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

Thursday, July 10, 2025 | 12:30 to 2pm ET

Transcript

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

Susan Winckler:

(00:00) Hello, everyone, and welcome to our event today. My name is Susan Winckler and I am pleased to welcome you to our virtual conversation on the FDA's final rule on 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. I am pleased to be here as part of the Reagan-Udall Foundation for the FDA. For those of you who are new to our 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. And one way we do that is by convening meetings such as this one to help the agency share information and hear from stakeholders about important issues. And we are happy to be collaborating with FDA on today's meeting.

These engagement opportunities help inform the agency's work, but I will note that the Foundation does not advise the FDA on regulatory decision-making. So before we begin, we have just a few housekeeping issues to navigate. Because of the size of the meeting, attendee cameras and microphones will remain off throughout the event, but we do want you to engage with us. To ask questions or to share your comments, please use the Zoom Q&A function and we will do our best to answer as many of your questions as we can. I'll also note that we are recording the meeting and we will post the recording along with the slide deck and the transcript on the Foundation website, which is reaganudall.org, early next week.

So let's take a look at today's agenda. In just a moment, we will hear opening remarks from leadership at the FDA and then we'll be following that with presentations on outbreak investigations and food traceability rule implementation activities. Then we'll have a panel discussion with experts from across the food industry about their experiences and perspectives on piloting and implementing the food traceability rule.

With that, that takes us through our agenda and what it is that we plan to do today. And so I am going to welcome to the stage Dr. Don Prater, who is FDA's

Principal Deputy Director for Human Foods, and he is going to kick off our meetings. So Dr. Prater, let me turn it to you. The floor is yours.

Opening Remarks
Donald Prater, DVM, Human Foods Program, FDA

Dr. Donald Prater:

(02:12) Well, thanks very much, Susan. It's a pleasure to be with you this afternoon. And first let me just extend on behalf of the FDA team, my appreciation to the Reagan-Udall Foundation for hosting today's webinar. The Foundation has been a tremendous partner to FDA in helping bring together external stakeholders to share insights, expertise, perspectives on the challenges and opportunities for industry and meeting the requirements of the traceability final rule.

As you all know, there are new and unique aspects of the rule as compared with some of the other FSMA rules. By requiring the sharing of product traceability information between members of 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 key changes to processes and procedures. There is a degree of complexity to implementation with this rule, and even more so for those foods that pass through many hands between the source of the food and the point of sale.

It requires coordination across manufacturers, processors, packers, holders, and sellers of food on the food traceability list to maintain and share this required information. The Foundation-led roundtables conducted last year with industry were critical to increasing our understanding of the challenges of different sectors in the food industry that they have encountered as they work to meet the rule's requirements.

So as you all are aware, FDA has announced its intention to extend the compliance date for the final food traceability rule by 30 months. And we'll do this by appropriate procedures, including publishing a proposed rule in the Federal Register. We're taking this step because we're drawing near to the original compliance date of January 2026, and we heard significant concerns from the industry about their ability to be in compliance across the food supply. So the bottom line is this, for us to achieve the full public benefits, public health benefits of the final rule, all the covered entities must be in compliance.

While we continue to support industry with technical assistance we've been providing since issuing the rule, the compliance state extension gives covered entities the additional time necessary to ensure complete coordination across the food supply chain to fully implement the final rule's requirements, ultima

tely providing FDA and consumers with greater transparency and food safety. We'll use the extended time period to continue the agency's work with stakeholders, including by participating in cross-sector dialogue to identify solutions to implementation challenges, and by continuing to provide technical assistance tools and other resources to assist industry with implementation.

However, our willingness to delay the compliance stage should not be read as an opportunity for industry to take their foot off the gas. Our expectation is that by allowing an additional 30 months, firms will have the needed time to complete coordination across the supply chain and fully implement the final rule. Our team has already had over 200 meetings and answered over 400 questions through our technical assistance network.

And I'll also note that we made a point of including in our announcement that this compliance date extension does not amend the requirements of the final rule. We remain committed to the requirements, since implementing the traceability across the food supply will result in dramatic improvements to food safety and will protect public health overall by allowing for faster identification and removal of potentially contaminated food from the market, resulting in fewer foodborne illnesses and deaths.

So I know that we can complete this work together and achieve compliance with the rule. With today's webinar, we'll hear from those of you who are working to implement the rule, as well as from FDA on how helps us during outbreak investigations. Hearing and learning from each other helps us to increase our collective effort in realizing the requirements of the rule. We really appreciate you being here to help us advance our goal of a safer food supply. And myself and the FDA team are looking forward to today's webinar.

