FDA's Final Rule on Requirements for Additional Traceability Records for Certain Foods

Monday, October 7, 1pm to 3:30pm ET

Agenda

Welcome

Susan C. Winckler, RPh, Esq., Reagan-Udall Foundation for the FDA

Susan Winckler (00:04:04):

Hello, and welcome to the virtual meeting on final requirements for additional traceability records for certain foods, as required by the Food Safety Modernization Act, or what we will call the Food Traceability Rule from here on out.

(00:04:17):

I am Susan Winckler, and I serve as the Chief Executive Officer for the Reagan-Udall Foundation for the FDA, and we are pleased to collaborate with FDA to convene this public meeting.

(00:04:27):

For those of you who are new to the foundation's work, we are the nonprofit, non-government organization created by Congress to help the FDA do more to protect and promote the public's health. One way that we do that is by convening meetings like this to help the agency share information and hear from stakeholders about important issues. These engagement opportunities help inform the agency's work. Of note, the foundation does not advise the FDA on regulatory decision-making.

(00:04:59):

Before we begin our meeting today, let's address a few housekeeping issues. Because of the size of the meeting, attendee cameras and microphones will remain off throughout the event, with one significant exception. Those of you who confirmed in advance to present stakeholder comment will be granted access to unmute and transmit your video during the comment period. We are recording the meeting and we'll post the recording, along with the slide deck and transcript on the foundation website, reaganudall.org, a few days after the meeting. We will also post all written comments received at final rule at reaganudall.org after the October 25 deadline passes.

(00:05:41):

So let's take a quick look at our agenda. In just a moment, we will hear opening remarks from agency leadership, and then turn to a panel discussion, with experts from across the food supply chain, about their experiences and perspectives on implementing the Food Traceability Rule. Then we will move to a critical part of our meeting, hearing perspectives from you. I thank everyone who requested the

opportunity to provide public comment. We were able to accommodate all requesters, which might extend our meeting by just a little bit, but I think we'll fit everyone in within the allotted time.

(00:06:17):

Now here is some detailed information about how the public comment section will operate. We have about 25 individuals slotted to speak, and each will have up to three minutes to present comments. We will begin the public comment at about 2:00 PM, in alphabetical order by speaker last name within each of the designated topic areas. As a reminder, the topic areas are traceability, lock codes, and labeling, implementation, schedule, and awareness. The third is warehouse management systems and technology. And the fourth is pilot or concept testing.

(00:06:54):

As we proceed through the public comment, I will provide a rolling list of three speakers. So with the exception of our very first two speakers, you will hear your name twice before I call on you to present your remarks. For example, we will begin in public comment by announcing that our first three commenters are, hypothetically, Jane A, Jane B, and Jane C. I will then call on Jane A to present her remarks.

(00:07:19):

When you hear your name for the first time, please use the raise hand function so that we can more quickly see you. And when the speaker before you concludes their remarks, unmute yourself. I will note, when you hear your name the second time, turn on your video, and then you'll have that step out of the way. When you hear your name the third time, that's when you should unmute. Our producers then will highlight you when you are introduced to speak.

(00:07:46):

Our speaker coordinator is reaching out to you now. If you have not heard from her, please send a chat to the hosts and panelists. So now we can take a deep breath, because I think we're ready for the public comment period at the end. But we have important material to present before then. Specifically, let's move to the substance of the conversation, and welcome to our stage, FDA's Deputy Commissioner for Human Foods, Jim Jones, who is here to help us kick off the meeting.

(00:08:14):

Deputy Commissioner Jones, the floor is yours, and thank you for joining us so early into the major reorganization that is now real.

Opening Remarks

Jim Jones, MS, Deputy Commissioner for Human Foods, Food and Drug Administration

Jim Jones (00:08:25):

Thanks so much, Susan, and good afternoon, everyone. First, I want to extend my appreciation to the Reagan-Udall Foundation for hosting today's public meeting. And thank you to everyone joining this meeting today, in particular, our panelists.

(00:08:40):

The Reagan-Udall Foundation has been a tremendous partner to the FDA in helping bring together external stakeholders to share insights, expertise, and perspectives on the challenges and opportunities for industry in meeting the requirements of the traceability final rule.

(00:08:57):

There are new and unique aspects of this rule, as compared with other FSMA rules. By requiring the sharing of product traceability information between members of the industry, and between industry and the FDA, that haven't been required in the past, firms must establish new communication platforms as well as implement significant changes to processes and procedures. There's a degree of complexity to implementation, and even more so, for those foods that pass through many hands between the farm and the point of sale.

(00:09:28):

It requires a high degree of coordination across manufacturers, processors, packers, holders, and sellers of food on the food traceability list to maintain and share the required information. The foundation-led round tables with industry were critical to increasing our understanding of the challenges different sectors of the food industry have encountered as they have worked to meet the rules requirements.

(00:09:49):

This added visibility into these challenges is the best way for us in the human foods program to ensure solutions that work for as many covered entities as possible are identified. There's no question that this is a heavy lift, but this is a rule whose time has come. For each foodborne illness outbreak, by meeting this rule's requirements, we will be able to remove contaminated foods more swiftly and efficiently from the marketplace.

(00:10:17):

This will allow us to improve public health through the prevention of illness and death, as well as prevent the tremendous waste that results from recalls that are overly broad.

(00:10:28):

I'm encouraged that we will get to where we want to be with this rule. We know from our many interactions, that industry recognizes the importance of traceability. And as we apply what we've learned through earlier industry efforts, we can see a future where traceability across those foods on the food traceability list enables us to work together to reduce the number of people that become sick or die from foodborne illnesses.

(00:10:51):

With today's public meeting, we will hear from those of you who are working to implement the rule, as well as those of you outside the industry who also have a stake in the safety of the US food supply.

(00:11:04):

I believe that the best decisions come from hearing all points of view and collecting as much data as possible to lead us in the right direction. And getting input and information from those in the research and consumer and health sectors, as well as from consumers themselves, is critical to our understanding the applications of the latest technologies and having access to the wide range of perspectives that can help inform our regulatory approaches.

(00:11:29):

We appreciate your being here to help advance our goal of a safer food supply, and myself and my team are looking forward to today's meeting. Thank you.

Susan Winckler (00:11:40):

Thanks so much, Deputy Commissioner Jones, and it's been so interesting and informative to work with you and your team on these discussions and in this meeting. And I know we're going to find the further

discussion even more illuminating today as all of the efforts that are going on to implement this rule. So thank you so much for joining us.

(00:12:01):

Panel Discussion
Panelists:
Karleigh Bacon, PhD, McDonald's

Jodi Blanch, MS, Gorton's Seafood

Johnny McGuire, The Nunes Company, Inc & ProduceSupply.org

Sarah Sorscher, JD, MPH, Center for Science in the Public Interest

Lindy Wiedmeyer, MPH, REHS, PCQI, Sendik's Food Markets

And with that, we will turn to the next portion of our meeting, which is a discussion with a collection of members of the food supply chain. And they are going to provide us some insight on the complexity, and what I would call the nitty-gritty of the systems changes required to generate the necessary information that Deputy Commissioner Jones just mentioned.

(00:12:20):

I welcome our panelists to the virtual stage, and we are going to jump directly into our conversation. So let's start towards the beginning of food production, in one of the first stages in the first traceability requirements.

(00:12:36):

For that, I'm going to turn to Mr. McGuire. You have two roles where you are actively working on traceability. As director of information technology for Foxy Produce, and as Chief Operating Officer of ProduceSupply.org, which is a consortium of some of North America's leading produce suppliers, who are working to facilitate technology adoption in the produce supply chain.

(00:13:01):

What are the two or three items that are top of mind for you as you think through implementation of this rule?

Johnny McGuire (00:13:11):

Good morning, Susan. I'm in California, so it's still morning here. Firstly, I want to just thank you, and Reagan-Udall, and FDA for hosting this very, very important discussion, and your willingness to work together with industry, with that critical end goal of keeping consumers safe, and producing good food, and keeping producers safe.

(00:13:37):

So as I look at two or three higher level top of mind things, as we're very much embroiled in the implementation of FSMA 204, the first thing I think about as a real positive is the success of the Produce Traceability Initiative. As we look at the growers shipper end, upstream, and the supply chain, we should be very proud of how far we've come, already, with traceability and the development of an adoption of PTI standards in our businesses.

(00:14:10):

When I started, I'm in Salinas, California on the central coast, the salad bowl of the United States. And when I first came here, probably 20 plus years ago, every case of produce on the field trucks coming by had these little bread stickers on.

(00:14:26):

Now I'm very heartened to know that there's a traceability label front and center on all that produce, and all that can be linked to digital records already. So I guess my point here is an appreciation, that the FSMA 204 implementation framework is really based on a lot of the existing standards for case and pallet labeling, and data interchange, and work that was done some time ago. We've still got a lot of work to do, but I'm happy that we have the base. So that's really, on the positive side, that's one thing that I'm top of mind for me.

(00:15:08):

A couple of other things that, more that are keeping me up at night a little bit is, I think for growers, it's really important for us to leverage the existing frameworks that we have in place. Although this is an opportunity to apply technologies and new technologies, we want to be careful with too much of that. As an IT manager with that hat on, we've got a lot of different requests coming in from trading partners for different different integration points, that kind of thing.

(00:15:48):

But we have very robust existing frameworks, particularly around EDI, that we can leverage with our trading partners to share data forward on these critical tracking events, where we actually need to, receiving and shipping where we need to actually share the data. So I think that's one concern that keeps me up a little bit, is too many portals, too many integration points is going to be untenable for us. And we have a lot in place already. We want to leverage that as we look at FSMA 204. A third thing, I think, do I have time for a third thing?

Susan Winckler (00:16:27):

You do.

Johnny McGuire (00:16:28):

Is really data interoperability. As growers shippers, we do a lot of buying, selling, and trading from each other. So if grower one is short of a product, broccoli, then we're going to go to grower two and we're going to buy that broccoli for them. And each of those transactions represents a critical tracking event, or a shipping and receiving event, where we have to share forward and store that information. My concern with that is, unlike outbound to our trading partners and our customers, there's not a lot of digital interchange in place there.

(00:17:10):

So we're relying on very much paper-based systems. And now when the product shows up at our distribution centers, at our coolers, the information we're getting is a piece of paper, that's probably poorly written, and probably could have errors on it. And now my receivers have got to go and they've got to punch in all that information. We've got to take that information, store it in our systems, and then pass it forward to our trading partners.

(00:17:41):

I have a concern about that. With data entry errors, there's a lot of data around that, that just that happens. And my concern is, are we making the traceability a little more fragile there? We have existing traceability in place we're very proud of, where if we're buying and selling behind the scenes, with other

growers shippers upstream, then we know exactly where that product came from, who to contact. We know that one step back. And I'm just concerned about now, with really tying those pieces together, that that's going to make us a little bit more fragile. So that's one concern I have going here.

(00:18:25):

But I think that the success of PTI, certainly on the grower shipper side, has put us in a very good position, to take on the new requirements for FSMA 204.

(00:18:37):

Again, the importance of using what we have now. We do EDI transactions to all our customers every day. Let's use that. We've got specifications that we're building, where we can do that. Let's leverage those existing frameworks. Rather than going berserk with all these new technologies, RFID, that kind of thing, let's use what we've got. And then, on the grower shipper side, we've got work to do to work out how we're going to get data into our systems, how are we're going to send data to other growers who are buying produce from us, and that kind of thing. So two or three things for you, with both my hats on, that concern me.

Susan Winckler (00:19:18):

Yeah, really helpful. And particularly, as you reminded us, you start with a good base, which then gives you some existing frameworks, and to think through how to best use those. As you have. You're also trying to incorporate additional information-

Johnny McGuire (00:19:37):

That's right.

