: Thank you for your remarks. Our next speaker is Bryan Hitchcock Institute of Food Technologist.

MR. HITCHCOCK: Good afternoon. I'm Bryan Hitchcock, the Senior Director of Food Chain and the Executive Director of the Global Food Traceability Center at the Institute of Food Technologist. IFT is a nonprofit scientific institute whose mission is to advance the science of food and its applications across the global food system to ensure sustainable, safe and nutritious food for all. Established in 1939, IFT has more than 15,000 individual members in over 100 countries. IFT appreciates the opportunity to provide input on the New Era of Smarter Food Safety. We commend efforts to leverage digital and physical technologies to enhance the safety of the food supply and the efficacy of the food system. IFT has a long history of active engagement in food safety and partnership with the FDA. Key domains of expertise include food safety issues, traceability and food processing to name a few. Over the past 20 years, IFT undertook several FDA task orders, addressing microbial activation kinetics, preventative control measures, evaluation and definition of potentially hazardous foods, allergen related manufacturing and label practices and food defense. Further IFT lead food product tracing pilots for the FDA as required by FSMA section 204 to evaluate methods to improve food traceability and protect public health. IFT define the Key Data Elements, KDEs, and critical tracking events, concepts and drove the development of industry wide traceability frameworks.

Since then we established the Global Food Traceability Center, created and executed domestic and

international traceability pilots through the global dialogue on seafood traceability and delivered effective education, integrating traceability concepts in the food safety. IFT has also been active in other areas such as Codex Alimentarius, Scientific Publications and Roundtables. Key Examples include a whole genome sequencing roundtable, co-sponsored with JIFSAN in 2018, activities addressing antimicrobial resistance and a publication on date labeling which addresses food safety and quality and the advantages of smart packaging.

Evolving food safety is not an option, but an ongoing mandate. Breakthrough technologies are driving digitization of food chains in ecosystems. In our experience, global pre-competitive public private partnerships are key to productive collaborations, driving voluntary standards and best practices for traceability. Combined with interoperability principles, standards can drive efficiencies and scale up adoption. Our experience in the global dialogue with over 70 seafood industry organizations is just one example.

As with the creation of FSMA, education and training on digital technologies will be immensely important. Digital technologies can be intimidating and require new skills. Whether it's producers, processors, quality professionals, retailers or consumers, awareness and new mindsets will be needed. We highly encourage the education and training be given careful consideration.

In conclusion, IFT appreciates the opportunity to participate in this exciting new journey. Consumers are counting on all of us to give them great tasting, nutritious and most importantly safe food. Thank you.

MS. BARRETT: Thank you. Our next speaker is Jonathan Sarager, Western Growers.

MR. SARAGER: Good afternoon. My name is Jonathan Sarager, I'm Director of Federal Government Relations for Western Growers. For those who don't know, it's a trade organization that represents growers and handlers of fresh fruits, nuts and vegetables in California, Arizona, Colorado and New Mexico. Western

Growers members grow and ship more than half the total U.S. output of fresh produce, including more than half of the organic crop. We will also be responding to the request for written comments in detail, but I'm here today to declare interest in and support for New Era of Smarter Food Safety.

In fact Western Growers has been working on and advocating for tools, technologies and culture relating to Smarter Food Safety for several years now. Key elements of a Smarter Food Safety system as we see it are to, one, shift from a snapshot-oriented audit driven food safety system and culture to one in which there is visibility between supply chain partners. Two, to leverage food safety performance data out of discrete company silos and into structures, which can benefit the entire industry in our constant efforts to reduce public illness. Three, to reduce supply chain friction with new risk management tools and four, to drive for higher levels of transparency for consumers.

Our work has been focused on efforts to get food safety information at the farm level, off paper and into a digital format that will allow us to put the modern tools of AI and machine learning to work to further understand vulnerabilities, test controls and mitigation strategies and ultimately help us to predict and prevent food safety issues. As we progress on that effort, we are now working with trusted partners to carry that digital information into aggregated databases that can be used by Western Growers and potentially made accessible to the academic and regulatory communities for more quantitative risk analysis.

In addition, that same information is valuable within the supply chain, and we are working with partners to create real time red light, green light warnings that could indicate a supplier's or buyer's failure to follow and meet established food safety specifications, whether they're set by FSMA, LGMAs other audit programs or individual company specifications. We think the FDA can help in these efforts by working directly with grower groups such as Western Growers to establish key needs and standards

for data, developing incentive programs for data sharing and recognizing companies that are employing the highest levels of food safety. We look forward to engaging with the agency and other stakeholders as we all strive for a New Era of Smarter Food Safety. Thank you.

MS. BARRETT: Thank you. Our next speaker is Suzanne Livingston, IBM.

MS. LIVINGSTON: Thank you, FDA, for highlighting the critical role technology is playing now in food safety. For IBM and its partners, the New Era of food -- Smarter Food Safety is here now. We are proud to be helping companies radically redefine food safety with technology while keeping pace with consumers who demand digital transparency. Early last year, IBM and Walmart proved that with blockchain we can trace food in seconds over the traditional methods that can take days. Today, there are more than 170 global brands who have joined our blockchain network, sharing data such as where food originates, where it has traveled, its condition along the way, IoT readings, inspection reports and more.

Building such a network was unprecedented. We had to prove that sharing data creates a stronger industry. We had to prove that we could be trusted to facilitate this work and we had to prove that it can be done cost effectively, even for small players. Our partners include not only household names, like Dole, Golden State Foods, Walmart and Driscoll's. But also small farms, like the ones in California where the majority of our leafy greens originate. They have a common set of goals, deliver fresher, safer food to consumers, ensure unsafe food is traceable.

For them and others the benefits are clear. Blockchain creates a permanent shared record of every transaction across the supply chain. Companies are continually joining this network called IBM Food Trust. And today it has more than 16 million transactions covering more than 16,000 food products. We are applying advanced AI and analytics to food and IoT data, giving insight into food freshness and risk to companies and to consumers. Last week, we launched a

seafood partnership, so consumers can use their smartphone to trace the origin of Wild Caught Scallops also in seconds.

We fully support the FDA's mission to bring innovation to food safety. We believe that should start by making paper-based food tracking a concept of the past. We recommend that FDA facilitate data sharing, both between companies and key government regulators and between regulating agencies themselves to foster public private collaboration during an outbreak and give consumers more trust in their food. American consumers fear products aren't genuine, are fraudulently substituted or have food safety risks. The FDA can create incentives to use technologies that support sharing open standards and interoperability, like Blockchain. Blockchain is a game changer for food safety. We now have the capacity to transform the food supply chain. And we've shown that we can add scale for all companies, great and small.

IBM looks forward to continuing this all-important work with you and the food industry. Thank you.

MS. BARRETT: Thank you. Our next speaker is Alex-Paul Manders, Information Services Group.

MR. MANDERS: Good afternoon. My name is Alex-Paul Manders. I'm a consultant with the Information Services Group, ISG, a global technology research and advisory firm. My role at ISG is to lead and manage our global blockchain services and consulting solutions. I have spent my entire 20-year career in strategic management, consulting and technology roles. In the fall of 2018, I was appointed as ISG's global blockchain leader, and I am a leading proponent of blockchain technology and blockchain consortia. My experience of blockchain dates back before my formal role at ISG, having assembled blockchain computers in my living room to learn the technology and to understand its potential impact when applied to business processes. Since that time I've incorporated and expanded my blockchain experience in my work with clients. I have designed and developed, distributed software applications for enterprise and

organizations. Presented it at the University of Texas, Austin. Facilitated roundtable discussion with CEOs and corporate board members at MIT and studied at Stanford University to deepen my understanding of supply chain.

Through my work with clients, technology partners and market researchers, I have seen an exciting explosion of new food, beverage and snack products into the United States market over the past 5 years. This innovation and competition give consumers more choices. New requirements may impede product innovation and could slow the adoption of real world blockchain track and trace solutions comparable to Walmart's ability to digitally see a supply chain journey from harvest to consumer.