So thank you very much to Reagan-Udall Foundation. Thank you to all the participants that are participating in this webinar and we really look forward to a productive session today. Back over to you, Susan.

Conducting Outbreak Investigations
Angela Fields, MPH, Coordinated Outbreak Response, Evaluation & Emergency Preparedness, FDA
Adam Friedlander, MS, Coordinated Outbreak Response, Evaluation & Emergency Preparedness, FDA

Susan Winckler:

(07:16) Great, thank you so much Dr. Prater, we appreciate you being here and framing the conversation for us today so effectively. So now I want to turn... I'll note that as we have heard discussion about the food traceability rule, we've heard questions about how outbreak investigations work and how implementation of the rule is expected to improve that process. To help us explore these questions, I'm happy to welcome Angela Fields, who's a senior consumer safety officer for FDA's Coordinated Outbreak Response and Evaluation Network, and Adam Friedlander, who is a policy analyst for Coordinated Outbreak Response Evaluation and Emergency Preparedness, to our virtual stage. As we see there, I've got Angela and I know you are there with Adam. So I'll say, Angela, if you're ready, I am going to turn things over to you and to Adam.

Angela Fields:

Great, thank you so much everyone. So today I know we've heard a lot about the requirements of the rule and so we wanted to talk a little bit more about the outbreak process and how this rule will impact our process over at FDA. We've gotten a lot of questions to understand about what our information requests look like, understanding how we're going to use the traceability data. So we wanted to kind of walk through today a little bit more of the application process when it comes to applying the food traceability rule and what that looks like in context of an outbreak response.

So first, when we're trying to identify whether there's an outbreak happening, we have phases within FDA that we utilize. In addition to our partnerships with states and CDC, we also have a team of folks of epidemiologists at FDA that help us identify these outbreak investigations. So first we have to figure out who is sick. Is it an FDA-regulated product? Is there something that we can do about it? And so as we walk through these processes, you all will kind of better understand what our decision-making looks like and how that impacts our investigations.

So of course the purpose of our traceback investigations is to, of course, identify the vehicle that made people ill, and that's through the questionnaires that are utilized when we asked sick people what they had the week before they became ill and trying to identify any commonalities when it comes to the foods that were reported being consumed.

And then once we identify a potential food vehicle, then we also want to determine what is the supply chain and what was the source of that particular product. That way, of course, we can determine what our next regulatory steps are going to be. What actions do we need to take? Are the root cause analysis things that can take place based on our findings when we look at what's happening at that source? And then, of course, ultimately in the spirit of protecting public health, of course, we want to be able to inform consumers. So what information do we have that is actionable for consumers to again help protect public health?

So as I said, we utilize and have a lot of partnerships when it comes to this outbreak response process. So there's a role for state and local partners, of course there's a role for CDC and then the roles that FDA has in these situations. So as I mentioned with our state and local partners, of course, they're the initial step where when ill persons are reported and identified, they will go and collect all the exposure history. They'll understand what foods they consumed, they'll of course document and sometimes follow up and do more specific questionnaires to identify particular brands, to identify if there's particular varieties of food products that are available. And then of course they'll visit the points of service, so retail, food service, institutions. They'll go and ask questions, obtain records and interview and observe what's happening in those locations. And then they sometimes will initiate their own traceback investigations in their particular state. And then of course they'll communicate that information up to CDC and FDA.

From CDC's perspective, of course, they assist us also in the epidemiologic information collection and analysis. So they will assist us in understanding

where these commonalities are across the various vehicles. They'll also help us understand are there specific brands that have been identified? Are there particular food types or locations, multi-ingredient products? They try to help us tease out a particular ingredient as opposed to trying to look at that commodity as a whole. And then, of course, in addition to that, they help provide the line list information that identifies when people became ill and really highlights what they ate so that we can keep track of all that exposure data.

And then from FDA's perspective, of course we're trying to coordinate from a more regulatory perspective of things. So we are in charge of performing the traceback investigations, identifying what cases are important for us to trace. We do not trace every person that is an identified in an illness cluster. So there are some cases, of course, that have better recall, and so they may have more information about what they ate versus others that are just a part of the outbreak because they submitted a stool sample and it matched that cluster. So we're really trying to identify the people that really remember what they ate, where they purchased it from, to be able to confirm where they purchased those products from, because all of this information will help us identify the product source and also identify what commonalities there are that exist.