Susan Winckler (00:19:38):

... like the information that you get from your growers. And I hear you on the potential fragility and data entry.

Johnny McGuire (00:19:46):

That's right.

Susan Winckler (00:19:46):

So thank you for painting that picture for us. So we know a little bit now on the produce side, let's turn to another affected commodity, and I'm going to turn to Jodi Blanch. Will you do, Ms. Blanch, and then I'm going to turn to first names as we proceed through our conversation. But you have a seat at Gorton's Seafoods, where you're Senior Quality Assurance Manager of Regulatory Affairs & Compliance, which I think might be shorthand on your business card as having a control panel perspective, or at least control panel awareness, of what's involved in implementing the traceability requirements. What two or three items would you call out as important in the seafood space?

Jodi Blanch (00:20:34):

Yeah, thank you very much. I do appreciate this time to be able to speak today on the new upcoming traceability rules, specific to the seafood industry. Many people may or may not know, but the vast majority of seafood consumed today in the United States is imported, and it's imported by over 120-50 countries. So per the law, the importers themselves are exempt, making international outreach by FDA critical in terms of scope and timing.

(00:21:04):

Gorton's, as well as other seafood producers, are notifying and training their own importers as well, their own suppliers, of this upcoming law. At this point in time, we are mostly the ones swimming upstream, to train our importers and suppliers, then swimming downstream to train and work cooperatively with our warehouses, all while treading water to do what we need to do ourselves. This outreach and training is a big burden on top of what we ourselves need to do legally to comply with the law.

(00:21:41):

The new law is very large, that it took a lot of time to understand what is needed to comply, as well as all the allowed exemptions. Gorton's has been working on this for over a year, and is now in the process of designing or purchasing new systems that need to be put in place in order to comply with the law.

(00:22:02):

As you have heard from others in the food industry, as well as you'll hear from other panelists today, IT systems need to be designed to handle the required key data elements. Most current IT systems, including warehouse management systems, are older and either need to be updated, if that's even possible, or scrapped. I'm going to share just one example of an IT glitch that we just occurred. We had told our warehouse that for our TLC, our traceability lock code source, we will use the widely accepted global location number.

(00:22:40):

And they said, "Great." I said, "That's good. Our new GLN number is 13 digits." And they've replied, "Well, not so great. We can only handle eight digits." They don't have space to accommodate a standard number that could be used. And to complicate it, we ship it to five of their warehouses. So now they have to figure out how to update five different systems that receive our product.

(00:23:07):

Changing to a different area of the supply chain, retailers. We have been notified by two large retailers that they are mandating key data elements for all foods. Foods like pickles, chips, pretzels, and salad dressings, not just the ones on the FDA food traceability list. I am sure this was not FDA's intention, and one example specific to seafood is canned tuna. Canned tuna is legally exempt from the law, due to the canning process, but these retailers are not assuming it is so.

(00:23:44):

So the food industry needs to meet customer requirements, as well as FDA requirements. So this extra demand by some of the retailers is putting resources and money where it's not needed. These retailer requests are coming in late, and now companies that thought they were exempt are not, at least by the retailer standards. And to add further complication, these retailers are demanding earlier compliance timing date than the FDA of January 2026.

(00:24:19):

And lastly, some retailers are demanding that suppliers like Gorton's use specific third party software to transmit the key data elements. Each software platform has their own cost, often large, and their own way of accepting the data At this time, many of the third party software platforms are not able to accept the same data in the same format, meaning that we will have multiple systems, yet to be determined, or have to manipulate the data differently for each of these third party platforms. So thank you very much.

Susan Winckler (00:25:00):

Jodi, you packed a lot into those three examples there.

Jodi Blanch (00:25:02):

Yes.

Susan Winckler (00:25:03):

And I just have to applaud you, what a brilliant metaphor. Johnny, I just don't think you could do that in the produce field-

Johnny McGuire (00:25:09):

No.

Jodi Blanch (00:25:09):

Yes.

Susan Winckler (00:25:09):

... the way that Jodi could bring us literally-

Jodi Blanch (00:25:12):

Swimming.

Susan Winckler (00:25:12):

... into the stream. Yes, literally swimming there.

Jodi Blanch (00:25:14):

Yes.

Susan Winckler (00:25:15):

But really helpful examples about the systems that require updating, some of those limitations, and then the real impact of that there's a requirement. And then when players in the supply chain broaden that requirement, then you've complicated it. It strikes me that then you're upstream or downstream, you're swimming upstream again, and trying to broaden that reach. So very, very helpful.

(00:25:52):

And then, of course, the dynamics of being required to use certain software. That really helpful, but it tells me we need to move to another stage in the supply chain. So let's keep moving through that supply chain, to a place where entities are working with even more products, and traceability requirements, and suppliers. And so for that, we're going to turn to Dr. Karleigh Bacon.

(00:26:17):

And I just have to say, I'm going to guess that you consider a lot of things when you sit as Director of US Supply Chain Food Safety & Quality Systems for the McDonald's Corporation. Your highlighted items might be slightly different, but I think we're going to start to hear some resonance. But why don't you share your couple of items?

Dr. Karleigh Bacon (00:26:43):

Yeah, happy to. And thank you so much, Susan, and to the Reagan-Udall Foundation, to the FDA, for giving us the opportunity to talk about this very important topic and something that I talk about, feels like non-stop these days. So happy to do it, happy to be here, and to speak a little bit to McDonald's, and how we're thinking about what we call FSMA 204, or the traceability regulation.

(00:27:07):

And I do think that you'll hear some common themes as we work through this, so don't be surprised at all. Just a little bit of a reminder of where McDonald's sits on the supply chain. In our position, we are a restaurant, so we're at the very end of the supply chain. So all of the stuff that we've talked about so far will eventually be passed down to McDonald's as a receiver. You may be surprised or interested to know that we do not produce any product or manufacture any product that comes to our restaurants.

(00:27:42):

So we receive the product and we receive the data. So that's the position that we're looking at it and trying to ensure our compliance in that respective. And that really goes to the importance then of the data that's coming in. We need for it to be valid and true, and we need to be able to work with and link with all of the other nodes within the supply chain in order to receive it.

(00:28:08):

In particular, everything that's associated with the traceability lot codes that we've heard about already today. And thinking about how this data flows from the supplier, and all the information that goes into the supplier node to start with, and then moves from the distribution center to the restaurant. Again, the focus on that traceability lot code and how we're all working together to ensure that there's seamless transition, there's a very strong reliance on our end, of our upstream partners to execute and communicate this accurately.

(00:28:43):

And we want to emphasize that the transfer of this data has to work across each of these partners. So I know that we don't have anyone on the panel today representing the distribution center, but also a very important piece of this whole puzzle, as they both receive and ship product that we would be next in line for.

(00:29:04):

Another thing I wanted to highlight, that Jodi has already spoken to a little bit too, and how we're looking at it from our lens, is dealing with products that are on the food traceability list. Because we do receive products that are both on and not on the food traceability list. And so we have that decision that we have to make when it comes to how are we going to approach this with the system. Managing two systems and maintaining the products that are on that list can be very challenging.

(00:29:35):

A lot of the products we receive are regulated under USDA, or they're regulated by FDA, but they're on the traceability list. So it really is important that you come up with a solution, I guess for us, that works seamlessly at the restaurant level, again, at the distribution level as well, to be able to manage these systems. And it could be really difficult and challenging to decide how you're going to approach that.

(00:30:03):

The other thing I wanted to talk about was a little bit about the data itself and the collection of data. And I think that you will hear these trends resonate again and again, but the key areas of focus are the ability to collect that data that we receive. And one of the very first things we did when we started thinking about how we're going to tackle compliance to this regulation, were just to pull together some workshops.

(00:30:31):

And so we pulled together a group of our distribution centers, sat down with them. Additionally, we pulled together a handful of our suppliers and sat down with them. And we said, "Okay, what data do we have at our fingertips right now? Does the data that we need exist? Is there additional data that we need to capture that we're not currently capturing? What does it look like? What data systems do they sit in? Who owns that data? And additionally, if we needed to pull this information quickly within a 24-hour timeframe, and get it into a format where we're actually putting it into an electronic sortable spreadsheet, what does that look like?"

(00:31:11):

The very first thing we did, where is the data? How quickly can we get it? What are our challenges in pulling that? And try to come up with a solution, working from what Johhny had already talked about, the systems that we already have in place. And then once we have that, how do we build upon that to get where we would be comfortable for compliance to FSMA 204? And when you think about FSMA 204 compliance across the industry, it's not necessarily going to be a one size fits all solution. We're all going forward and trying to figure out what problem we're trying to solve. And it's the same problem, but we're probably going to do it in different ways. So each different node of the supply chain, those are different independent businesses, different data management systems, different ways to name and transfer data, which we've already heard about a little bit. So trying to solve for this and connect the data quickly and efficiently, making sure we're able to recover, share, and ultimately execute on something if there is action needed, is ultimately where we're trying to land.

(00:32:13):

So our suppliers and our distribution centers have other customers. It's not just us. And they're in service to many people who are watching, or listening, or not. But again, we're not their only customer, and we understand that there are a lot of pain points that may come to being compliant, which each of the customers requests. So as we try to create a solution to the same problem together, we just are very aware of the high levels of communication that need to take place, the collaboration across all nodes of the industry, and each part of the supply chain, because we can't work this in isolation and have everyone come out successful.

Susan Winckler (00:32:57):

Karleigh, really helpful. And I think you've triggered for me, a theme that I think we're going to come back to after we've heard everybody's initial voice, and that's that idea of that collaboration. Because I'm hearing it, I'm sensing, as Johnny was talking about pieces of paper he's going to be taking from his growers, you're thinking two or three steps later when that's coming into your restaurants, and how did that information move?

(00:33:27):

And similarly, the information from Jodi's imported product, and what's there and what's not. And also, appreciate you calling out somewhat of the complexity of having a list, and that it's an advantage to have a discrete list that you're working against, but it also then says you're collecting a lot more information about the things on that list, and you have a whole other set of products that you are also collecting information but in a very different way, and perhaps some of the tension that's created there. Did I hear that right?

Dr. Karleigh Bacon (00:34:04):

Yeah, that's right. All the considerations that come with that, absolutely.

Susan Winckler (00:34:08):

Yeah. Okay. So let's pivot from restaurant, and turn to another important consumer-facing stage, and that's the grocery store, the retailer. So joining us from Sendik's Food Markets is Lindy Wiedmeyer. Lindy, you are the Food Safety & Sanitation Manager, and you've heard the comments as we've been leading to you. What are the two or three things that are top of mind as you think about Sendik's efforts to implement the Food Traceability Rule?

Lindy Wiedmeyer (00:34:42):

Well, I want to thank Reagan-Udall Foundation and the FDA for allowing me to participate on this panel. I think it is a tremendous opportunity for all avenues of the supply chain to get together and put out their thoughts and ideas. And I know with Sendik's being not one of the larger grocers and not one of the smaller ones, we're right there in the middle, we buy directly from a large number of vendors and usually particularly in areas of produce or seafood. But unlike the larger grocery stores, we usually rely on a smaller number of large wholesalers. Because of our direct buying model, it allows us usually flexibility and freshness, but it somehow complicates our traceability efforts because at a store level, the technology, the abilities of those vendors, we have small local vendors that we purchase from. So helping them become compliant with FISMA 204. They may not have that ability to implement a UPC code or a QR code and create that lot to go back from where they got it.