Surprisingly, I found the primary challenges with blockchain technology, adoption or non-technical. Based on my observations, the top challenges facing the food and beverage industry with blockchain are first, incomplete awareness and understanding of technology, vendors, solutions and business to business collaboration models. Secondly, the lack of established industry and governance frameworks. And third, markets influenced by enterprise supply chain participants with a disproportionate pool of resources. I believe the FDA has demonstrated leadership to address these challenges.

In addition, I believe the FDA should consider the following. First, an FDA sanctioned blockchain research study to outline and assess technology providers, software vendors, solution providers and options for how to develop investment models. And provide guidance for developing business to business collaboration models, digital supply chains and change management methodologies, in part to reduce paper-based records. Secondly, provide clarity around how new standards are implemented. I believe this can be achieved with an FDA sanctioned research study, in part to deliver practical and actionable guidance on designing blockchain programs. And finally, consider appropriating funds or grants to provide farmers, harvesters, distributors and retailers with access to

capital, to implement distributed ledger technology and operating models based on a series of qualifying factors.

Thank you for your time.

MS. BARRETT: Thank you for your comments. Our next speaker is Jennifer McEntire, United Fresh Produce Association.

MS. McENTIRE: Good afternoon, and thanks for the opportunity to provide public comments. I'm Dr. Jennifer McEntire, VP Food Safety with United Fresh Produce Association. United fresh is a national trade association for the fresh produce industry representing about 1500 companies involved in the growing, fresh cut processing, distribution and sale of fresh produce. We will be submitting detailed written comments because FDA has posed several thought provoking questions. So in my 3 minutes here, I'd like to focus on a theme that emerged as I was crafting our written comments. And that is on FDA's dual and sometimes conflicting role as a regulator and as a public health agency.

Several of the questions in the Federal Register notice, ask how FDA can encourage evolution within the food industry especially in areas where FDA lacks the regulatory authority to simply mandate practices. In some cases FDA has historically been lax in enforcing requirements that are already on the books. For example, the current one up one down traceability recordkeeping requirements specify that firms need to provide information within 24 hours. But we're not aware of consequences imposed when firms don't adhere and that may send a signal, a negative signal, to the rest of the industry. This is where FDA as a regulator should build a bigger step.

We all know that sharing information and true collaboration are keys to prevention and progress. But there is a real risk in companies airing their dirty laundry and sharing data, particularly as they pertain to near misses or real misses. If there's a fear that information will be used against a firm or against an industry, it's going to be a very difficult sell. When it comes to prevention, people should be rewarded for doing the right thing. And FDA should put its mission

is a public health agency above that of being a regulator. Incentives such as clear safe harbors, decreased inspection frequency and perhaps public recognition should be used to incentivize and reward those firms who go out on a limb to make investments, share data and try to do the right thing.

Finally, while the smarter era of food safety is more expansive than just the use of technology, I'd be remissive if we didn't encourage FDA to pitch this effort as not only a way to improve food safety for the good of consumers, but also as a way to ensure that younger generations are attracted to careers in food industry. I'm in awe of technology that my daughter views as ordinary and Mary Wagner said this morning, she said that Generation Z is their digital natives. And if we as a food industry aren't keeping up, using available technology, then we are falling behind. And despite the low profit margins in the food industry, we realize the need to up our game to remain competitive and attracting new talent into the industry.

United Fresh will continue to finalize our written comments and we look forward to seeing FDA's blueprint so that we can work together on implementation. Thank you.

MS. BARRETT: Thank you for your comments. Our next speaker is Randall Querry, American Association for Laboratory Accreditation.

MR. QUERRY: Hello, I'm Randy Querry, Director of Government Relations with the American Association for Laboratory Accreditation A2LA. I am pleased to provide comments to you today on behalf of A2LA.

A2LA provides food testing accreditation to ISO standards for over 450 certificates both domestically and globally. Our customers include in-house manufacturing laboratories, commercial testing laboratories, and government sector laboratories such as the FDA. Testing laboratories serve as the foundation of the national food safety structure. And laboratory accreditation is a cornerstone for competence and technical accuracy. Both in U.S. and throughout the world government regulators and consumers seek assurance that food products are safe.

A2LA recommends that the FDA rely on third party independent accreditation bodies that assess and provide accreditation to the international standard ISO/IEC 17025. This standard provides quality management system requirements such as corrective actions, root cause analysis and internal auditing and technical requirements for personnel, equipment and facilities. The standard also focuses on validation, traceability and risk assessments. These attributes not only support the laboratory ensuring data quality, but also assist the laboratory in exploring new innovations and technical advancements in keeping with the administration's New Era blueprint.

A2LA encourages the FDA to entrust the existing accreditation structure, the International Laboratory Accreditation Cooperation or ILAC. Signatory accreditation bodies to this global arrangement are required to operate their systems to the ISO standard, ISO/IEC 17011. This standard provides requirements for the quality management systems and technical competency of the accreditation body. In order to achieve ILAC recognition, accreditation bodies must undergo rigorous technical peer evaluations. This recognition assures regulators that renewal assessments are timely and occur on a consistent cycle. That onsite assessments are performed by technical experts matching the technical aspects of the laboratory services and that the laboratories are conducting appropriate proficiency testing.

In summary, Laboratory accreditation is a rigorous but necessary assessment of food laboratories to ensure accurate reliable testing results. Thank you.

MS. BARRETT: Thank you. Dana Downing, TraceGains. Dana Downing. Okay. We'll move forward. Jeanne Duckett, Avery Dennison.

MS. DUCKETT: Hi, my name is Jeanne Duckett. And I'm with the Avery Dennison Corporation. A lot of people don't really know who Avery Dennison is even though we're a Fortune 500 Company because we tend to be the brand behind the brand. Or they remember us

from office products like labels that go through office printers or binders. But we've been connecting the physical and digital worlds for over 85 years. Avery Dennison was there in Troy, Ohio when the first UPCA barcode was scanned, and we're the largest UHF RFID manufacturer in the world. Today we're here to talk about the Smarter Food Supply Chain, which contains both enabling traceability through technology and building a culture of food safety. I'd like to touch on both of those topics today.

A common buzzword is sustainability. Recently I heard a very good definition of sustainability: "Sustainability is enabling a people friendly world, a process friendly world and a world where businesses can be profitable."

A lot of people are surprised to hear the word profitability linked with sustainability, but I believe it's a key component in enabling the smarter food supply chain. One of the major learnings that Avery Dennison got in a decade-plus of enabling visibility and supply chains was that visible inventory can lead to optimized inventory levels, enables waste reduction, strategic recalls, all which both enable consumer trust and save money.

When we talk about creating the tech-enabled traceability or the tech behind the food supply chain, that very first thing that you have to do -- and touched on it today here -- was enabling the producers, whether it's a seafood farmer or a farmer, in creating that digital to physical link.

And that digital-physical link has two components of it. One of it is like the data carrier or the data identifier, which is a barcode or an RFID, and lot of people tend to get really tied up on that. But what you really should be thinking about is what the data content is in the data carrier, because the UPC-A barcode was scanned 45 years ago and data carriers will change over time. But that data content, if it's harmonized and normalized, will really fuel the tech-enabled digital supply chain.

So your transparency story really starts -- as we've heard about paper trails today -- your

transparency story really starts when your digital identity starts. So the key data elements in that digital identity such as a global unique identifier, like Angela touched upon, allotted (ph) serial number and a relevant date, such as an expiration date, really give you the ability to identify an individual instance.

So perhaps the final key in enabling the smarter food supply chain and bringing transparency to consumers are these data rich carriers on pack. So we're moving to a world where these data carriers will be able to bring transparency to traceability and to consumers, both.

So I like to wrap up just by saying that Avery Dennison is looking forward to working in the smarter food supply chain and we'll continue to support standard organizations and other industry leaders. Thank you.

MS. BARRETT: Thank you. Our next speaker is Shelley Feist, partnership for food safety education.

MS. FEIST: Thank you. Thank you. A pleasure to be here today. I am Shelley Feist, Partnership for Food Safety Education. And we're a non-profit that develops and promotes effective education programs to reduce food borne illness risk for consumers.