So of course we're doing this jointly. And sometimes these cases can be identified through the traceback or through the outbreak process. So there could be a number of cases that are identified at the start of our outbreak investigation. And then as we go on, there could be new cases that are identified that then they decide that they are good cases to trace, and so we'll then add them to our traceback investigation. So this can happen in a layer in a multitude of ways. It's not always just from the time we start our investigation, those are the only cases we consider. We are always continuously trying to identify and get as much specific data as we can to help bolster the investigation.

So I know a lot of you probably already seen this slide, but again, I always like to show what the records look like that we are receiving. So as you can see, we have some examples of the paper records that we currently receive. We have redacted them. So those are the posted notes that you see on the records. But as you can see, there's a lot of handwritten information, a lot of just various ways that people are documenting information. I did also want to include a snapshot of an electronic record that we receive, because I do want to state that we do currently receive electronic records in spreadsheet form. So we often will get a mix of records. Sometimes we'll have them on all paper, they'll be all PDFs. Sometimes we'll have pictures of receipts. And then of course sometimes we'll have actual spreadsheets that contain data that we need to look at the shipment.

So talking a little bit about our record requests. Currently we are looking at ranges. We've talked a lot about how that lack of specificity and standardization that currently exists, that we often don't know what pieces of information be available to us when we need to request that data from a particular firm. So with that, we currently use a range of dates, or if we do happen to have lot code information, of course, we will utilize that as well to help scope our record request. But for the most part, we're using a date range that aligns with when

people purchase their products or when people became ill, if we don't have confirmed purchase dates.

So the impact of the rule that we'll have is because now that we will have access to more traceability and more standardized data, these key data elements that are required within the rule such as the traceability lot code will be very vital for us to help scope and frame our records request so that we can try to be more specific and narrow those record requests, So as opposed to saying that we need to look at an entire month of records, we can specifically identify four or five lot codes that we've received that we can follow through supply chain to again help narrow that scope of the information, which ultimately will impact the time that it takes for industry to provide us with those records.

Also, right now, as you saw on our records, and as you all know, people keep information in different ways on these records, and so we often have to have a lot of discourse back and forth to identify the information that's contained on those records so that we can understand how to analyze that information. And so with the rule, because we have things like the traceability plan and then also that requirement that requires those that provide records to us to explain any abbreviations, provide glossaries, et cetera, to help us understand and analyze, we will have a better foundation to start with analyzing these records than we currently do. So again, that'll just help us be more efficient and jumpstart that process without having to have a lot of that initial back and forth.

And then with the rule, our plan has always been to skip steps. So right now what we're doing is we're going to each location, asking for information and then we have to confirm how those products are coming in and how they're leaving the facilities and then also confirm how they move across the supply chain. Well, now because we'll have the ability with the traceability lot code and the traceability lot code source, we'll be able to skip some of these steps and not have to have as much time dedicated to visiting each location, requesting records, waiting to receive that information. Whereas we can now jump around and we can maybe prioritize better how we're requesting this information and where we're requesting this information, while also simultaneously potentially requesting information from different locations to verify later if we need to do that.

So, again, just really trying to explore those opportunities to have increased efficiency. So I wanted to show you all an example of an exposure line list so that you can kind of see some of the things that I've been talking about. So what you see here on your screen is a line list. So you can see state, age, sex. It'll have onset date, or when the person became ill, various exposure information is contained in the line list. And so, again, this is what documents and allows us to have access to information about where ill people ate, what they ate, and allows us to really hone in on the locations that we need to request information from.

So we take this line list once we receive it from CDC, and again, this is continuously updated throughout the outbreak investigation, and so we always have new information that we can utilize to help support what we're doing. And we take that line list and we incorporate that information into our data

requests. So this is an example of a data request that you might receive from Core. Now when you work with your FDA point of contact in your state, oftentimes they may send you a subset of what this record request looks like. But, again, I wanted just to highlight so people can kind of understand what information we ask for when we are giving these information requests.

So it'll have typically a summary of what's going on in the outbreak, so that top paragraph which will contain some of that demographic EPI information, and then, of course, we'll talk a little bit about how your particular firm is connected to the outbreak, so who did they supply and where they are in the supply chain. And then of course we'll have a series of questions that ask about, for specific timeframes, we'll ask for your traceability data. What's your delivery practices? What are your handling practices? How does the product received? Do you have processor information? Do you have farm information? We'll ask a lot of these pieces of data earlier in the supply chain even now because, again, we're trying to get to the source of the product as quickly as we can.