(00:36:16):

Our stores' production departments, the deli mainly is one of our very large areas that creates items off of that FTL list and transform them and then get shipped out to other stores. So while there's many benefits in that process of creating pasta salads or sandwiches and shipping them to other stores for freshness, it includes a lot of clerical work for accurately identifying and capturing all of those ingredients in a lot code and then generating those new lot codes. So we struggle very much with trying to get the consistency, the accuracy amongst the staff. I mean it's going to be a warehouse to a store, to an associate scanning items and creating another lot code.

(00:37:23):

And we also deal with, because we have our own distribution center, we still pick by pen and paper and creating with vendors coming in. If one person, and I think that Karleigh mentioned this in hers, the different types of ways that lot code information is transpired to us through those other vendors and trying to develop a system that creates a very large cost for us. I think those are two of the main things that we look at is just the consistency and accuracy amongst our staff and our associates. And then creating and working with a lot of those either local vendors or wholesalers.

Susan Winckler (00:38:22):

Right. So that's really helpful, Lindy, particularly illustrating that dynamic of when the food's transformed in your deli and then you are creating, you need that information and are sharing it as well as appreciate the voice you're giving to the distribution center dynamic and how do you move that information to your stores and then the staff piece. So thanks for that illustration. I was trying to come up with your equivalent of Jodi swimming upstream and I'll get it before the end of our conversation. We'll pull that together.

(00:39:02):

So let's turn to the one person who I haven't turned to yet on this panel and providing perhaps the most important voice because it's the individuals for whom all of this work is being done and that's the food consumer. Sarah Sorscher, we have asked you to give voice for the consumer perspective from your role

as Director of Regulatory Affairs at the Center for Science in the Public Interest. The consumer is at a slightly... Your view is looking back at all of the information that's been collected, it's just looking at it from a very different perspective. So what would you highlight as important in this process and what benefits consumers might or should see or we hope to see from the results of the rule?

Sarah Sorscher (00:39:55):

Well thanks, Susan. That's a great question and I really appreciate you giving me a seat at the table here to represent the consumer voice. We're all consumers, but very few groups directly represent that voice and interest in these high-level policy conversations. And that's the work that we do at Center for Science in the Public Interest. My organization, we were actually one of the leading groups that headed up efforts to pass the Food Safety Modernization Act, which required this traceability rule. And that was signed by the president nearly 14 years ago. We're coming up on 14- year anniversary for that bill.

(00:40:33):

It's frustrating to see that while some sectors like the produce sector have implemented complete traceability for their sector, we still have businesses particularly further along the supply chain as we move closer to the consumer that are only now moving to fully implement traceability. And for us, for everyday shoppers, this is sort of common sense. We live in this era of big technology when our own activities are constantly being tracked and traced by companies to sell us products. And we figure you ought to be able to figure out where a bag of lettuce came from.

(00:41:09):

But I think sadly, when it comes to actually investigating these outbreaks, we often don't have that information because it's been lost. And that has two impacts on consumers. The first is that we have contaminated food that circulates for longer and people keep eating it. And that's because if FDA is struggling to find the source of an outbreak or if companies are struggling to figure out where the food was shipped, that's hours and days and sometimes it's weeks or even months when the food is still there on the shelves, still being put on people's plates and folks are still being exposed, and that's more people being put in the hospital and some of those people are potentially not making it home because they ate that food.

(00:41:57):

And the second impact that we have is that if FDA and CDC can't find a single source and they're forced to issue a broad public warning as they did, they've done it in the past multiple times, but I think one of the most memorable and recent memory, at least for me, is the 2018 outbreak when CDC and FDA warned against eating pretty much all of the romaine lettuce in circulation in this country, unless you could verify that it hadn't been grown in Yuma, Arizona, which most of our lettuce was coming from in that period, and that was because people were dying of E. coli poisoning in multiple states. And it seems like ages ago now, but I think many of us still remember seeing those completely bare lettuce shelves in the grocery store due to this outbreak. And those are the types of images that tend to stick with us.

(00:42:45):

I don't know about other listeners on this meeting, but I still think twice when I buy romaine lettuce. What season is it? Does it look okay? And unfortunately, a lot of the foods that have made it to that traceability list because they're hard to track, are also the foods that Americans are already under-consuming. So it's the lettuce, the fresh fruit, the vegetables. And the last thing that we need as consumers when we're looking at a menu and choosing between the salad and the french fries for our meal is that thumb on the scales against the salad. And the cost to our health of this loss of consumer confidence in the fresh fruits and vegetables has never been calculated, probably cannot be calculated.

But given the high rates we have of chronic disease in this country with one in five US deaths now being from heart disease, which is a diet-related condition, that negative impact of this lost confidence is very well potentially higher than the initial impact of the outbreak itself and the illness we have from it.

(00:43:48):

FDA has made it very clear and they built the case exceptionally well in the rulemaking docket for this rule that it is essential that they have the lot code information in order to solve these outbreaks faster. And so that's what this rule will provide. With those codes available, outbreaks can get solved in hours or days and without that information it can take weeks and many outbreaks are never traced back to the source and solved. So the key thing that this rule does is that it supplies that lot code information and that is what's going to make the difference for consumers.

Susan Winckler (00:44:29):

Sarah, really helpful to remind us so that we can do a better job of finding the causes of an outbreak of foodborne illness and being more precise in that information so that there can be an emphasis there. I hear you on the romaine and recall that dynamic and there've been other situations where it simply would've been helpful to, not simply, I'm not allowed to say simply on this call because there's not a simply here, right? This is a complex set of data, but reminding us that we do want to get to a better sense, have better information and for the agency to be able to trace the source of a problem.

(00:45:26):

Which brings me back to, I heard from each of you say something about interdependence or collaboration or data sharing and information, and it just seems that if we want to deliver on that promise of improved traceability of certain food products, which is the promise that Sarah was just speaking to, we have to have a lot of collaboration to do that. So I'd love to hear some thoughts on where collaboration will make the most difference. And for that, let's start somewhere in the middle and do grocery and restaurant perspective. Lindy, do you want to go first and then we'll turn to Karleigh?

Lindy Wiedmeyer (00:46:09):

Sure, I can do that. I think collaboration is a huge part of anything for us in food safety and working to make sure that we are putting out safe food, whether starting with a grower or a restaurant or a grocery store. And I think that a good place to start is doing a staged approach and collaborating and working... You can't start something right in the middle and expect everybody to adapt. Starting from the beginning and working our way forward, it helps us take into account all the numerous amount of variables that are going to show up with either certain suppliers using a UPC code or a QR code or any means to import their data into that information or in that little data that they put on their shipments.

(00:47:19):

And for smaller stores, smaller restaurants, retailers who may need to adapt to that and either employ more employees just to handle that or multiple technologies just to... If we have one vendor that works with a UPC code and we have another vendor that does a QR code and now we have to figure out as a company how to adapt to that and does that mean for us multiple technologies and how much is that going to cost us? And I think if we collaborate and do a staged approach or some sort of pilot implementation, it allows us to look at those challenges and identify where those necessary adjustments are and before we finalize anything or while recalls are extremely important, extremely important, and if we don't do it the right way, we end up creating more of an issue and a longer process to try and get

that information. If we're doing this and another vendor's doing that and now we have to adapt, it just creates that smoother transition with a better overall success for everybody.

Susan Winckler (00:48:44):

So collaborating and thinking about approach and actually how you're making it happen so that there's some consistency.

Lindy Wiedmeyer (00:48:51):

Right.

Susan Winckler (00:48:53):

Great. Karleigh, what might you add or amplify there?

Dr. Karleigh Bacon (00:48:57):

Sure. Well, collaboration I think is such an important piece of this whole regulation and making it work for everyone. When I think about collaboration in this space, I'm thinking about two different primary areas. One is within your own supply chain, within my own supply chain. So who are the direct partners that I'm working with to receive this data, my distribution centers, my suppliers, understanding what data systems and elements are being shared amongst the supply chain partners so that we can come together and talk about it and make sure that the solutions that we go after work for all of us within the supply chain.

(00:49:40):

Suppliers are typically, I guess if you look specifically at the McDonald's area of it, it really is our suppliers who are creating these traceability lot codes and sending that relevant information down to the distribution centers, the distribution partners who may be sending, it may go to a forwarding warehouse first and then to a distribution center. And so all of these things connecting together, working closely with them so then when we receive this data, we are ensuring that there's some interconnectedness there that we're not trying to detangle the data as we need to pull it together and hand it over. It's there and it's fluid.

(00:50:20):

The other area of collaboration is outside of just our little piece of the supply chain. It's across the industry, collaboration from different restaurant brands with other retailers, with other distribution centers and other suppliers all the way up. So that we're talking about and having discussions where we're sharing what are our compliance approaches, what data details are we going after, what are our expectations, so that we can learn best practices so that we can maybe come up with solutions that we hadn't already thought of on our own.

(00:51:02):

And I've found that in these types of discussions right now, the focus on the data itself and the conveyance of that data is really what people are interested in talking about and not so much the technology that we're using or we may be using or maybe not using to transfer this data because that's going to be a very, I think, personal choice to each of the companies that we're talking about. And again, if there's collaboration opportunities for groups who are using similar data or who want to learn more about what you've learned as you're conducting pilots using certain technology, then there's opportunities for that.

(00:51:47):

So I think recognizing the opportunities to collaborate in the data space and there's other opportunities to discuss technology use as well, but the interest in sharing this information is really high right now and more and more people are asking to talk about it and reaching out. So I think it's a really great opportunity for us to share what we know and come along together. But ultimately the goal of collaboration is to ensure that all of the parties are speaking to each other in the same data language. We know what you mean when we look at this data and this is what you're trying to convey because the data is really the crucial element for compliance regardless of what sort of technology you may or may not choose to use.

Susan Winckler (00:52:35):

Really helpful, Karleigh, and I appreciate not only the collaboration on the data and the actual implementation, but collaboration in education and best practices sharing that can be helpful.

(00:52:48):

Jodi, what about from the seafood angle? What would you highlight as important in thinking about collaboration?

Jodi Blanch (00:52:55):

Yeah, thank you. So I'm going to piggyback a little bit on what Karleigh said, but I mean in my opinion, the greatest need for collaboration that will make the most difference is on the IT technology side. We've been saying this, but we need systems that communicate easily with each other, easily between producers, warehouses, third-party software. There needs to be some more work in this. We have done some work in this area, but there needs to be more time and money in order for the systems to be spread and developed wide range and tested before they can go live. So more work with these and collaboration with IT solutions to transmit the KDEs.

Susan Winckler (00:53:40):

And then I heard you on the, let's test this, right?

Jodi Blanch (00:53:43):

Yeah.

Susan Winckler (00:53:43):

Let's see how this works. All right, Johnny, I have to say, just in thinking about producesupply.org as a consortium, it strikes me that collaboration is kind of a hallmark for what you're trying to do there. So what would you underscore here?

Johnny McGuire (00:54:00):

Exactly, Susan. I think this collaboration has to be layered and at every level we have to be very good at collaborating. I was trying to make an onion analogy here to get Jodi back on that, but anyway.

(00:54:16):

So I think increased collaboration with the FDA at a higher level, increase collaboration with groups like us and PSO with other membership companies. I think we need to collaborate there. Like I said in my opening remarks, I think the growership of community has to collaborate closely to establish those, how

we're going to interchange data and send that into the supply chain. And then I think any trading partners that we have where we do a shipping or receiving a critical tracking event will require significant collaboration. So there's going to be a lot of touch points here and just want to acknowledge, Karleigh, your comments on the data health and data standardization is going to be so important. Doesn't matter what system you've got, the structure of your data needs to be right.

Susan Winckler (00:55:12):

Great, really helpful, Johnny. Sarah, again from your slightly different perspective, but where do you think that the collaboration might be most impactful?