We're also a convener and steward of a network of organizations and resources that support the consumer education work of thousands of health and food safety educators across the United States. These educators are in public health agencies at local, county and state levels. They are in cooperative extension, in schools and in other non-profits that serve vulnerable populations. As Mary Wagner said this morning: "It's like we need extension again from the 1960s." Well, there is a network of educators that we communicate with constantly and develop programming for.

The Partnership has unusual origins and has a track record of public-private cooperation and collaboration for more than 20 years. It was created during 1997, MOU between the U.S. Department of Agriculture and the U.S. Department of Health & Human

Services, including the FDA and the CDC, along with leading food industry associations and the Consumer Federation of America.

Working with industry experts and our federal agency liaisons, the Partnership developed the original consumer food safety education campaign called Fight Bac! and the evidence base for the four foundational home safe food handling practices - clean, separate, cook and chill.

Working together with the federal agencies and other experts, we also convened around development of advice for consumers on the safe handling of fresh fruits and vegetables. This collaboration resulted in a tested consumer platform called Produce Pro. That's just one example of the government-industry collaborations that the Partnership has led.

I'd like to briefly comment on the two sections of the Food-for-Thought paper on the new era of smarter food safety. I believe the Partnership and now more than 30 contributing partners are qualified and ready to activate and support some of these powerful new ideas.

In navigating the last mile, Partnership -- food retailers, food service companies and key leaders in food safety like AFDO and IAFP can be brought together through the Partnership to collaborate on consumer interventions to navigate the last mile in food safety.

Our partners meet quarterly and meet continuously in committee work and taskforces. They're ready to leverage their individual resources and channels to improve industry and consumer education in navigating the last mile.

Developing smarter food safety consumer education, this can and should be done through the Partnership, consistent with collaboration that resulted in the original evidence-based consumer campaign called Fight Bac! in 1998.

In short, we strongly support -- strengthening food safety education in United States is integral to the new era of smarter food safety. I thank you for the opportunity to address this public meeting. On

behalf of our 32 partners, thank you for your commitment in this area, and I look forward to working with you further. Thanks.

MS. BARRETT: Okay. Thank you for your comments. Our next speaker is Ramkirshnan Balasubramanian, Florida Organic Growers and Consumers. Do we have someone from the Florida Organic Growers and Consumers? Okay, we'll move on. We next have Stephanie Harris, Food Marketing Institute.

MS. HARRIS: Good afternoon. My name is Stephanie Harris with the Food Marketing Institute. FMI is the trade association that represents and advocates on behalf of the food retail industry. FMI member companies operate nearly 33,000 retail food stores and 12,000 pharmacies, with close to 5 million workers and a combined annual sales volume of $800 billion.

FMI appreciates the opportunity to participate in FDA's Public Meeting on A New Era of Smarter Food Safety. We plan to provide more detailed written comments, but wanted to offer some initial thoughts as the agency develops their blueprint moving forward.

Food safety has been and continues to be our number one priority. FMI members strongly supported the passage of the Food Safety Modernization Act and appreciates the work FDA has done throughout the development of the foundational FSMA rules.

Two of the key principles that have made FSMA successful are flexibility and a willingness to engage with stakeholders throughout the process. We hope FDA continues this approach going forward into this new era.

We would like to comment briefly on three of the topics raised at today's meeting: traceability, smarter tools and approaches for prevention and challenges of new business models and retail food safety.

First, FMI agrees that new and evolving digital technologies will play a pivotal role in traceability moving forward. We encourage FDA to allow for flexibility and the adoption of technology to allow for innovation now and in the future. As such, FDA

should provide flexibility regarding the technology used for traceability and should recognize that there are multiple ways for companies to embrace technology to improve food safety and traceability.

Regardless of what technologies are used, we encourage FDA to identify essential data elements necessary for food safety and public health purposes that should be collected and shared throughout the supply chain. Simplifying key data elements will speed up investigations and streamline the critical information that must be communicated to improve response time and accuracy.

Second, with respect to smarter tools and approaches for prevention, FMI believes that collaboration between stakeholders and the agency is critical to both responding and preventing food safety problems at the outset.

Critical stakeholders and the agency should be committed to sharing timely information on outbreaks and contamination to better understand learnings and ways we can work together to prevent food safety events in the future. Transparency throughout investigations is also essential so both the agency and industry can improve based off of past learnings.

Third, in terms of evolving business models and retail food safety, we encourage FDA to see FMI as a continuing partner in this area. We appreciate the agency's statement in its Food-for-Thought document that FDA should increase engagement with industry and regulatory partnership groups to promote implementation of effective intervention strategies to reduce retail risk factor occurrence.

FMI has extensive experience understanding the sector, including application of the Retail Food Code, and welcome the opportunity to collaborate with FDA.

Finally, FMI shares FDA's goal of enhancing existing processes to make them more effective and efficient to improve food safety.

We look forward to continuing this dialogue and appreciate the opportunity to participate in today's meeting.

MS. BARRETT: Okay. Thank you. Our next

speaker is Mark Sestak, Association of Food and Drug Officials.

MR. SESTAK: Good afternoon. I am Mark Sestak, and I'm the vice president of the Association of Food and Drug Officials, and I'm also a public health regulatory official from the state of Alabama. On behalf of AFDO, we want to thank you for allowing us the opportunity to participate in today's public meeting.

AFDO represents food and medical product regulatory programs at the local, state and federal levels. The Association was founded in 1896 and has actively collaborated with Dr. Harvey Wiley to secure the passage of the Pure Foods Act (sic) in 1906.

The era of smarter food safety contains many components that relate to the work routinely conducted by state and local programs. We are particularly excited that the retail food has been included as a key element in this initiative. Many opportunities for modernization exist in the retail arena.

We believe the food regulatory system must be more agile in an era of smarter food safety and more able to quickly address new and innovative technologies, production techniques, preparation methods and distribution systems.

With the speed at which these and other emerging areas are adopted by both the industry and consumers, waiting years for regulatory answers is no longer acceptable.

Lastly, investigative techniques for food borne illness must be modernized to focusing on root cause analysis approach that uses the best investigative techniques. In the age of whole genome sequencing, culture-independent diagnostic tests and instant information sharing, the regulatory community must be able to quickly investigate and find the cause of food borne illness and prevent additional outbreaks. Particularly, retail investigative methods have not kept pace with those and other areas of the food system.

In 2017, Centers for Disease Control reported almost 70 percent of the food borne outbreaks were

associated with restaurants. In conjunction with several state programs and the CDC, AFDO has begun to address this issue by developing and delivering a hands-on environmental sampling training course specifically for retail food borne outbreaks. Currently, there is more demand for the course that can possibly be filled.

With FDA, state and local agencies, industry, consumers and other stakeholders working together as partners in this effort, we are confident that an era of smarter food safety can be achieved. Thank you.

MS. BARRETT: Thank you very much for your comments. Our next speaker is Diane Wetherington, iFood Decision Sciences.

MS. WETHERINGTON: Good afternoon. My name is Diane Wetherington, and I am CEO of iFood Decision Sciences. We're a food safety and quality software solutions provider focused on real-time process controls and continuous improvement within individual companies and across the supply chain. We serve growers, packers, shippers, processors, distributors, food service and retailers directly and in partnership with leading technology companies and industry trade associations.

Whether we are helping customers implement supply chain solutions or addressing issues such as listeria and preventive controls in operating environments, we see our customers and indeed the entire industry facing several challenges and opportunities every day.

First, we need real-time food safety measures. Today the industry is focused on audits and testing as their primary measures of food safety. Audits are important, but they are one point in time. Product testing may help us identify and avoid gross contamination at one company, but what is happening to that product along the supply chain? We can test products at the field level, but what happens if it's contaminated in a facility or transportation or on the retails shelf?

To achieve a supply chain solution, we need new collaborative real-time metrics used by small and

large growers, distributors, transportation, retailers and food service companies.

Second, for real-time solutions, data is critical. Throughout the supply chain, we're collecting data mostly on paper, but were documenting what's being done throughout the day in our food safety operations. That data has great value.

At the industry level, we need to be in a position to have data for companies to investigate their own food safety operations, product varieties and otherwise and to collectively understand how those risks apply to similar operations and products and can impact best practices.