So once we receive those records from our record request, we then have to analyze and determine what connections we can make to help us identify any specific lots that may have been available for ill persons to consume at the time they became sick. So on these examples that you see on your screen, again, these are two examples of bills of lading and records that... in an invoice that we've received during an outbreak response. And so as you can see, and initially it's very difficult to figure out what the connections are, right? There's not a lot of identifying information that connects records from one location to another. So if you look at the records, and for Santa Foods in this particular outbreak, we were looking at cantaloupes, we have a shipment of cantaloupes that we've identified.

Now we don't have any other lot code information, so we have to document all of these numbers on the records to figure out what piece will be that connecting and that linkage to the next point in the supply chain. So we also have an example of a bill of lading down here. And so in this particular instance, once we were able to move through the supply chain and really kind of get towards the end of that supply chain, we were then able to identify what was called the identity number, which then was able to help link the shipments across the supply chain.

But as I just mentioned, this is something that occurred towards the end of that supply chain. And so as you can imagine, that took a number of weeks for us to be able to make those connections. And so the hope is with this rule that, again, having these pieces of data like the reference records, having the traceability lot code and the traceability lot code source, again, will allow us to make these in linkages more quickly so that we can move through the supply chain faster as well as come to some conclusions a lot faster when we're analyzing these records.

So once we get all the records and we make these connections, then we're able to create what we call a timeline. We have a timeline which documents all the shipments across the calendar. And so, again, it really allows us to see how a product is moving when shipments are occurring so that as we're implicating

shipments or identifying those shipments that we feel are of high interest, we can see the connection across the supply chain across multiple locations.

We also create what we call a diagram. And so, again, this traceback diagram just allows us to visualize the supply chains. And so, of course, for the purposes of today, this is redacted, but we do typically have all of the firm information for every firm that's involved in the outbreak investigation. And particularly once we are doing our traceback investigations, we of course will remove firms if we identify that they are not a part of that traceback investigation. Or we find out there's a reason that we can rule them out, we will remove them off of our documentation.

So I want to quickly talk about this concept of traceability, lot code and traceability lot code source just to kind of drive home the need for this to help create the sufficiency. So as you can see here, we have a very vast traceback diagram from a Romaine outbreak in November of 2019. You can see that there are a number of points of sale to the far left of your screen, and then you can see it's a very complex... There's a lot of farms and ranches that were evolved ultimately as identifying when we were trying to identify the source of the product.

And so as I mentioned, our normal process is that we have to visit every location to request records. Now we're not always physically visiting these records, but these can be virtual records requests. But as you can see, we have at least five points in the supply chain that we have to visit in order for us to obtain the information.

Now, there are some instances where, especially where they're vertically integrated or trading partners have really great relationships, they will provide us with some of the data further down the supply chain. They'll work with their trading partners to provide us a more complete view of that supply chain. So we don't always have to request information location by location, but majority of the times we are required to do so because people feel more comfortable, companies feel more comfortable with just providing the data that's specific to their location.

So as you can imagine, that is extremely time-consuming and can create a lot of delays because, of course, we have to draft information requests for each of these locations and request this information, analyze it, understand it, analyze it, and then go to the next point in the supply chain to do that all over again. Now with the traceability rule, what our goal is in trying to identify these traceability lot code source, we're going to be able to skip these steps.

So we'll make our initial information request at the point of sale, which will then provide us with traceability lot code information. And at that point, once we'll have that traceability lot code information in the traceability lot code source, we're able to then skip some steps or skip locations within the supply chain and go from the retail food service locations or institutions, all the way to a processor without having to necessarily collect information at the distributor.

Now, it doesn't mean that we won't collect that information at a later time, or we may collect that information simultaneously, but it won't be as necessary for us to go to that distributor because we'll have that traceability lot code source

information, which will then help us prioritize those requests. So once we get to the processor, again, if there's another step where there is another traceability lot code source in the supply chain, we can then skip over that second line of distributors and go straight to the farm.

So as you can see, utilizing the traceability lot code source is very important for us because we do truly feel like this will create efficiencies. Because now there are only three stops in the supply chain that we're going to be required to get information or able to prioritize getting that information, which again will help us save a lot of time because we'll be able to create these linkages a lot more quickly. Because in some cases, like I mentioned, it can take weeks, even months to identify these sources because we have to collect so much information along the supply chain.