Sarah Sorscher (00:55:22):

Yeah, thanks, Susan. There's no question that this rule is going to take investment by every member of the supply chain, including retailers, distributors, folks represented on this panel. And I want to give credit also to the retailers, including Kroger, Walmart, obviously my co-panelists who are already working to put these systems in place because again, businesses have known this was coming for 14 years and we now see that the leaders have been moving to comply. They're collaborating with their suppliers and their customers and they're trying to solve this problem.

(00:55:58):

I want to talk a bit about interoperability to Jodi's comment because for that I see a real role for third-party solutions providers. We do already have some of these providers offering services to help with the technology compatibility challenge. Everyone is not on the same system. I think it would obviously take a lot of investment to get everybody onto the same compatible technology with each other. But another solution is to have a third party that can facilitate that communication by being able to speak with multiple systems. So kind of a technology translator to get those key data elements that are required by the rule and be able to plug them into various systems.

(00:56:37):

This is not the first industry that's had to deal with technology interoperability challenges and the healthcare industry springs to mind as one example. They have a lot of insurance providers they need to communicate with. And so there are approaches and solutions to solve these challenges. They're very solvable, but it does take time and we know that it will take longer for smaller businesses to invest in technology systems and for consumers the response is we should give them more time. We know it's not going to happen overnight, particularly for smaller players.

(00:57:10):

But I do want to emphasize that the response can't be saying that we're going to take entire sectors of the food supply chain and just carve them out of the world, this point about collaboration. And there have been some bills, some efforts to get Congress to actually do that. It's a very anti-collaborative approach and consumer groups really strongly oppose those efforts. But it would be like having a fire bucket brigade and everyone's doing their part, they're passing the water buckets along and then the last person in the chain, instead of throwing the water on the burning building, they're just dumping the bucket out on the ground and they're saying, "We're going to stand here, we're going to be part of the line, but we're not going to participate in solving these problems."

(00:57:52):

We know that no one wants to see a system like that actually. But we do have something like that now to the effect that we have suppliers, we have the produce industry in particular participating in traceability, passing along that information, but then no one's there to receive it. So it's effort that's

going to waste. We need to have that full participation and collaboration so this rule serves the purpose that we need it to serve and ultimately so that as consumers, we can have the benefits of this rule.

Susan Winckler (00:58:28):

Sarah, I hear your fire bucket piece that leads us through. Johnny, I've almost got the onion working for us. We'll get there [inaudible 00:58:40], but this is one where it's got to move through.

(00:58:43):

Well, we're approaching just our last five to six minutes for this discussion. And so I want to come back to each of you for a final thought and it can be in the vein of either, I wish I had said this or I really want to underscore that. So this can be something new that you're saying, ah, we really should have at least mentioned this or something that you heard that you want to highlight. So I've got just about a minute for each of you. I don't have the timer set up as we're going to for our public commenters, so I'll let you think through the minute. But, Sarah, instead of making you go last, you get to go first. So we'll go Sarah, Jodi, Johnny, your one-minute rapid fire. What do you perhaps wish you had said or what do you want to underscore? Sarah?

Sarah Sorscher (00:59:34):

So I want to underscore the point I made about how important it is to solve these outbreaks quickly. And I'm going to do it by going back to that 2018 outbreak I described. And in that outbreak there was a family in Rocklin, California who had a six-year-old boy. This is a real person, but I'm going to call him by a made-up name to protect his privacy. I'm going to call him Robert. His mom took him to eat at a Papa Murphy's restaurant in Rocklin, California. And being a responsible mom like we all want to be, she ordered him a salad to go with his meal. And the salad unfortunately was tied to this outbreak. It was contaminated with the outbreak strain from Yuma. And two days after eating it, he became very sick. And two days after that he was in the hospital, he had fever, really agonizing abdominal cramps, bloody diarrhea. And he developed a condition known as hemolytic uremic syndrome, or HUS, which is a form of organ damage that can be life-threatening. And he required four blood transfusions and he got better from this.

(01:00:45):

But the organ damage that he experienced has the potential to impact him for the rest of his life. And his mom said later, "I didn't know that there was an E. coli outbreak at the time that I purchased this meal. And I definitely was not prepared for the devastating impact that it had and it continues to have on our lives." And CDC and FDA had been working hard during this time to trace that outbreak and they had some lot code information, but it didn't account for all of the cases. And eventually they had to give up on pinpointing the source and they fell back on this nationwide warning. And the day they issued that warning was April 10th, which was the same day that Robert sat down to his meal with his mom in that Papa Murphy's in Rocklin, California. If they had managed to shave even 24 hours, even a day off that and gotten the word to that restaurant, then that meal would never have been put on his plate and he would've been spared that illness.

(01:01:42):

And I say this not because I think that the listeners don't know what an outbreak looks like. A lot of folks on this call know better than I do what these illnesses look and feel like. But I say this because this is what motivates me to want to do this work. And I hope that it motivates you all and we're all here in this event because we care about the food system and we care about making it better. There are kids out

there today like Robert, who are going to be the beneficiaries of this work that we're doing, and we truly need that support and motivation to make it a success.

Susan Winckler (01:02:18):

Yeah. Thanks, Sarah, and always helpful to illustrate and we know why this work is being done. Jodi, Johnny, and then Lindy.

Jodi Blanch (01:02:30):

I mean, I do have a wishlist and I'll go through three quick wishes and they're not in any particular order. One is I wish the Food Traceability List would list fish by species or even groups of species that were truly only a high risk. Just let me explain briefly. Right now, there's three buckets of these fish. There's fin fish that are histamine producing, fin fish that are ciguatoxins, and all other. This all other bucket is the vast majority of the remaining fish species. And specific to Gordons we don't use any of those for that reason and others, which I won't go into. I would wish that the FTL list had a more categorical breakdown specific to fin fish.

(01:03:16):

The second wish that's complicating the industry, and I feel like we could move faster is if we did not need this TLC source, this traceability lot code source. I wish this was not included as a KDE. We're struggling. I feel the law code itself could, if we continue to do a good job passing that along, that FDA will be able to work its way backward much quicker and in a reasonable amount of time compared where we are today.

(01:03:45):

And lastly, as I mentioned, seafood is a bit unique. We have farm raised, wild, domestic, imported, fresh, frozen, land based, sea based. So as you can imagine, there's a lot of nuances and gray areas that we're dealing with. I had submitted an inquiry to FDA through that email system and the response was that they would provide this information in a draft guidance to be issued at a later date. Well, the later date's coming, we're trying to build systems around things we don't know what we're building. And so my last wish, we are urgently requesting that FDA release the draft guidance to this law as soon as possible as we are working on internal systems, writing traceability plans and spending capital dollars to comply. So thank you.

Susan Winckler (01:04:34):

Thanks, Jodi. Johnny, Lindy, Karleigh, closing thoughts here. Johnny?

Johnny McGuire (01:04:39):

Yeah, just a few thoughts. There has to be nuance here too. Certainly in the produce industry there's crop specific nuance. We've got friends in the Northwest, stone fruit, apples, that kind of thing, multiple lots per pallet, every different case on a pallet is a different lot. It presents a lot of challenges. Small and local grow requirements. How are we going to manage the nuance of that? Domestic versus foreign suppliers in the produce industry, lots of challenges there. Underscore on the need for standardization. I'm kind of talking out of both sides of my mouth, right? Nuance and standardization, but it's critical. Data health is just so important for us to support Sarah's goals and keeping those consumers healthy. And then maintaining engagement with FDA is going to be critical. Don't make this a punitive thing on growers. Work with us and let's get it right. It's not time for value propositions and capitalism. It's time

to stick to the standards and do it all together. Let's not do something because it's going to make money. So just a few thoughts from me.

Susan Winckler (01:05:56):

Really helpful. Thank you, Johnny. Lindy, and then Karleigh.

Lindy Wiedmeyer (01:06:01):

I have to agree with Johnny in saying the data implementation and that uniformity and that standardization is huge. If we collaborate in that, it just would make consistency across the board a lot clearer and a lot easier to implement. And it greatly benefits at every stage in the process in the supply chain. It just benefits them a lot better. And I think that's really the main thing we all should take from that is standardization, uniformity and making sure we're getting that right information.

Susan Winckler (01:06:43):

Thanks for capturing that so succinctly, Lindy. And, Karleigh?

Dr. Karleigh Bacon (01:06:47):

Yes. So I'm just going to re-hit on some of the things that have already been discussed, but again, just recognizing the complexity of the rule and as Johnny was saying, the importance of standardization for the areas where we can standardize on and collaboration and making sure that we're talking, so that we're not all trying to solve this on our own little box when again, we are all trying to solve the same problem. So let's help each other out there.

(01:07:14):

I think just the thought that compliance on day one might not look like compliance down the future because you can build a perfect system and you may not start with a perfect system up front, but as long as you are able to pull that information and share it with FDA within 24 hours and the data is accurate, that's great. And then you can look at some of the more advanced technologies, maybe like an RFID or a QR code scan or data imagery, something like that. Sure, that's an option. But what you want to make sure that we're all focused on is collecting, creating, sending, and receiving data that is valid and effective because ultimately this rule, as Sarah said, is to serve the consumer and public health and that is what we're all going after.

Susan Winckler (01:08:05):

Yeah, thank you, Karleigh, and thank you to all of our panelists for helping us see the rule from a number of different perspectives in the dynamics of implementing it, what are going to be some of the specific challenges and opportunities, and then obviously why the rule is being put in place, which is to help us more quickly trace challenges. You knew I was going to have to come back to the swimming example, but I think, Karleigh, what you just underscored is that we're also going to get stronger in treading water and going upstream and downstream and that there will be opportunities to continue to improve. So there will be the initial implementation and then strengthening as there is additional implementation and learning and technology opportunities. I have to say to Lindy, Karleigh, Johnny, Sarah and Jodi, thank you for sharing your insights and helping us get this picture of what it takes to implement the Food Traceability Rule. I really appreciate you taking the time today.

Stakeholder Comment

And then we'll turn now to the final part of our meeting, which is the public comment. I'm now going to turn to those who have pre-registered for public comment. As a reminder, we are going public comment in alphabetical order by last name within each of the topic categories. We're covering the topics in this order. First, traceability lot codes and labeling. So I've got in the queue, Andrea Gill, Sue Hunter, and Mala Parker as the first three folks in that topic. Then we'll do implementation schedule and awareness, warehouse management systems and technology, and pilot and concept testing. As I introduce each speaker, I'll list the next speakers who are in the queue.

Susan Winckler (01:10:03):

So as I mentioned, our first three speakers in the queue, Andrea Gill, Sue Hunter, and Mala Parker, when I announce your name, that's your queue to use the... press the raise hand function so that we can find you. Our producers will then promote you to panelists, and when it's your turn to speak, that's when you will unmute your microphone. So first time you hear your name, raise your hand. Second time you hear your name, turn on your camera. Third time you're hearing your name, that's when you're ready to go with your three minutes.

(01:10:35):

So unmute, and I will turn the microphone to you. If you do not begin speaking within 10 seconds of my turning the virtual stage over to you, we'll move to the next commenter. If it's an audiovisual issue and we have the opportunity to come back to you, we will do so. Just note we have a short period of time. We'll have a grace period, and then we'll move on. You will see a countdown clock showing the time that you have remaining, and I will come back on screen when you have about 15 seconds left. When get to the three-minute mark, then you will... we will mute you and move to the next speaker. So let's turn now.