Traceability has a critical role, particularly in the event of an outbreak. But we should not stop at traceability. We need to know not only where a product came from in the supply chain, but also what happened to that product at each and every step along the way.

Third, implementing the new era of food safety will require the industry from the smallest grower to the largest retailer to invest in improving food safety. Before recommending one technology approach or testing type or measurement, we need to consider not just the food safety improvements, but the reality of what will take to achieve the food safety improvements. Does it require companies to invest? Will it require new worker skills? How much product development is needed to introduce a solution? Will it scale?

It maybe some food safety solutions are not viable today, but will be in 5 years. While no one wants to increase consumer prices, we need to face the reality that consumers may need to pay more.

Finally, when we communicate food safety to public, we need to make it clear that food safety is a process and will be constantly change in improvement. There is no one solution that will address all the issues. We should inform the consumers and invite them to become involved in our journey to safer food. Thank you.

MS. BARRETT: Thank you for your comments. Our next speaker is Sanjay Gummalla, American Frozen Food Institute.

MR. GUMMALLA: Thank you, Kari. Good afternoon. My name is Sanjay Gummalla, and I am with the American Frozen Food Institute or AFFI. On behalf of AFFI, I appreciate this opportunity to share with the FDA our perspectives as the agency modernizes its protection of the food supply in a new era of smarter food safety.

On our end, AFFI and its members are committed to advancing food safety and this is our priority. In support of FDA's Food-for-Thought caption to describe its ideas on how to begin a new era of smarter food safety, I like to share three themes for your consideration to truly advanced food safety.

Frankly, three areas that really echoed in the discussions and the issues I've heard all morning. First, continued reliance on science. Consistent with the principles of Food Safety Modernization Act and its foundation on science-based and risk-based standards for the safe production of food for human consumption, FDA's new era should rely and operate on scientifically sound knowledge and data. And AFFI maintains that FSMA's focus on preventive controls and prevention is the right priority and should, in the words of Deputy Commissioner Yiannis, drive smarter food safety.

And we further appeal that the agency utilizes necessary and adequate science to inform its regulatory policies, guidance and compliance actions.

On the theme of reliance on science, the academic and industry communities contribute a considerable body of science and scientific knowledge that continues to evolve and -- our understanding of pathogenesis, prevalence, exposure and related food safety testing systems and controls. And we encourage the agency to build regulatory approaches based on scientific consensus; that the evolution of food safety sciences continues to be the agency's bedrock even as the revolutions of technology are ushered in.

Two, transparency. The foundation of effective communication is transparency and clarity about the agency's objectives and actions. AFFI is encouraged by FDA's resolve to adopt new technologies and improve outreach to consumers on recall and

outreach scenarios.

Just as critical is the underlying motivation and intent of these communications. As an example, issuing public announcements for every Class II recall or withdrawal does little to build consumer trust or deliver desired public health outcomes.

At the same time, we recognize industry needs to make strides in its food safety culture and behavioral ethos as these are essential to implementing successful food safety programs. We are encouraged by the agency's intention to train its own personnel in this important area. Inspections remain among the most varied and challenging activities for both agency and the industry and that training and uniformity will be critical elements moving forward.

I'm getting the cue to leave. So three, a smarter food safety continuum and the role of consumers. AFFI is really encouraged that implicit in FDA's new era of smarter food safety is the role of consumers in driving public health outcomes and we agree that newer and smarter technologies can be that bridge to address consumer awareness and behaviors and stand ready to work with the agency to inform and educate consumers.

I want to end with a quote by Edward Teller, an American theoretical physicist: "The science of today is the technology of tomorrow." And I believe it is critical that a smarter era of food safety at FDA continues to remain tethered to scientific principles as the foundation of its public service efforts. Thank you.

MS. BARRETT: Thank you for your comments. Our next speak is Mary Lou Bosco, AIM.

MS. DUCKETT: Hi. Good afternoon. My name is still Jeanne Duckett.

MS. BARRETT: Or her proxy.

MS. DUCKETT: AIM Global has asked me to speak for them this afternoon. I sit on the board of directors for AIM Global and we like to thank the FDA for holding this open public forum to exchange idea and information.

In addition to being on the board of directors

for AIM, I'm also the North American food policy chair, I'm on the ISO Technical Experts Group and the previous chair of the Internet of Things, the RFID Experts Group and the Traceability Committee. For my day job, I still work for Avery Dennison.

So anyway, we were founded -- AIM Global was founded in the early 1970s. So with nearly 50 years of experience, AIM has a long history of promoting standards developments and barcodes, RFID, automatic identification and tracking. And the reason why AIM is here today is to be the voice of the solution providers.

AIM is an unbiased technology agnostic open resource for the FDA and others as they're making their guidelines as our membership has the technical expertise and experience in the supply chain transparency.

In addition, AIM is currently outlining a series of webinars that will be publicly available providing information on different touch points of the interoperable supply chain.

AIM has spoken on Capitol Hill on a number of initiatives, including the UDI, the IUID and the DSCSA Bill. In some ways, the FSMA can be compared with the Unique Device Identification Bill in that it needs a data carrier containing a globally unique digital identity, creating a digital identity to show provenance.

Our goal is standards-based interoperability for traceability with the belief that it's going to benefit all supply chain participants by lowering the technology and financial barriers to adoption.

Interoperability is one of those things that can be hard to define but you know it when you see it, because users enjoy a seamless experience. Those seamless experiences such as your cell phone or your internet access is actually powered by standards.

However, I don't want to minimize the difficulty of some of the tasks ahead of us: the physical digital data capture and the very diverse food supply chain capturing multiple types of data from sensors, temperature, CO2, humidity along with that

globally unique digital identity, and also we're going to need to determine what supply chain steps are needed to ensure transparency and interoperability.

Another aspect of AIM's mission is education. Recently, we've been working on the outline of Transparency for Dummies, a publication that will assist users to determine implementation steps, business benefits and relate success stories from adopters.

To summarize, AIM's going to support the smarter food supply chain through standards development, advocacy and education and AIM Global user committee plans on submitting comments to the FDA request for comments. Thank you.

MS. BARRETT: Thank you. Our next speaker is Sathya Narasimhan with SAP. Do we have an SAP? Alright. You're not filling any other roles? I'm just kidding.

MS. DUCKETT: I'm done with today.

MS. BARRETT: Okay. Alright. Perfect. We're going to move on. Paige Smoyer, National Confectioners Association.

MS. SMOYER: Good afternoon. My name is Paige Smoyer with the National Confectioners Association or NCA. NCA welcomes this opportunity to learn more about this new era of smarter food safety, the creation of a more digital or traceable food system and the next steps of FSMA implementation.

NCA is the leading association representing the $44.6 billion U.S. confectionary industry. Our members are committed to providing consumers with quality chocolate and candy products that can play a unique role and a happy and balanced lifestyle. NCA and our members are also committed to a safe, secure and transparent food system for all foods, including our members' chocolate and other confectionary products.

NCA supported the passage of FSMA and appreciates the work FDA has done to implement it. We support the agency's efforts to continue to build upon FSMA and seek new ways to enhance food safety. As such, we are interested in learning more about the ways

FDA plans to collaborate with industry to use food safety data to identify best practices in a non-regulatory framework.

We also support the future development of education, training and other tools to foster best practices that will reinforce best food safety culture throughout the food distribution chain. We look forward to working with the agency to promote and strengthen company cultures that embrace food safety as the top priority.

Like their counterparts in other food categories, NCA members devote significant efforts to the security and safety of their supply chains. As you know, the supply chain for cocoa beans is highly complex, involving multiple exchanges and distribution channels.

Cocoa beans begin their long and intricate journey to becoming finished chocolate products on small family-owned farms in a few countries around the world that have the unique climatic conditions needed to grow cocoa successfully. Once harvested, fermented and dried, cocoa beans are then collected and aggregated.

Given this reality, achieving end-to-end digital seed to spoon traceability for cocoa represents a complex undertaking and we urge FDA to consider that complexity as it contemplates traceability systems for various food products.