(01:11:21):

This is the important part where we want to hear the public comment. I will note that this is a listening opportunity, so there will not be a response to the comments, but we are actively gathering your input and so appreciate you investing your time in providing comments today. So, as I said, we'll start with Andrea Gill, followed by Sue Hunter and Mala Parker. I want to confirm that I see Andrea here, and I will note. Do I have Andrea here and ready to see? Andrea, if you are ready and available, we are ready to hear your comments? Andrea Gill? All right, we'll turn... So I'm going to turn to Sue Hunter. In the [inaudible 01:12:21]... In the queue is Mala Parker Max Valentine, and we will turn then to topic two with Mara Burr. So, Sue, I see you here and ready. Go ahead. Please proceed.

Sue Hunter (01:12:34):

All right, thank you very much. There are numerous terminal markets within the US. Because of our uniqueness as a distributor, we would like the FDA to recognize our sector within the supply chain and help us with our hurdles as we move to make sure we understand and follow the guidelines of FSMA 204. We are the boots on the ground. Some attention needs to be given to terminal market companies because we do play a large part in the supply chain, yet we are always the one forgotten supplier within the supply chain and often overlooked when guidance is communicated. By the time terminal markets receive the product, it may have changed hands through two to five different suppliers before we receive it, and then once at the terminal market, the product can be bought and sold amongst ourselves multiple times. If the farm and the originator of the TLC codes or source does not begin correctly, the entire traceability history of the product's movement along the supply chain will be incorrect.

(01:13:27):

Who will be blamed? How do we receive the product then? It's easy to say, "If a supplier does not provide the required information, don't use them." In reality, customers need the product while also making sure traceability does not suffer. Product coming into the terminal markets is by the full pallet. Many loads could be pallets with mixed lots, multiple products per load, as well as items are on both the FTL and not on the FTL list. We receive approximately 700 pallets per day, or around 60,000 a week. We, in turn, ship out to either the customers by the pallet or by a single case for each of those orders, amounting to around 8,000 packages per day. More guidance from the FDA is needed for the following. Mixed pallets shipments may have more than two lots on a pallet and multiple lots or items per truckload. How do we receive in this scenario?

(01:14:17):

In receiving, the supplier doesn't provide the TLC source or the codes. The loads arrived. We need to receive it immediately and sell it. We're dealing with perishable product, and it cannot sit or be delayed in our unloading at 3:00 AM while trying to get a hold of the supplier for the information. How will all companies be held to the same standards when they don't comply? Customers will still purchase from them because they need the product, and we lose the business because we are trying to follow the rules. We sell between each other regularly without a lot of time of collecting the full traceability information. How do we implement the guidelines within the operations of terminal markets under this rule? Walking cash customers, capturing their information, they don't necessarily want to provide it. Not all companies have scan guns, barcodes, or labeling abilities. Most do have warehouse systems.

(01:15:04):

The cost to implement the innovative programs or the labor to input data will be astronomical. Each supplier and customer will want their preferred method or of sending and receiving the information. We are at the mercy of them and caught in the middle. We may need to enroll in and pay for a minimum of 10 computer systems. We were just told today that we need to sign up and pay $300 a year for just one customer. Multiply that by 300 customers and 500 suppliers. Too much vagueness surrounds how terminal markets should apply the rules and standards yet still be able to operate in the way in which we were designed to do so. We were designed to fill a niche. Examples should be provided for terminal markets separate-

Susan Winckler (01:15:43):

Thank you.

Sue Hunter (01:15:43):

... from [inaudible 01:15:44] standalone distributors.

Susan Winckler (01:15:47):

Thank you very much. And we'll... our next speakers in the queue are Mala Parker, Max Valentine. And then turning to topic two will be Mara Burr, followed by Stephanie Harris. Mala, please proceed.

Mala Parker (01:16:00):

Good afternoon. I'm Mala Parker with the International Foodservice Distributors Association, a non-profit trade association representing the industry that delivers 33 million cases of food and related products to more than 1 million professional kitchens such as restaurants across America every day. On behalf of IFDA, I'd like to thank the Reagan-Udall Foundation for holding this public meeting and for the

opportunity to share our unique perspective on the challenges associated with the implementation of FDA's Food Traceability Final Rule. We continue to support solutions to address those challenges so we can work together to enhance traceability throughout the food supply chain, and greater flexibility is needed to achieve that goal.

(01:16:37):

Foodservice distributors are deeply committed to food safety. It's at the core of what they do. They have substantial experience in facilitating traceability activities and have highly effective tracking and tracing systems already in place to ensure they know exactly what food products they've received, when they received those products and from whom, and to which customers products went and when. This is despite the large volume of products they handle from hundreds or thousands of suppliers each day. Foodservice distributors have a strong record of providing FDA with critical traceback information in a timely manner due to their successful practices.

(01:17:10):

While IFDA appreciates the core objectives of the Food Traceability Rule, we remain concerned that certain components of the rule are overly complex and place undue burdens on industry. Our members continue to dedicate significant time and resources to building traceability programs to comply with the rule. But as the Foundation's top-line summary states, the rule “will likely require, at varying levels, firms to seek and invest in new systems and new processes.” This is no small task and at no small cost. One of the greatest challenges of the final rule is the requirement that distributors maintain and send KDEs linked to the specific traceability lot codes of products in each shipment, which effectively requires case-level tracking.

(01:17:47):

Distributors receive products from suppliers in pallet-level quantities. Each pallet typically contains multiple cases of a single product like tomatoes, and those cases may have different traceability lot codes. When assembling an order, the distributor would have to know the TLC on each case picked for the order. But to know this on a mixed-lot pallet or pick slot, labels with the TLC would be needed on each case, and each label would need to be coded correctly, readable, and scanned, which has not been necessary to track products successfully in the past. Moreover, there are no regulatory requirements that foods on the FTL must be labeled with the TLC on the products.

(01:18:20):

So the ability of foodservice distributors to comply with the rule is dependent on whether they receive the records in a manner that makes compliance possible, and it is also dependent on an overhaul of existing operational processes and systems that enables tracking to the case, which is unnecessary and time- and resource-intensive likely to result in increased cost for consumers. IFDA believes FDA can resolve this challenge by giving distributors the flexibility to pass forward a reasonable range of possible TLCs associated with each shipment. Such flexibilities would eliminate the need to track to the case while preserving the rule’s core structure. In closing, the foodservice distribution industry remains committed to working with FDA and other stakeholders to improve food traceability and strengthen compliance with the rule. Many thanks to the Reagan-Udall Foundation for facilitating this engagement.

Susan Winckler (01:19:05):

Thank you. Our next speaker is Max Valentine. Then we'll turn to topic two, implementation schedule and awareness, to Mara Burr, Stephanie Harris, and Stephanie Johnson. Max, please, the microphone is yours. Please proceed.

Max Valentine (01:19:21):

Thank you. I'm here today representing Oceana, the largest international ocean conservation organization, solely focused on protecting the world's oceans with more than 1.2 million members and supporters in the United States where we work to promote seafood traceability to keep a legally sourced product out of the supply chain and ensure that our seafood is safe, legally caught, and honestly labeled. We appreciate the opportunity to provide comments today. Fish are the most heavily traded food commodity in the world, with intricate supply chains that are often very opaque.

(01:19:54):

Further complicating the path to markets and the reliability of the product sold is that there is a significant amount of illegal, unreported, and unregulated seafood that is laundered into the supply chain. Global estimates suggest that as much as 31% of the global marine catch is caught illegally or unreported. Furthermore, NOAA estimates that more than 85% of the seafood consumed in the United States is imported. The complex path the seafood takes from the point it is caught to the point it is sold to a consumer makes it difficult to isolate where in the supply chain the illegally sourced fish may enter. Illegal, unreported and unregulated seafood poses significant health risks for consumers due to the lack of oversight and enforcement of safety standards in its production and distribution.

(01:20:41):

Without proper regulation, a lack of traceability increases the chances that mislabeled or spoiled seafood enters the market, putting consumers at risk of foodborne illnesses, allergic reactions, and long-term health issues from exposure to toxic contaminants. Seafood fraud, specifically species substitution, can confound these issues, proving a new identity for illegally sourced product hampering efforts to stop illegal fishing. It's critical for the FDA to require all firms in the seafood supply chain to identify and maintain records for all critical tracking events and corresponding key data elements, such as unique vessel identifier. And it's important to verify that the legality of the seafood products, a measure for both food security and food defense as well as the chain of custody of seafood is required.

(01:21:31):

In addition, with respect to seafood, the FDA should align with the requirements of the National Oceanic and Atmospheric Administration's Seafood Import Monitoring Program and harmonize data collection requirements with best practices, expanding the requirements to all seafood products and require electronic record keeping and removing the exemption for fishing vessels and pair traceability with expanded consumer labeling. With the Seafood Import Monitoring Program and the FDA's Traceability Rule are promulgated under different authorities and implemented by separate agencies, the US government should not take a one... or should take a one government approach to seafood and ensure that these programs are not established in silos. Thank you for allowing me to provide comments today.

Susan Winckler (01:22:18):

Thank you, Dr. Valentine. We'll turn now to topic two. Our speakers are Mara Burr, Stephanie Harris, Stephanie Johnson, and Katy Jones. I see you, Ms. Burr. Please proceed.

Mara Burr (01:22:34):

Thank you. My name is Mara Burr, and I'm the vice president for Regulatory & Technical Affairs at Consumer Brands Association, which represents 2000 iconic consumer packaged goods brands, including food and beverage. I want to thank the Reagan-Udall Foundation for organizing this meeting and for the opportunity to provide comment on FDA's Traceability Rule. Our members view their

obligation to protect consumer health as their first priority and are rightly proud of their ability to effectuate recalls quickly and to facilitate traceback investigations.

(01:23:04):

Our members are diligently implementing the Traceability Rule with the goal of meeting FDA's mission to make traceback investigations efficient and actionable. To be able to meet this goal, our members are investing significant resources and record keeping and other solutions to ensure they're not only implementing the rule's requirement but are also creating an effective traceability landscape. Unlike the past record query... record-keeping initiatives, such as the one-back requirements of the Bioterrorism Act, the Traceability Rule requires significant collaboration and harmonization across the industry and includes all supply chain members.

(01:23:41):

In order to make this collaboration effective, industry needs time to work together to identify solutions and common systems that will meet FDA's needs in a unified and efficient manner. Specifically, there are currently several ongoing industry initiatives aimed at overcoming challenges to the Traceability Rule's implementation that need more time to reach fully developed strategies and solutions. Our members have been working hard to educate their suppliers, customers, and internal stakeholders about the rule. This process is complicated by the fact that some retailers are requesting traceability records for foods that are not on the traceability list.

(01:24:17):

Because of this, the scope of businesses impacted by the wider application of Traceability Rule has grown. It is important that businesses may not be covered by the rule but that our implementing traceability systems, due to customer requests, engage in the rules implementation process to ensure consistent practices across industry. More time is needed to engage all stakeholders. Second, ensuring the different data systems used across the industry are interoperable or, more simply, able to communicate with each other is key to the success of the Traceability Rule, and for improving traceback investigations. Industry is working to develop interoperable data standards to the newly formed partnership for food traceability.

(01:24:59):

This important work aims to developing efficient and effective record-keeping across industry, but it's still in the development stage. In sum, our members are working hard at ensuring implementation of the Traceability Rule, but more time is needed to allow these initiatives to fully develop, learn lessons, and provide a strong foundation for a successful rule. Thank you very much for your time. I appreciate the Reagan-Udall Foundation allowing me to speak on this important topic. Thank you.

Susan Winckler (01:25:27):

Thank you for providing your insights. Our next speaker is Stephanie Harris, followed by Stephanie Johnson, Katy Jones, and then Eric Marshall. Ms. Harris, you have the floor?

Stephanie Harris (01:25:39):

Thank you. FMI appreciates the Reagan-Udall Foundation holding today's public meeting and for the opportunity to provide comments. Central to FMI and our members is a commitment to providing consumers with a variety of safe and wholesome foods. Food safety is our top priority, and achieving this mission. Industry has provided consumers with immense choice and convenience, allowing consumers to find products that match their tastes and needs. We know this choice is important to consumers.

(01:26:04):

However, providing consumer choice and convenience creates complexity in our food system. Over the past several years, our members have been working to balance the benefits of this complexity with the need for transparency and traceability in the supply chain. We appreciate FDA's engagement with industry during the implementation process. FMI and our members have spent countless hours and millions of dollars working to implement the Taceability Rule and to collaborate with FDA. The biggest challenging facing industry is the overwhelming complexity involved in implementing the rule, which stems from both the number of products the rule implicates, the reliance on other entities' compliance to ensure your own obligations are met, and the need to evaluate new technologies and systems and the desire to ensure interoperability. These challenges highlight the need for greater flexibility specifically related to the use of traceability lot codes and more time to perform pilot projects and implement the rules requirements. First, the complexity of the rule, coupled with the tens of thousands of products that are covered, creates significant challenges. There are concerns regarding the need for education and a fundamental lack of awareness of the rule and its requirements for many covered entities. This creates additional challenges for those further down the supply chain, like retailers and wholesalers, who rely on their suppliers for the information that needs to be shared and maintained under the rule.

(01:27:25):

Second, the complexity of the supply chain coupled with the rules requirements mean that distribution centers and warehouses will need to engage in case-level tracking, a potentially infeasible and incredibly costly task. We believe that pilot projects are needed to explore lot code flexibility and other solutions. Pilots also would identify gaps or inconsistencies in current and planned practices that could hinder an efficient traceback investigation and should be completed before compliance with the rule is required.

(01:27:54):

Again, pilots are needed before significant investments in technology, record-keeping systems training, and more have been made. Pilot projects would also enable industry and the agency to explore alternative solutions that reduce the burden on industry while still protecting public health. Finally, the variety of compliance approaches under consideration and the need for pilot projects to support implementation highlight that more time is needed to effectively implement the rule.

(01:28:21):

Full compliance requires all members of the supply chain to fully understand and implement the rule in an interoperable manner, and it is clear that additional time is needed to ensure this happens effectively. I want to again thank the Reagan-Udall Foundation for its engagement on this important matter and for its openness in considering multiple perspectives on the implementation of the traceability rule.

Susan Winckler (01:28:43):

Thank you for providing comment. Our next speaker is Stephanie Johnson, followed by Katy Jones, Eric Marshall, and Roland McReynolds. Ms. Johnson, please proceed.

Stephanie Johnson (01:28:53):

Thank you Susan, and thank you for this additional opportunity to provide comments on this rule. I'm pleased to represent the National Grocers Association. We are the trade association for the independent food, retail, and distribution industry. NGA is committed to food safety and supports the spirit of FSMA to move food safety forward in this country, but we have... but what we want to highlight several

challenges our members are facing in implementing this new Traceability Rule. First, a regulation with the implications as broad as this rule requires significantly more time to implement.

(01:29:27):

If we work in an organized and tiered manner, we are hopeful that we can comply as an industry as early as 2032. With the need to rework almost all software systems and processes throughout the food system, we ask for additional time and flexibility to ensure proper compliance. Second, traceability lot code management is creating a significant issue at every step in the supply chain. Warehouse management systems across the industry are not standardized, making it difficult for distributors and retailers to integrate and track lot codes.

(01:30:02):

Additionally, many software applications used to manage inventory throughout the supply chain use different configurations that require complex integration consulting that is costly and time-consuming. We currently have the ability to trace many foods back to where they came from, especially within the retailer and wholesaler setting, and we think this additional piece of data is making the world prohibitively difficult and is not making food safer. We ask that you grant flexibility on the traceability lot code and focus on reaching foods impacted by foodborne pathogen outbreaks.

(01:30:40):

Other ongoing challenges include special circumstances of which many we've heard here today where it's unclear the rules should be applied. While the FDA has diligently answered many of our questions, special circumstances continually arise where members are unsure about whether or not the items that they have need to be tracked. Determination is so complicated that we are asking some industries to tell us whether or not their items are traceable or not because it's just too difficult to tell in the packaging and through the ingredients.

(01:31:12):

We're not asking the FDA to leave us alone for eight years while we figure this out. We are asking for your active involvement to ensure that this system we create meets your needs and ours. We ask that you participate in several pilots to ensure this rule works as intended and helps quickly prevent the spread of foodborne illness. Thank you again for your continued willingness to listen to us over the past two years, and I urge you all to give us the time and flexibility to do this right. Thank you for your time.

Susan Winckler (01:31:41):

Thank you for providing comment. Our next commenter is Katy Jones, followed by Eric Marshall, Roland McReynolds, and Jayan Nallacherry. Ms. Jones, please proceed.

Katy Jones (01:31:52):

Thank you. Thank you for the opportunity to speak today. My name is Katy Jones, and I'm the CEO of Trustwell. FSMA 204 is a critical framework designed to protect public health and ensure a robust, accurate traceability system is in place. At the heart of this ruling is the inclusion of the lot code. Lot codes are one of the foundations of accurate traceability, enabling us to narrow down the scope of an investigation or recall. Some in the industry have proposed, in lieu of maintaining accurate lot level data, that the FDA should also allow for a calculated lot calculating a percentage likelihood of a lot code suggesting that this would ease the burden on implementation.

(01:32:31):

While this may sound practical, it undermines the entire premise of FSMA 204 and creates additional work to capture, maintain, and manage multiple lots. When a foodborne illness or recall occurs, that, quote, unquote, easier approach will cost us accuracy and time. If the FDA chooses to allow this, I implore the FDA to restrict the number of lots that could be grouped or calculated as the shortcut approach diminishes the entire purpose of the rule. GS1 data standards are also critical here. By adhering to these globally recognized standards, we ensure interoperability between systems and data sharing across the food supply chain. We encourage all industry partners working in collaboration with associations and the FDA to continue to conduct pilots and share those learnings to support the implementation and rollout the FSMA 204.

(01:33:21):

At Trustwell, through our food logic traceability platform, we've been helping companies achieve lot-level traceability since the early 2000s. Our work has been built on years of pilot programs and phased implementations working with our customers who have already achieved real-world scalable traceability solutions. We have captured over 230 million critical tracking events to date. The work our customers and their supply chain partners have done is not theoretical. It's a proven, effective approach to traceability that supports interoperability with existing systems' collaboration across the supply chain and provides the accurate data needed when it matters most. The impact of delaying or scaling back FSMA 204 implementation is also not theoretical.

(01:34:05):

This issue is deeply personal for me, as I'm sure it is for many of you. My son, who has a life-threatening food allergy, will be heading off to college next year, and for him and the over 30 million people who deal with food allergies, it's imperative that we keep FSMA 204 in place and not push out the critical deadlines to make this a reality across the food industry. It is time. Recent food outbreaks have left families and communities devastated as lives are lost to tainted foods that were perceived to be safe. Let's maintain the integrity of FSMA 204 and continue to focus on solutions, not shortcuts that compromise public health. Thank you for the opportunity to speak today.

Susan Winckler (01:34:49):

Thank you for providing insight. Our next speaker is Eric Marshall, followed by Roland McReynolds, Jayan Nallacherry, and Brian Ronholm. Mr. Marshall, please proceed.

Eric Marshall (01:35:01):

Thank you. Thank you for the opportunity to speak, and thank you to Reagan-Udall for the important work of convening this conversation. My name is Eric Marshall. I'm the executive director of the partnership for DSCSA Governance, a public-private partnership between the pharmaceutical industry and FDA supporting the implementation of drug traceability.

(01:35:18):

Along with colleagues from the Atchison Group, I've also been working closely with food industry leaders to develop a similar independent public-private partnership to support interoperable food traceability called the Partnership for Food Traceability or PFT, and we are especially excited that FDA has formally agreed to collaborate through PFT as a public-private partnership.

(01:35:38):

The most important theme that we've heard consistently today is collaboration, collaboration, collaboration, both among industry and between industry and regulators. I want to applaud Reagan-

Udall and the stakeholders for highlighting the value of a PPP in its written report. This concept actually goes all the way back to the 2012 study that IFT did for FDA, and it is still being called for.

(01:36:01):

I'm excited to be part of the team leading the effort to finally make that a reality through the partnership for food traceability and independent non-profit public-private partnership to support interoperable food traceability. The pharmaceutical industry is nearing completion of its journey to traceability, and its collaboration with FDA, through a public-private partnership, has been instrumental in achieving a comprehensive vision for how interoperable traceability should be achieved.

(01:36:26):

Two components of that model had been critical. First, PDG provides the industry of forum and decision-making mechanism to discuss key requirements for traceability and make collective industry decisions so that industry can move forward quickly and confidently with their implementation. Second, PDG provide a mechanism to engage continuously and constructively with FDA and state and local authorities in that process.

(01:36:50):

The same model of collaboration can streamline and simplify the pathway to interoperable traceability in the food industry as well. There is a lot of good work happening throughout the industry, but there is no central coordinating function to share information in real-time and address the type of thorny technical issues that we have heard repeatedly today.

(01:37:08):

Again, I want to highlight that FDA, as well as the Association of Food and Drug Officials, have signed on to PFT and are ready to collaborate with industry through the exact type of public-private partnership that speakers have called for throughout this meeting and we are grateful for that.

(01:37:23):

We all share the same goal to bring greater traceability to the supply chain so we can respond to outbreaks more effectively and efficiently. And PFT will provide a mechanism for all of us to work together toward that goal, but time is of the essence, and engagement from people like those on this call is critical. We're excited to kick off PFT's substantive work and look forward to connecting with many of you and sharing more. Thank you for the opportunity.

Susan Winckler (01:37:46):

Thank you. Our next speaker is Roland McReynolds. Then, we will hear from Jayan Nallacherry, Brian Ronholm, and Sonia Salas. Mr. McReynolds, please proceed.

Roland McReynolds (01:37:59):

Thanks very much, and good afternoon. My name is Roland McReynolds. I'm executive director with the Carolina Farm Stewardship Association. We are an organization representing farmers serving the markets for local and organic foods in North and South Carolina. I want to echo the appreciation that other folks have shared for the Reagan-Udall Foundations convening this forum and taking input.

(01:38:23):

I'm going to start by describing a program that our organization has been operating since as a response to COVID that is currently funded with USDA funding from the local Food Procurement Purchasing Assistance Program. It's a program that essentially is working with 18 community-based distribution businesses in North Carolina that are purchasing food from small farms that is... with money that is

provided from this grant sources and then distributing that food for free to community... to food-insecure individuals across the country.

(01:38:57):

But there are purchases involved. The farms that are supplying the food are... typically are not exempt. The food distribution businesses are not exempt, and these businesses do not have the capacity to make the investments that are required to come into compliance with Section 204. You have heard from large-scale businesses here on this call express the dramatic impacts that these complex requirements establish and the difficulty of compliance for large-scale international businesses and terminal markets.

(01:39:36):

We're talking here about businesses, farms with less than $100,000 in annual revenue, distribution businesses with less than half a million dollars in annual revenues. These businesses are operating on tiny margins, often with a community-based mission, and they are in no position to undertake the expenses necessary to comply with a standardized and harmonized system.

(01:40:03):

These are businesses that are typically operating in supply chains that have two to three to four steps along the whole supply chain, and these local and regional small short supply chains need different treatment, need to be exempted from this scheme that is predicated on the Produce Traceability Initiative and large-scale efforts orchestrated by large-scale business.

(01:40:33):

These opportunities to serve communities and grow opportunities for small local farms to have a viability in their future is compromised, and our food program that I described would not be able to operate if these businesses were required to comply with Section 204 as it stands right now. We've worked with FoodLogiQ to try to create systems to support that are adaptable to these businesses, and it has not worked, so this is a critical concern that's facing businesses in the local and regional food [inaudible 01:41:05].