Acting Commissioner Sharpless has identified the pharmaceutical traceability system currently being implemented in the Drug Supply Chain Security Act, or DSCSA, as a possible model for this food traceability initiative. We believe the DSCSA provides some useful learnings on the complexity of building any fully interoperable electronic traceability system. We note that pharmaceutical traceability is the product of negotiated legislation and will take 10 years to implement.

Through modifications to the Federal Food, Drug, and Cosmetic Act, including its passage of FSMA, Congress has provided guidance to FDA and industry on food traceability. We look forward to working with FDA

to make sure the current statutory framework is fully realized.

As with any initiative focused on enhancing food safety, we urge FDA to issue a one-size-fits-all approach in favor of a proportional one that focuses on those areas of the food supply where enhancements would deliver demonstrable incremental benefits to food safety and public health.

NCA members have been working to improve the security and transparency of complex food supply chains for many years. We look forward to collaborating with the FDA as the agency works towards a blueprint to usher in a new era of truly smarter food safety.

NCA thanks you for this opportunity to present our views and will submit written comments to the docket. Thank you.

MS. BARRETT: Thank you very much for your comments. Our next speaker is Don Durm, Personalized Lifecycle Management.

MR. DURM: Good afternoon. I'm with PLM. I'm the vice president of Customer Solution. So in my role at PLM, I've had a unique seat at the nation's temperature controlled supply chain for nearly 25 years, at transport vehicles observing the complex, matrix of storage and transportation hand offs between trading partners.

On a personal note, my wife lives with a compromised immune system and consuming safe food is of at most importance to our family. In 2011, the Food Safety Modernization Act was signed into law. The sanitary transportation of food for human and animal consumption, that is 274 printed pages, I can honestly say that there is nothing new or modern here.

We've all heard the statistics from the agency, from the scared act of eating something. Additionally, Oceana did a study and randomly tested our seafood, and it resulted in one-third of it being mislabeled. The Grocery Manufacturers Association reports that a average recall is $10 million. The fact is that pushing food down the food supply chain is a 2 percent business at best with very slim margins, not something I would want to invest my 401(k) plan in.

Emerging -- engaging business is what I'm really here to talk about. Smarter food safety system really means a more efficient and a cost savings system. For business, technology is a disruptor. Mandating technology is not good enough. Technology will need -- will add only complexity and cost to our overburdened food supply system. Technology will only be effective if we can use it to solve our business challenges in food safety and to drive cost out of business.

I believe that the food manufacturers and distribution companies are coming from a good place. They want to provide food that is safe to our families.

The ability to cut transactional cost and help stakeholders to gain additional financial benefits. One point interestingly enough in distribution comes from -- the Federal Motor Carrier Safety Administration completed an impact study last year that said that 1.3 billion in lost revenue during hand offs in transportation.

Digitizing our food will give the industry the ability to drastically reduce our associated cost, especially with recalls.

Understanding the velocity of traveling food that has a short shelf life, it's difficult to track, and over half of the cold supply chain actors never take an inventory. This is a money loser in any business. Blockchain is tough to sell when you're using humans to input that data. Dirty data makes blockchain not trusted.

We are living in a unique time: the digital convergence of IoT devices that make it possible today to reduce human errors and bring trust into the blockchain.

Disruptive technology is only going to be adapted if it solves for problems in the food supply chain. The blockchain is related technology, will bring trust and transparency to food supply chain, driving out significant cost between trading partners.

I applaud the agency's leadership for bringing stakeholders together for a smarter food safety system and to bring modernization to the food safety rules.

Thank you.

MS. BARRETT: Thank you. Our next speaker is Riccardo Accolla, Ripe Technology.

MR. ACCOLLA: Good afternoon. My name is Riccardo Accolla, and I am director of Digital Food Science with Ripe.io. Ripe.io provides a blockchain powered platform to access information on the origin, the journey and the quality of food. Thank you to the FDA and to Frank Yiannas for organizing a critical public meeting. We applaud your tireless efforts and leadership towards a new era of smarter food safety. We are truly humbled today to share some insights with all of you.

I like to start with data. So improving the time to trace a contaminated food batch is necessary but hardly enough to shift the focus from responding to preventing food borne illness. We need to marry the speed of detection to reliability and completeness of the data collected across the many steps of the supply chain.

We believe that improved data access in such a fragmented, complex, and in most cases, low trust environment is best achieved through a digital platform featuring blockchain technology at its core. The industry must accept that digitization is a necessary requirement.

We are currently witnessing a tectonic shift in the application of software and technology within the larger food and agriculture supply chain. The introduction of blockchain into this ecosystem has yet to reach maturity, but there is increasing evidence that features like the centralized ledgers, security and immutability can improve efficiency, transparency and provide more reliable traceability.

Ripe.io's blockchain platform aggregates, validates and securely stores supply chain data, transaction and documents from multiple sources, including sensors and enterprise management systems.

By bringing a major focus on the onboarding and digitization of the farmers, our solution bridges the gap between the pre and post-harvest data. Analytics and visualization tools provide then a window

into tracking progresses in supply chain metrics, including FSMA rules compliance.

Beyond traceability, the goal of the platform is to contribute to create new standards for higher quality, more sustainable food system through a transparent 360 view of the supply chain and generate business value to all stakeholders along the way.

I would like to conclude my remarks by inviting the participant to this forum, the FDA and the food community at large, to include in this new era of food safety efforts to produce safer food for the planet as well.

Embracing biodiversity and regenerative agriculture practices no doubt will benefit for the quality and most likely the safety of the food itself. The future of food will be more personalized, more digital, addressing the consumer demands of transparency, nutrition, sustainability and taste.

Technology is ripe and ready to monitor and reward improved supply chain practices. We all need to do our best to speed up and incentivize adoption. Thank you very much.

MS. BARRETT: Thank you. Our next speaker is Karil Kochenderfer, LINKAGES Global Trade.

MS. KOCHENDERFER: Good afternoon. My name is Karil Kochenderfer, and I represent the fast-moving food, consumer goods and retail sectors through LINKAGES, my consultancy. LINKAGES reflects the seamless supply chains operating in the marketplace today, the highly connected consumers talking to other through social media, and the new partnerships that are being pursued across supply chains.

LINKAGES aptly sums up my farm-to-fork perspective of the world, including pursuing not one, but two WTO challenges on product traceability in Geneva.

The success of the agency's smarter food safety initiative relies on three elements that we all know very well: process, people and technology.

Let me speak first about the process. Any food safety professional will tell you that there are too many and too varied food safety management and

traceability standards in the marketplace today. This is redundant, this is inefficient. Time and resources that could be better spent on food safety are instead being spent discerning the differences between these private standards and paying for additional audits, numerous and many audits. This is particularly onerous for small businesses or specialty importers.

The agency needs to make sure that there's one clear food safety management traceability standard to minimize and eliminate the redundancy in the marketplace to eliminate this inefficiency.

Fortunately, one standard exists and it is a publicly available transparent standard. It is ISO standard 22005. It reflects the science-based codex standards developed for food hygiene and HACCP. Governments in Europe and Asia permit businesses to demonstrate compliance with their national food safety systems using this standard. It is aligned with GS1 supply chain standards that are used by over 2 million businesses around the world and in the United States. And critically, most importantly for the conversation today, it establishes a common language, a common foundation for the blockchains that are envisioned under the smarter food safety initiative -- which gets me to technology.

Clearly, a lot has been said about the promise and the hype about blockchain, AI, IoT, smart contracts, sensors, and we can go on and on. None will deliver on the promise of this technology without good data quality. It is up to the smarter food safety blueprint. Therefore, the agency should devote significant time and resources to ensuring good data quality management programs are a part of this initiative.

What do I mean by a good data quality management program? Such programs require data quality, accuracy and completeness. They are practiced by all food safety management team members in an organization and they are measured and rewarded by the C-suite at the highest level of the organization. It sounds quite a bit like food safety culture, doesn't it? But technology is worthless without good data and

therefore we need to have these programs.

And finally, people. The agency must invest in extensive education and training at the state and local levels to ensure that its smarter food safety approach is understood, assimilated and is being acted upon in the marketplace, just as it did with FESMA. It was a paradigm change then, just as this is now. And it is happening in a fast moving and a volatile marketplace with small margins, often less than one percent, and requiring significant investment to boot.