Susan Winckler (01:41:06):

Thank you for your comment. Our next speaker is Jayan Nallacherry, followed by Brian Ronholm, Sonia Salas, and Lisa Wedig. Dr. Nallacherry, please proceed.

Jayan Nallacherry (01:41:16):

Hello. Good afternoon, everybody. This is Jayan. I'm from India, Bangalore, founder of TRALEXHO, and we are a research-based startup organization focusing enabling digital traceability through our AI-empowered interoperable traceability platform, and especially we are focusing at solving some of the critical adoption challenges for the Indian scenarios. And first of all, thank you, Reagan-Udall Foundation, for the opportunity to participate in this program.

(01:41:48):

Over the last two decades of international expertise working with organizations like IBM globally, we actually began the journey of introducing such a platform here in India. It's a digital traceability platform, especially focusing at how we can develop adaptable platform and affordable to countries like Indian requirements. And we have been working very closely with APEX bodies like Marine Product Export Authority of India and such organizations, and recently we also got endorsed by them in their conclave for wider adoption.

(01:42:27):

Now, considering the timeline for adoption is fast approaching, what we actually found as we engage with many exporters from Indian seafood and [inaudible 01:42:39] products, we realize they are not fully aware of the timelines and also many of the requirements. So it will be great to see how foundation can support us to collaboratively work with such organizations in running pilot programs in terms of how we can get more learning from other organizations and also see how the learning from Indian scenarios and a few other countries, which we are actually focusing.

(01:43:09):

We can actually collaborate and share our learnings so that the adoption is actually faster and also help many organization to actually participate for wider and faster adoption. And also, we have realized that some of the products may still require a lot of clarity, whether or not they require traceability, because it may be a little bit gray in certain products. So those aspects will also get clarified as we do the pilot adoption programs with many organizations.

(01:43:43):

And we also believe that if you do that collaboratively with some of the early adopters we have identified, it will also help the overall export community to actually learn, and they will become the trendsetter for others to adopt so that in the journey, we can actually bring more exporters participating and they all can actually get adopted earlier, easier, and beyond the journey. So looking forward to hear from you how we can collaborate in this journey. Thank you.

Susan Winckler (01:44:17):

Thank you for providing your comment. Our next speaker is Brian Ronholm. Then, in the queue, we have Sonia Salas, Lisa Wedig. Then we'll turn to topic three, Warehouse Management Systems and Technology, and Benjamin Cote will be the first commenter. Mr. Ronholm, please proceed.

Brian Ronholm (01:44:33):

Thank you, Susan. Hi, this is Brian Ronholm, and I'm director of Food Policy for Consumer Reports, and I appreciate the opportunity to make remarks today. The compliance state for the Traceability Rule should not be delayed further.

(01:44:45):

As Sarah mentioned, FSMA and the traceability provision is almost high school age now, so there's been plenty of time for everyone to prepare. We've had 14 years to study for this final exam and all of its complexities. It's amazing that we're still waiting because better traceability can't wait. Tell the kids who were sickened by lead poisoning from the applesauce pouches last year that this delay is necessary. Those products were still on store shelves after the recall was announced. Tell the families of the people who got sick or died from the Boar's Head listeria outbreak that more time is needed. There have already been a number of pilot projects done by the FDA and by the industry. We can't continue to pilot this forever to the point where the process stagnates, while new excuses get formulated. Some retailers have already announced that they expect to be compliant way before the FDA compliance date of January 2026.

(01:45:37):

Last December, Kroger told suppliers they expect to be compliant by July 2025, a full six months sooner than the compliance date. Several weeks ago, Walmart told their suppliers that they should be compliant before the compliance date. Just this past August, Cisco announced that it would support the rule and implement advanced traceability measures. This clearly demonstrates that it's possible to meet the requirements in the traceability rule, and the breakthroughs you're seeing already are occurring

primarily because of the main components of the rule, establishment of key data elements, critical tracking events, and a food traceability lot code.

(01:46:14):

Lastly, I want to express concern over how this rule has been deliberated recently. There was a series of secret off-the-record meetings over the summer between FDA representatives and members of the industry groups who are seeking to delay the compliance date for the rule. The Reagan-Udall Foundation did release a report about the meetings and its convening this public meeting, but that was only after FDA received complaints about the off-the-record meetings. However, the substance of the report was only five pages long. And while it identified the people who participated in the meetings, there was nothing to indicate their affiliations.

(01:46:46):

Many of us know here who we are and who we represent, but for those who don't work on food policy on a continuous basis, it's not evident, and it's difficult to ascertain from the report which viewpoints were associated with which organizations. It's difficult to believe that material covered in six-plus hours of meetings could be summarized in only five pages. For those of us in Washington, we know it typically takes all of us that long just to clear our throats when talking about an issue. In addition to the secret off-the-record meetings, the groups that want to delay the rule also are being provided the opportunity to make comments today. This doesn't seem like a fair process, and it raises bigger questions about the lack of transparency, and how policymaking decisions are being made by the FDA. Thank you for the opportunity to make remarks today.

Susan Winckler (01:47:32):

Thank you for your comment. Our next speaker is Sonia Salas, followed by Lisa Weddig. Then we will turn to topic three and hear from Benjamin Cote, and followed by Kerri Marbut. So Ms. Salas, please proceed.

Jodi Blanch (01:47:48):

Thank you. Greetings everyone. I am speaking on behalf of Western Growers Association representing fresh produce farmers, they produce over 50% of the fresh produce consumed in the United States. We thank the Reagan-Udall Foundation and FDA for the opportunity to share our comments today. The produce industry, as was mentioned earlier in the discussion, has been long committed to improving traceability with the Produce Traceability Initiative as a prime example. Today, I'd like to comment on three key areas, technology, compliance, flexibility, and implementation. First, regarding technology, we want to stress that is crucial that systems across the supply chain communicate seamlessly. Interoperability and integration are crucial for the effective implementation of the rule. Without them upstream suppliers such as the fresh produce growers, packers and shippers are forced to adopt multiple systems and redundant practices to meet demands from downstream entities. We urge the FDA to promote a more efficient and seamless traceability landscape by prioritizing the development of a unified interoperable framework.

(01:49:06):

We secondly want to urge the FDA to develop a fair compliance framework across the supply chain. For example, if the FDA were to develop a flexibility or allow flexibility to track and trace lots only to the last mile or downstream entities, it will place a disproportionate and excessive burden on upstream supply chain members who are already facing implementation challenges as buyers are expanding requirements beyond the items of the Food Traceability List, and also requiring diverse systems to

collect and transfer information. This situation makes the implementation more complicated, increases costs, and also harms efforts to enhance traceability across the supply chain, and with that, advanced public health. Lastly, we also want to ask the FDA to address implementation for foreign suppliers.

(01:50:03):

Since brokers and importers are not covered by the rule [inaudible 01:50:07], there will be gaps to... they are going to slow down trace-back investigations, and create an unfair burden to domestic producers. FDA needs to make sure that there is a strategy that covers both domestic and foreign companies. Equal compliance standards and inspections of overseas suppliers must be considered. That means that we would like to hear more about FDA's plan for addressing this issue. In conclusion, we urge the FDA to work with industry to find consistent interoperable solutions through the whole supply chain and address issues on implementation of the rule. Thank you for considering this comments. We appreciate it.

Susan Winckler (01:50:47):

Thank you for providing your comment. Our next speaker and the last in this topic area is Lisa Weddig. We will then turn to topic three and hear from Benjamin Cote, Kerri Marbut and Jessica Marino. Ms. Weddig, please proceed.

Speaker 1 (01:51:02):

Hi, good afternoon. I'm Lisa Weddig, chief food safety officer with the National Fisheries Institute. NFI is the leading trade association for the seafood community in the United States. Now, this might be an understatement, but the Food Traceability Rule is complex. While it may not seem like it with a simple read, once one tries to figure out how to comply, the challenges are revealed. The expectations are simple. "Have a traceability plan. Maintain records of KDEs at specific CTEs. Pass-forward certain KDEs when shipping products use a traceability lot code to link CTEs and provide FDA with certain records when requested." At NFI, we often say that implementing this rule is more challenging than implementing the landmark Seafood HACCP Regulation in the mid-1990s. The seafood industry had two advantages with the implementation of that rule that are not relevant to the Food Traceability Rule.

(01:52:04):

First, there was a concerted effort on the part of FDA, state agencies, university and Sea Grant extension programs, and industry trade groups through the Seafood HACCP Alliance to develop and provide the widespread training and resources necessary to educate the industry, and to ensure that no one was left behind. These efforts started even before the rule was finalized. While a standardized Food Traceability Rule curriculum is in development through the Food Safety Preventive Controls Alliance, those materials are not expected to be completed until early 2025. Leaving less than one year before the January 2026 implementation date for further outreach.

(01:52:50):

Second, Seafood HACCP could be internalized within a company. There was little need for companies to collaborate with suppliers and customers. The Food Traceability Rule is different. Companies cannot move forward out without knowing how their suppliers will pass-forward KDEs, or how their customers expect to receive the applicable KDEs. It is an endless chain of challenges that each company is now making internal decisions and expending resources, both time and money, that may not later be accepted by the next step in the supply chain.

(01:53:28):

NFI has spent the last year and 10 months providing the awareness, understanding, and resources necessary to help our members implement the rule requirements, but NFI has about 200 members who are impacted by this rule. There are 20 times that number of seafood companies in the US alone, and this does not account for the size of the global food industry covered by the rule. All this to say, a three-year implementation period, while at first might seem generous, simply does not allow sufficient time for awareness, outreach, understanding, and finally executing the rule's requirements. Thank you.

Susan Winckler (01:54:24):

Sorry, Mr. Cote, please proceed.

Benjamin Cote (01:54:26):

Yeah, can you hear me okay?

Susan Winckler (01:54:27):

We can.

Benjamin Cote (01:54:29):

All right, thank you. And yeah, I want to start by introducing myself. I've been working for almost a decade with GoHACCP, with small businesses, medium businesses. And this idea of traceability and the comments that I've heard today are pretty much shared with all these small companies, except they really don't have the tools. They don't have any way to create lot codes. Often, they don't have any way to gather that information. And what we've found is they need to be given a really setup turnkey system, and they need to be trained. However, they often don't have the money for that. So obviously we're a for-profit business, so we do charge for a lot of these services, but we've also wanted to try to see how we can help with this because a lot of our clients struggle with that.

(01:55:17):

The reason I'm here is to talk about our solution... I was hoping to have a bit more of a collaborative conversation with somebody. I can see the format is more just talking, so I'll talk about the solution, and maybe in the future, we can have a bit more feedback. Essentially... Can you hear me okay? I've kind of lost my screen here.

Susan Winckler (01:55:40):

Yes, we can.

Benjamin Cote (01:55:41):

We can. Okay. Sorry, I'm traveling so I'm not in the office. The tools that need to be provided, in my experience, it needs to be really, really easy for them to create lot codes, snap [inaudible 01:55:55] lot code. And we have all that, but the final step is making all that information public. So we're just starting with a pilot program. I mean, we have over 9,000 clients that we've worked with, and that ranges from restaurants to small manufacturers. And again, it's the same problems that I hear these larger organizations talk about. The final step here, because we're able to gather that information, is making it public. So we're starting to do that. We're starting to get industry understand that it's important. We opened up a pilot program recently. If you go to safecheck.org, it kind of talks a little bit more about it and allows people to essentially sign up for free, build their database, and also provide forms for their clients.

(01:56:40):

Like maybe you're dealing with a smaller farm, or maybe you're dealing with other suppliers that don't have warehouse management systems. They can upload the information without even setting up an account. It's hard to really describe the entire program in three minutes, but I did want to kind of open up that conversation. If anybody's out there listening that's interested, obviously reach out, or just sign up and test it out at safecheck.org. I think Jennifer who signed me up for this has been kind enough to put the link there.

(01:57:08):

And I think there was an earlier comment about the putting out a fire with the water. And the businesses that don't even know what a warehouse management system is, or just they're in there, but they just don't have the tools, I think are the ones that are going to really struggle with this. And I think they really need to be handed a system somehow, and trained in that system. I can see you now. I don't know if that makes sense, but we're really working hard with industry, and trying to... I'm hearing a beep.

Susan Winckler (01:57:41):

Yep, thank you for your time. Thank you for providing comment. We'll now turn to Kerri Marbut, then to Jessica Marino and Ed Treacy, and then turn to our final topic on pilot and concept testing. Ms. Marbut, please proceed.

Kerri Marbut (01:57:55):

Thank you. Good afternoon and thank you so much for convening this session on the FDA's Food Traceability Rule. My name is Kerri Marbut, and I'm pleased to provide comments today on behalf of the Global Cold Chain Alliance. GCCA is an industry association that represents third-party temperature-controlled logistics providers, many of whom operate cold storage warehouses and handle foods that are listed on the Food Traceability List. As such, FSMA 204 will have a significant impact on our members. At GCCA, food safety is a top priority for us. Our members are committed to ensuring consistent and reliable traceability information for products within the supply chain, and we recognize the importance of these efforts. Since the finalization of the rule, GCCA has worked closely with its members and partners in the food industry to prepare for compliance. However, through this process, it's become evident that the system established by the rule is extremely burdensome.

(01:58:51):

The scope of food products subject to this rule extends into the tens of thousands, which is far beyond the high-risk foods Congress intended to regulate in 2011. FDA has yet to establish a comprehensive list of products that they expect to be traced, adding to this uncertainty. The rule places undue burden on the entire food supply chain with its complex product tracing and lot code requirements. This effectively results in case-level tracking, which is cost prohibitive, and we believe, in violation of FSMA. For our members who may have a wide variety of different listed products in their facilities at any given time, this creates significant operational complexity. Warehouse management systems will face a heavy burden, and their ability to comply will depend on system sophistication, which may require costly and lengthy upgrades. Or in some cases, even full replacements.

(01:59:40):

Additionally, the rule's requirement for industry members to maintain massive amounts of records for two years is well beyond the shelf life of most of the foods on the list, and this prevents a further challenge. Ultimately, we're concerned that this rule will impose significant costs on the entire US food

supply and delivery system, with consumers likely to feel its impact. To minimize these unintended consequences, we believe that additional time is needed for the industry to adapt to the new requirements. Pilot programs which include various segments of the food supply chain would be extremely valuable to ensure that the rule is not only feasible but also has meaningful results.

(02:00:15):

We're encouraged by the language included in both the House and Senate Fiscal Year 2025 Agricultural Appropriation bills, which directs the FDA to delay implementation and conduct pilot programs. We also believe that these provisions are critical for the successful implementation of the rule. Thank you once again for this opportunity to provide comment, and we look forward to continuing to work collaboratively with the FDA, industry stakeholders, and to ensure practical and sustainable approach to food traceability. Thank you.

Susan Winckler (02:00:45):

Thank you for your comment. We will now turn to Jessica Marino, then our speakers in the queue are Ed Treacy. And we'll turn to our final topic, pilot and concept testing, and hear from Derek Hannum and Joseph Lasprogata. Ms. Marino, please proceed.

Jessica Marino (02:01:01):

Hello, I'm Jessica Marino, food safety manager at Four Seasons Produce. We are a wholesaler distributor of fresh produce based out of Lancaster, PA, and the majority of our inventory is on the Food Traceability List. I want to express my gratitude to the FDA for allowing us to comment. Additionally, I'd like to thank the FDA for their openness to industry feedback, particularly this past September's Reagan-Udall Foundation meeting that published a summary of top-line learnings. This document clearly captures the issues that implementation of 204 will inflict upon our segment of the supply chain.

(02:01:38):

Specifically on page four of this document, it discusses limitations within warehouse management systems. We agree with this assessment, and have found that even the best-in-class WMS on the market cannot adequately meet FDA's requirements for 204 compliance. One of the main challenges is the common occurrence of having multiple products and lot numbers per pallet. The document also states that industry interprets the law to mean that every case must be scanned in order to provide the FDA with the information that they're requesting. We agree that there is no other viable option to provide the information to the FDA other than to scan every case received and every case that is shipped.

(02:02:18):

As the summary states, this will cause significant increases in labor, equipment, and required storage space. Additionally, cost per case on product with an already slim profit margin will skyrocket. This cost will then be passed on to consumers, who as you know, are already facing extreme inflation of food prices. The top-line learning summary also discussed using probability calculations to determine what lot codes had most likely been sent to customers rather than scanning every case in and out. As a distributor, we prefer this method of using an algorithm since it is similar to our current traceability process.

(02:02:56):

In order to obtain the level of traceability the FDA is looking to achieve, it needs to start at the grower-harvester level, and not wait for the initial packer or distributor. The grower-harvester level is the point in the process where the traceability lot code should be applied and then carried through distribution. We thank the FDA for considering how the traceability rule will negatively impact distributors such as us.

We encourage FDA to reconsider the need for case-level traceability, and ask you to place responsibility for applying the traceability lot code at the grower-harvester level. Thank you.

Susan Winckler (02:03:30):

Thank you for providing comment. We'll now turn to Ed Treacy, and then have our topic four, pilot and concept testing where our speakers are Derek Hannum and Joseph Lasprogata. Mr. Treacy, please proceed.

Ed Treacy (02:03:42):

I'm the VP of supply chain for International Fresh Produce Association. I've a brain disease which affects my speech. I submitted the proposal to FDA to allow DCs that service restaurants and retail stores to use their warehouse management system to calculate the TLC for only shipments to restaurants and retail stores. This proposal was created by myself, Frank O'Dowd of BFC [inaudible 02:04:36] and Andy Kennedy, one of the authors of this module for Final Rule when he was at FDA. And the founder of FoodLogiQ, the company Katy Jones runs, which is now called Trustwell. Katy spoke earlier against the proposal. She unfortunately did not take time to understand the details of our proposal. The proposal uses a tested and proven prescribed open-source algorithm. Our proposal is more accurate than DCs implementing case scanning because it eliminates the chance of the wrong label being scanned. Our proposal will see in excess of 8 million labor hours, or over $250 million a year. I urge FDA to approve the proposal, it'll... The speaker before me and Moll, and Stephanie of FMI pointed out this is a huge burden. Our proposal does not apply to any supplier or any other entity that does not sit directly to restaurants or stores. I here, again, urge FDA to approve it. Thank you.

Susan Winckler (02:06:42):

Thank you for providing comment. We'll turn now to our final topic on pilot and concept testing. We'll hear first from Derek Hannum, and then from Joseph Lasprogata. Mr. Hannum, please proceed.

Derek Hannum (02:06:55):

Thank you, and thanks to the Reagan-Udall Foundation and the FDA for this forum. We appreciate the opportunity to speak. I'm Derek Hannum, I'm the chief customer officer for ReposiTrak. I wanted to speak today to offer insight into cases where traceability is not only possible in the supply chain today, but it's actually happening, and being executed at very low cost. If you're unfamiliar with our company, ReposiTrak is a supply chain technology company working in the food supply chain for more than 25 years. We are a universal data translation platform similar to the type Susan mentioned earlier in the panel discussion.

(02:07:28):

Our company is currently working with 15 major grocery retailers and wholesalers to implement their traceability programs, which will at a minimum, enable them to meet the requirements of FSMA 204. As was mentioned earlier today, many of these companies are going beyond the FDA Food Traceability List to include entire product categories, and in some cases, tracing all food items. Our work includes collecting key data elements from a network that has grown to more than 4,000 suppliers, representing 5,000 plus facilities, using automated data exchange for shipments into retailer, wholesaler distribution centers and stores.

(02:08:06):

Now, there have been a lot of efforts to slow down or change FSMA 204 requirements, but there are also many supply chain of the future initiatives with this stated goals of creating more digitized, transparent and efficient supply chains. While the industry could certainly use some more time to get to full FSMA 204 compliance, it's also important to recognize that traceability programs require digital sharing of supply chain data. A regulated traceability program is in a sense, a type of stimulus for our industry in order to take the first major steps on the road to a truly digitally connected supply chain. A supply chain that is not only safer, but more efficient and more resilient.

(02:08:50):

Now that Kroger, and most recently Walmart, have communicated their traceability requirements to suppliers, which include tracing all food products, it's clear that food traceability in the United States is not only a regulatory requirement, it's now a market reality. We encourage all the stakeholders in the industry to adopt a spirit of collaboration, to help make the supply chain of the future a reality by first building robust digitally-connected food traceability networks. Thank you.

Susan Winckler (02:09:18):

Thank you. We will now turn to our final public comment which comes from Joseph Lasprogata. Please proceed.

Joseph Lasprogata (02:09:31):

Thank you. Thank you very much. I want to thank Reagan-Udall and the FDA for allowing me to speak. It's been great to hear from all my colleagues throughout the industry. I'll spare everybody about comments about 204, but it is going to be challenging. My name is Joseph Lasprogata, I'm senior vice president with Samuels & Son Seafood. Our headquarters is located in Philadelphia, and we have three other regional locations around the country. There's challenges. As a seafood wholesaler and distributor, we're responsible for that distribution of information both north and south in the supply chain. We deal with over 300 different species. We have thousands of different vendors, and even more customers that we accommodate on a daily basis. And there were some comments about some of the different vendors not really being ready. We still have vendors that are literally using crayon on their boxes to label inbound products that we receive on a daily basis.

(02:10:37):

We handled over 50 million pounds of products, both fresh, frozen, and pasteurized over the last year. So my viewpoint here, again, I'm not going to go over, it's certainly been covered today with all the different speakers about the negatives about the 204. We as a company, of course, are in favor of food safety, and doing whatever we can to not only guarantee the quality of the products that we sell, but also understand that the traceability of the products is key to understanding the regulatory aspects as well as the sustainability of the products. And people deserve to know where their products are coming from. My challenge is to the FDA to get more involved.

(02:11:26):

From the get-go, from the very installation of 204 from the last deputy commissioner of the FDA, it was supposed to be a non-intrusive and an inexpensive process. Well, it's the opposite of that. So at the very least, the FDA could be involved by providing some standardization of labeling. We need some best practices. We're not asking them to design any systems, but there needs to be some communication between companies and the packages along the supply chain.

(02:12:03):

Right now, we are developing a Tower of Babel. Everybody's spending millions, if not billions of dollars to design and install these new systems to allow their companies to comply with 204, but we don't know what we're designing for. It's like telling your football team you have a game in two weeks, but we're not going to coach you, and we're not going to provide you with a playbook. How is this program going to be successful if we don't know what we're building? So it is my hope that there will be some best practices for...

Susan Winckler (02:12:39):

Thank you for providing comment today. With that, I want to say thank you to all who provided comment. Your insights, personal stories and personal experience are valuable, and we benefit from your willingness to share that feedback publicly. I'll note that everyone has the opportunity additionally to provide written comment, please email comments to FinalRule@reaganudall.org by October 25th. Today's spoken comment will be posted on our website later this week as part of the meeting recording and transcript. We'll post the written comments by the end of this month. On behalf of the Foundation and FDA, we appreciate you joining us and contributing to the discussion. Thank you, and have an excellent rest of your day.