Success requires knowledge, but it also requires speed. And to paraphrase an industry CEO: "No future time will be slower than today." I encourage us to work forward together. Thank you.

MS. BARRETT: Thank you. Our next speaker is Robin Stombler, Food Laboratory Alliance.

(Beeping sound)

MS. BARRETT: Is there a…

MS. STOMBLER: Do you want me to stop before I start?

MS. BARRETT: Yeah, let's -- all good back there?

MS. STOMBLER: Okay.

MS. BARRETT: Thumbs up? Okay.

MS. STOMBLER: Okay.

MS. BARRETT: Thank you.

MS. STOMBLER: Thank you. Hello, I'm -- thank you for this opportunity to discuss the processes and tools needed for a safer food future. I'm Robin Stombler, director of the Food Laboratory Alliance. The Alliance is a coalition of organizations representing hundreds of food laboratories, hundreds of thousands of food testing products and services and serving millions of consumers.

Our focus is on the quality of food laboratory testing and its impact on the safety of the nation's food supply. We offer three recommendations today for the FDA blueprint.

First, broaden communications. With whole genome sequencing and eventually with metagenomics, the opportunities to capture data for traceability and prevention will be significant. However, the wider

community does not benefit from the data if it's not actually used.

(Beeping sound)

MS. STOMBLER: Data pipelines are likely to come from multiple…

MS. BARRETT: Robin, I'm sorry. We're going to interrupt just a second.

MS. STOMBLER: Sure.

MS. BARRETT: I'll tell you what. Why don't we just take a one-minute stretch. I know everyone's been sitting a very long time. If you just stand in your general area. Let's not leave the room, but if you just give yourself a stretch. It's been a long time sitting.

And then in the back, if you'll just give me a signal when you're ready.

(Recess)

MS. BARRETT: So please let's go ahead and take seats. I want to particularly thank Robin for her patience.

MS. STOMBLER: Oh. My pleasure.

MS. BARRETT: Okay. Robin, we're going to begin at the beginning. So…

MS. STOMBLER: Do you want me at the beginning?

MS. BARRETT: Yeah.

MS. STOMBLER: Or I can start where I left off.

MS. BARRETT: You're going to -- you can start at the top of your comments, please.

MS. STOMBLER: Alright. Sure.

MS. BARRETT: Thank you.

MS. STOMBLER: Well, then again, thank you for this opportunity to discuss the processes and tools needed for a safer food future. I'm Robin Stombler, director of the Food Laboratory Alliance. The Alliance is a coalition of organizations representing hundreds of food laboratories, hundreds of thousands of food testing products and services and serving millions of consumers.

Our focus is on the quality of food laboratory testing and its impact on the safety of the nation's

food supply. We offer three recommendations today for the FDA blueprint.

First, broaden communications. With whole genome sequencing and eventually with metagenomics, the opportunities to capture data for traceability and prevention will be significant. However, the wider community does not benefit from the data if it's not actually used.

Data pipelines are likely to come from multiple sources and some stakeholders will not be comfortable sharing their data. In ushering in a new era for smarter food safety, we must consider how to engage food laboratory leaders, raise awareness of new technology, enhance educational opportunities and speak frankly and openly about the expectations for laboratory data.

Next, fill the gaps. Technological advancement in the laboratory does not obviate the need for quality assurance; in fact, it expands it. New and emerging technologies make it more urgent to develop a new or amend existing standards and methods.

Gaps in reference materials and proficiency testing must be identified so that providers of these laboratory services may fill the void as seamlessly as possible. New technology can be exciting, but its efficacy and accuracy must be proven.

Finally, finalize regulations. FSMA was signed into law in 2011. Yet FSMA Section 202, addressing laboratory accreditation and model laboratory standards, has yet to be released. The FDA acknowledges that testing plays a "very important role in ensuring the safety of food and that an important purpose of testing is to verify."

To ensure that all laboratories follow recognized testing practices, we again call for the promulgation of FSMA Section 202.

We are excited about what the future holds for food laboratory science. We look forward to partnering with you in advancing food safety. Thank you for your time.

MS. BARRETT: Thank you very much for your comments. Our next speaker is Acacia Alcivar-Warren,

Environmental Genomics. Okay. Alright, we'll move on. Julie McGill, FoodLogi Q -- FoodLogiQ.

MS. McGILL: Got you.

MS. BARRETT: I just saw that Q at the end. Thank you.

MS. McGILL: That too, yeah. And apparently, there's paparazzi up here in the front as well. Good afternoon. I appreciate the opportunity to provide comments today. My name is Julie McGill, and I'm the vice president of Supply Chain Strategy and Insights at FoodLogiQ.

Our mission is to map the world's food supply chain and make it as safe as possible. Using a SaaS software solution, we enable food companies to efficiently oversee their supplier management, food safety compliance, whole chain traceability and recall management.

End-to-end traceability is being realized today. Our consumers and our customers are gathering key data elements, they're sharing critical tracking events, and connecting their supply chains end-to-end leveraging this data.

Today we have over 23 million critical tracking events in our system, and those numbers continue to grow. Through our customer implementations at FoodLogiQ, we have seen firsthand the critical investments that need to be made in systems, resources and processes to make traceability a reality.

These changes do take time. But implementing traceability programs allows companies to have this data at their fingertips, reducing the time it takes to investigate issues from days or even weeks down to seconds. Traceability data also provides invaluable insights into inventory management and food waste reduction.

Our customer, IPC, the Independent Purchasing Co-Op for Subway restaurants, is delivering end-to-end traceability through the Subway system. Here's an excerpt from a recent case study published earlier this year entitled "Delivering the Promise of End-to-End Traceability Throughout the Subway System." "For IPC and its restaurants, a bread recall demonstrated the

power of end-to-end traceability. IPC was alerted that nine cases of bread with a high risk of contamination had been shipped to restaurants.

Rather than having to call or even visit over 730 restaurants served by the distribution center, the procedure prior to the implementation of traceability, IPC with the assistance from their distributor who was participating in the traceability program was able to locate all nine cases within 2 hours."

They ended the case study with this: "Other traceability benefits are incalculable. At the end of the day, it's risk avoidance and safety of our consumers that we care about most."

This is why we are here. Consumer safety is our utmost concern and we're confident that food companies can adopt processes and interoperable technologies to make end-to-end traceability across the food chain a reality. Thank you.

MS. BARRETT: Thank you. Our next speaker is Terrance Mulgrew, Sanist Technologies. Do we have a Sanist Technologies representative? Okay. We'll go to Matt Brauner, National Customs Brokers & Forwarders Association of America.

MR. BRAUNER: Yes. Good afternoon. My name is Matt Brauner with Brauner International, and I'm pleased to be here today representing the National Customs Brokers & Freight Forwarders Association of America.

Customs brokers have always played a unique role in the supply chain. Licensed by CBP, brokers serve as skilled and trusted partners with FDA, delivering the agency from the chaos of dealing with tens of thousands of different importers.

Not only do we understand what the FDA is trying to accomplish, customs broker act as force multipliers, extending the agency's reach by educating our importer clients and enhancing the integrity of the data on food shipments submitted through the ACE and the ITACS system.

Today the global supply chain is undergoing profound change. New approaches are needed. It is not surprising that the blockchain seems to be everywhere.

Customs brokers participated last year in blockchain pilots with CBP. Both of these successful initiatives gave us an early glimpse into the potential for blockchain to transform the import supply chain system.

As FDA explores how blockchain and other new technologies can revolutionize food safety, the NCBFAA offers the following observations. "As the availability of data continues to expand in the supply chain, blockchain offers opportunities for all participants to share data that can provide critical information to regulatory agencies earlier in the process."

Customs brokers are poised to assist small and medium sized businesses with the collection and filing of that data and to ensure widespread participation of these vital players, who may not always be familiar with all of the regulations and processes. We can do that on a shipment by shipment basis or on a larger product basis or a supply chain basis by company.

Brokers can strengthen the accuracy of the data placed into the blockchain. With processes already in place to identify the parties and the elements of each shipment, we can add value to the blockchain consensus mechanism by validating important details of the transaction.

It is often said that blockchain is not the silver bullet to solve all the supply chain problems -- we agree. But it is important to understand what blockchain can do and what it cannot. Blockchain will not replace ACE or ITACS, but it will complement and enhance the existing systems immeasurably. Achieving a smooth interaction with the current processes will be a critical focus for both FDA and the trade.

NCBFAA stands ready to work with the FDA and all of its stakeholders to leverage blockchain and other new technologies to achieve smarter food safety. Thank you.

MS. BARRETT: Thank you for your comments. Our next speaker is Thomas Johnson, Qlean Tech Enterprises. Thomas Johnson? Okay. We'll go to Eric Moore, Testo North America.

MR. MOORE: You caught me off guard. Not in

order there.

MS. BARRETT: Well, take a minute.

MR. MOORE: Sorry.

MS. BARRETT: Yeah.

MR. MOORE: Good afternoon, and thank you for the opportunity to comment today on the new era of smarter food safety.

Since the year 2000, the FDA has been gathering and analyzing national food service industry data with the goal of identifying opportunities to make positive impacts on reducing the frequency of food borne illness in the food service industry. This has been a monumental task given the regulatory complexity, geography and limited resources necessary to gather all the information.

Technology is poised to make that process easier. Industry is rapidly developing and adopting new technology designed to provide real-time metrics across the entire food supply system. These metrics enable organizations to better understand their operating challenges around food safety behaviors, which then support a process of continuous improvement.

What if we took advantage of this opportunity to put that data to work for the greater good, which is reducing food borne illness? What if the industry -- what if our industry and regulatory were able to establish a collaborative data sharing platform built on anonymous real-time risk factor data that is self-reported by the people responsible for executing the process?

Just imagine the impact that a national baseline of industry reported -- I'm sorry, industry self-reported risk-based metrics could provide on identifying emerging trends in sharing best practices.

Some might think this to be impossible, but we're here to influence change, and that change is intended to reduce food borne illness.

I thank you for the opportunity to speak today and I look forward to being part of the solution.

MS. BARRETT: Okay. Thank you for your comments. We have one last speaker. We have Tim Gumbel. He's with the European Commission.

MR. GUMBEL: Good afternoon, and thank you very much for the kind invitation to your conference. It was a very interesting discussion to attend today for me, and I think there are a lot of messages also for us in Europe we can take home.

We could see that in the U.S. you face similar challenges as we do in Europe when it comes to managing risks, when it comes to defining, measuring what is the value of prevention.

We see similar trends, for example, when it comes to consumer expectation and the digitalization of our food systems. In Europe, we are moving towards a digital system now towards the end of this year, but it's of course a long-term process. And we believe that innovation and the growth of a food safety culture can of course best be achieved in a process where this - let's say, both sides of the Atlantic can also forestage (ph) others.

So as we congratulate you on your project of moving towards this new era of food safety, what we are ready to do is working with you on proportionate safeguards for food safety and especially in the area of new business models, and thus, also preventing unnecessary barriers to trade. Thank you very much.

MS. BARRETT: Thank you. Thank you for being here and for your comments. Let's give a round of applause for everyone who spoke today.

(Applause)

MS. BARRETT: We sincerely appreciate the time that you took and your presentations and comments. We are now going to do a set change. I want to thank our FDA panel. Thank you guys all for listening.

(Applause)

MS. BARRETT: We're going to bring up a new FDA panel. And so if our facilitators, who are giving breakout summaries, could come forward?

Alright. Well, thank you all. We're very pleased to have some of our hardworking facilitators join us the end of the day to give you a sense of some of the main themes that they heard in the various breakout sessions today.

So they're going to offer some brief remarks.

And with us we have, Tracey Forfa, who's the Deputy Center Director, Center for Veterinary Medicine; Jim Gorny, our Senior Science Advisor for Produce Safety at CFSA; Laurie Farmer, Director, Office of State Cooperative Programs and our Office of Regulatory Affairs; and Katie Vierk, who's our Director, Division of Public Health Informatics and Analytics at CFSAN.

So we're just going to work straight down the table. And Tracey, if you'll just note again your session and some of the key themes. Thank you.

MS. FORFA: Sure. I'll be happy to. Thank you, Kari. So actually this -- Kari said that it was hard work, but it really wasn't hard work because the ideas sort of just kept flowing. I was in the food safety culture group, facilitating that group. And thanks to Chris Waldrop and Kristin McNamara, my co-facilitators, who did a fabulous job. But I really want to thank everybody who participated.

It was a really, really good couple of sessions. And in some ways, I wish we had a little bit more time because they were just -- I had a sense that there was a lot more that we could have captured. But this is just the beginning, right? This is not the end, just the beginning.

So just to share -- I know I don't have a lot of time. So just to share some of the major themes that came out of it. One of the things was, it was interesting that -- we talk about food safety culture, but really I think the folks that participated told us it's really about food safety behavior.

We really need to focus on everybody, from what we do here at FDA to what happens in companies at all the various levels from -- all the way across organizations. So everybody really needs to remember why they're doing what they're doing and be -- really be bought in to food safety behaviors. How they do their work from the person that is sanitizing the line all the way up to the managers in the higher offices. It is a responsive -- it's everybody's responsibility.

We were also reminded that the reason that we do this -- yes, it's a paycheck -- but the reason that we do it is because there are a lot of people who have

suffered food borne illness and we always need to remember who they are and that we don't want it to happen to anybody else. And so we really have to humanize this work. This work is all about protecting humans, and in my case, the animals. And so we need to always bear that in mind.

Partnerships are critical. Maybe working a little bit on the compliance aspect and a little bit more on the collaboration, trying to find that really good balance. There a lot of good partnerships going on out there. I saw some people today that FDA has been partnering with for years. It was great to see them. Also, to leverage best practices that are already out there. There are a lot of really good food safety culture behavior best practices.

And also when we leverage, we also need to look at things that exist, standards that exist. There's data standards, there's ISO, there's Codex. We don't need to reinvent the wheel. Food safety work has been going on for generations and we need to leverage what is currently available to us.

And then education. We all need to be educated. We all can learn from each other. We all can teach each other, particularly with a focus maybe on the smaller producers who produce a great deal of the food that we consume.

And there was also -- I think you've heard it before in the public comments -- there was a plea to do as much guidance work as we can at FDA and kind of help translate that legalistic -- some of those legalistic things, that, as a lawyer, I think are just fine, but as people that have to implement them every day, it may not be quite so clear. So clarity I think and communication are also important. So that was it.

MS. BARRETT: Great. Thank you. And Jim, we'll go to you.

MR. GORNY: Yeah, the group that I was leading with Sharon Mayl and Joann Givens was the smarter food -- smarter tools and approaches for prevention.

There was just a general acknowledgement that this is the time to really be looking at new era of food safety and new concepts and what can be done and

taking those concepts that were presented to us earlier in the day, trust and transparency, and really getting down to the nitty-gritty.

I would say it fell into three categories. One is safeguards, the second is data, and the third environmental assessments and root cause analysis based on the questions that we had posed.

With regard to safeguards, there was a general concern with regard to data sharing and some challenges or constraints or barriers to that. And how do we get over those, you know, with regard to private information being shared with a public agency and vice versa, voidable information and limiting liability with that regard.

The second thing is in that area with regard to this data sharing challenges is retro -- a fear of retroactive investigations and the discussion of a statute of limitations, because someone could be, you know, brought into a specific issue and they weren't even at the company based on data that was, you know, generated years ago and maybe popping up again.

With regard to data itself, I think we've heard a lot of the themes that have been talked about in the public comments. We well recognize that there's a veritable treasure trove of existing data and we need to get started now, as Ian Williams said. I think both from an FDA and industry perspective there was a tremendous recognition of that.

And then it comes down to the types of data, whether it's aggregate data or firm specific data. You know, what are we going to analyze for with regard to macro trends versus specific information for a specific company? That's an important thing to sort out very quickly. And really the need to be clear as to what data will be most helpful to push the ball forward with regard to improving food safety really needs to be clearly defined so that we're not just collecting data to collect data.

And then we've heard a lot about it today, which is data standards, interoperability, accreditation. All those were tremendous buzz words that we heard today with regard to important concepts

with regard to the data itself and ensure that activities are accurately and precisely being defined.

And then with regard to environmental assessments and root cause analysis, speed, a promise of those, providing a dialog between FDA and industry with regard to more details about environmental assessments and root cause analysis, and then what are the expected outcomes if a company does a root cause analysis, corrective actions, verification.

And last but not least, we heard from our state partners about regulatory inspections and public health actions. Currently, the cooperative agreement that FDA has with the states to do -- for example, Produce Safety Rule inspection really predominantly deals with inspections and really what's the public health role of agencies, and there should be additional funding there. So that's it in a nutshell.

MS. BARRETT: Great. Thank you so much. And Laurie, we'll go down to you.

MS. FARMER: Sure. I want to thank all of you for your participation and also recognize my co-facilitators, Sharmi Das, Glenda Lewis and Mary Lee Hannah

In the adapting to new business models and retail modernization, there was a real big theme around harmonization globally and utilizing best practices that already exists. So I heard earlier: "Don't reinvent the wheel. If it's already out there, let's look at it and consider utilizing it." Establishing a consistent and common standard as a level playing field, I heard that several times today.

Clearly, defining regulatory jurisdiction, for example, standardizing consumer complaints and how those are handled. Like when you receive a product that's out of temperature, who will you go to? How do you maneuver that feedback?

Research. You know, there's already a lot of research in the arena of delivery methods, temperature controls, food packaging and weather tracking and cleaning and sanitization. But there was a desire for FDA -- communicated for FDA to identify the landscape of research. Potential research included reusable

containers, lab methods providing quicker results.

Developing models for commodities, for shelf life and shelf stable products. So smaller industries asking for support from FDA. Best practices for tamper resistance and the impact of shared kitchens. And a big part that we're here today because of this and -- the recognition of the need for collaboration. And we can do that with all of us here, but include academia to validate existing systems and to conduct research.

FDA identify best practices, an example is in the area of cold chain. And leveraging third-party groups that already exist like GFSI. And improve or expand existing guidance.

And there was a discussion this afternoon about other countries that have established best practices and industry capacity building.

And the last mile food safety training for industry and food delivery was emphasized. Recognizing -- rewarding foods that -- positive food safety culture behavior. Collaborations on calibrating and being consistent with inspections and auditing. Establishing single standards and educating ourselves -- I heard that repeatedly.

There was an interest in having an industry focus group to discuss food conversions, including the gaps and challenges. And do not create trade barriers was also communicated.

MS. BARRETT: Thank you, Laurie. And we'll go down to Katie.

MS. VIERK: Hello. I was co-facilitator in the tech-enabled traceability and food borne outbreak response sessions. My co-facilitators were Vinetta Howard-King and Kari Irvin and Charlie Pastel (ph). And I want to thank them and all the participants in those sessions for some really good conversation and discussion.

There were a lot of comments regarding, as we've heard from some of the others, establishment of standards as well as communications around that and considerations for FDA as we move forward in this initiative.

So we heard that creating data standards is

critical and communicating the minimum data elements needed for traceability is important as they are not currently required. So really doing some communicating around what is truly needed.

The importance of interoperability and technology systems and considerations for sharing sensitive data along the supply chain need to be addressed.

It is important for all points throughout the supply chain to collect the data and speak a common language. So that was definitely something we heard. As well as it's difficult for companies to be keeping track of things like the various systems that are being used by their various trade partners, and so that interoperability and data standards will really be key in helping that.

On communications, we heard that stakeholders would like to have regular and frequent meetings with FDA, especially during outbreaks, as well as more education on new technologies such as whole genome sequencing.

Timeliness of communications is key and sharing information and results helps firms in their decision making. So they would like to have more timely conversations with FDA.

We heard that industry would like help in understanding what is needed for traceability and what would be helpful and worth their investment and their cost there to advance traceability.

Companies would also benefit from a roadmap or recommendations on what they could do to start on their journey for traceability and what FDA suggest they do to get started.

And mentioned a lot was better communications needed between agencies -- not just better communications, but better communications with regards to sharing of data.

So many considerations were also voiced. FDA should consider all parts of the supply chain when thinking about traceability, and technology, including the size of firms, complexities of various industries as well as the complex practices within industries.

It was mentioned that traceability is costly and options for firms need to be provided. FDA should work to develop ROI models and consider incentives for firms.

So incentives were discussed kind of in general terms and they were mentioned as being needed. And we had some ideas around that, such as tax and insurance breaks, but I'm hoping we can get some more specific examples in the written comment period.

It was also voiced that options to help industry stay competitive but also work together would be helpful.

Finally, FDA should stay focused on the end goal of traceability and consider how traceability can be kept simple and easy, especially for farms and small firms.

So as I mentioned, we look forward to hearing from the stakeholders during the comment period and your written comments. And I especially like to ask for more information on two items: specific ideas on incentivizing adoption of end-to-end traceability and what FDA can do to support that, as well as what your specific challenges are in creating a more digital and traceable food supply and how -- what approaches FDA can help take to move that forward.

I think providing real life examples from your challenges really helps us to understand what approaches we can take to help in those efforts.

MS. BARRETT: Great. Well, let's give a round of applause.

(Applause)

MS. BARRETT: Really excellent summaries. Thank you so much. And I just again appreciate you being able to really wrap that up for us and provide those summaries.

And now it's my pleasure to bring Deputy Commissioner Yiannas back up for our end of the day wrap up.

WRAP-UP AND NEXT STEPS

MR. YIANNAS: Okay, we're in the home stretch now. What an amazing and informative day. I don't know if you feel that same way. I started off the

morning by saying this was going to be a great day. Well, did we meet your expectations? I think it's been more than a great day. To me, it's been what I would call a historic day. I genuinely view this as a major milestone on this journey towards a new era of smarter food safety.

I'm going to keep the comments brief. But one of the things I like to do in the last few minutes that we have left, thank a few groups. Number one, I would like to publicly just thank all of the FDA team members that have worked so hard over the past few weeks to make this meeting a success. There were a lot of FDAers working behind the scenes. Being new to the public sector, I will tell you it remains an honor and privilege for me to work with them. So I just want you to join me in thanking the FDA staff.

(Applause)

MR. YIANNAS: Second, but most importantly, I do want to thank each and every one of you, and I mean that sincerely. We realize there's a lot of things you could have been doing today, but the fact that you took time out of your schedule and traveled to be here with us has not gone unnoticed and we really appreciate that.

Rest assured that the comments that you've given us will be used. I've heard a lot of things, a lot of things that I had not heard before. And without question, it was time well spent.

We will use the input clearly that we've gained through the internal brainstorming sessions that we've had at FDA, but we also will use the comments. And we encourage you to submit additional comments in writing through the public docket, which, as you've heard, will stay open until November 20th.

We've heard so many good ideas and they've strengthened my belief that we will make better food safety decisions on the big food safety issues of our day when we work together.

Today reminds me of something that I read several years ago in a book called The Wisdom of Crowds, but I thought I saw it in reality living and playing out today. In that book, author James

Surowiecki said: "Listen to this. Under the right circumstances, groups are remarkably intelligent and often smarter than the smartest people in them."

There's a lot of smart men and women in this audience, but I think collectively we are smarter together. And so you see -- for me, it's been strengthened this idea that smarter food safety is smarter when we collaborate.

We've heard great ideas from people in the public sector. We've heard some great comments from folks in the private sector. We've heard consumer groups represented and some of the tech firms. Each one of you is making a difference in food safety, I know that, and you will continue to do so, and you should, and we're thankful.

But what's crystal clear to me, no matter where you sit in this room, when I see folks from various sectors and stakeholder groups, that there's more we can do together than by working alone.

We're all working for the same boss, the American consumer. And so let's get on with this journey of a new era of smarter food safety together because consumers are counting on us. Thank you very much. More to come.

(Applause)

MS. BARRETT: I don't think there's anything to add to that except to have a wonderful evening and safe travels. Thank you again.

(Whereupon, the meeting concluded.)