But once these linkages are created, allowing us to skip these steps, will be very vital in speeding up that process. So I'm now going to turn it over to Adam so that he can give you all an overview of the application of what it's going to look like for FDA's research purposes and traceback investigation purposes utilizing what we call our product tracing system.

Adam Friedlander:

Thanks so much, Angela. So I just want to briefly highlight that our traceback process at FDA, it is built off of peer-reviewed methodologies. It aligns with C4 guidelines and the traceback diagrams that you all saw in Angela's slides. Our method will continue to be built on evidence and understanding and analyzing the different records that we receive to be able to draw these boxes that you see on this screen.

So part of our mandate through the Food Safety Modernization Act was to develop a product tracing system. And so we're taking our peer-reviewed current methodologies that we're manually creating text boxes and arrows, and we're converting it into a software tool. Now, it's important to mention that this product tracing system, as we're calling it, is an internal system. It contains highly sensitive information during traceback investigations, so FDA will serve as the end user of industry's data.

And just as we're doing now in protecting commercial, confidential or trade secret or other sensitive information, we will continue to do that through our product tracing system. So this is an example of synthetic data. It's all fake, but just wanted to highlight for you all that once we're receiving records or spreadsheets, we'll upload that information into this PTS. And we have a variety of different features, filters, and we can also manually manipulate the information in here if we want to make a manual connection or manually create new trade items or locations. But we can also automatically ingest this information via spreadsheet as well.

There is also the capability through our product tracing system to use GIS or geographic information. And so this is what that traceback diagram will look like on this slide too. So we will be able to directly look at a map while we're looking at traceability information. And this is what it looks like zoomed in. So we're highly zoomed in onto a certain field, and this capability allows us to understand

the adjacent land as well, or other proximity information to other firms of interest.

So our PTS development will continue. We're actively testing our product tracing system during real-time outbreak investigations. And I just want to emphasize that just as we're doing right now, we will utilize PTS for all foods regardless of whether it's on the food traceability list or not. And we're doing that now and we will continue to do that.

And so lastly, I just wanted to highlight the importance of using this traceability data. As Angela mentioned, as Dr. Prater mentioned, being able to leverage this traceability information can help us more rapidly and accurately advise the public on potentially violative products. It can help us be more accurate in recalling products or withdrawing products from the market. And it'll also help us conduct root cause analyses as we go back in the supply chain, which those findings can help us ultimately prevent additional illnesses and deaths. And that is the most important aspect of this rule, is to prevent illnesses. And, yeah, I'll pause there and see if there are any questions. I want to thank everyone for joining today, and I'll pass it back to you, Susan. Thank you.

Update on Implementation Activities
Melinda Hayman, PhD, Office of Compliance and Enforcement, FDA

Susan Winckler:

(30:00) Excellent. Thank you so much, Angela and Adam. It's always helpful to have that illustration of taking the words on the page that are in a Federal Register final rule, and then have that illustration and clear understanding of how the agency would use that information. So we really appreciate you sharing that insight.

I'm going to move to the next presentation, which is coming to us from Dr. Melinda Hayman, who's a consumer safety officer in the Office of Compliance and Enforcement at FDA. And, Dr. Hayman, we are looking forward to hearing an update on implementation activities from you. I will turn the virtual stage over to you.

Dr. Melinda Hayman:

Thank you, Susan. Sorry it took me a second to click all the buttons I needed to click. Hi, good afternoon, everyone. I'm very happy to join today to provide an update on FDA's implementation activities related to the food traceability rule. I'm one of three co-leads leading the implementation efforts. Also there's been a fantastic team within and outside of FDA helping in these efforts as well.

Our food traceability rule implementation planning has followed the same blueprint that we have used to implement other FSMA regulations. The basis of this blueprint is an implementation plan that outlines our activities for these topics, and these include inspections and compliance, outreach and education, technical assistance for industry and for regulators, as well as performance metrics. And today I'll provide an update on some of these key activities. We don't have enough time to go over all of them.

The first thing I wanted to talk about is our inspectional approach for the food traceability rule. In developing this inspectional approach, we have considered existing mechanisms, partnerships, resources, as well as potential. We collaborated with a group of experts across FDA to develop inspectional approaches. We then brought in a group of state regulators to share these approaches, and they reviewed them for us. And then we had a number of work group discussions to go through their approaches and to gain their feedback and then incorporate this feedback into our approaches.

So we made adjustments based on their expertise and the things that they see during their regulatory activities. The next step here is to engage more broadly with our state, local, tribal, and territorial partners to coordinate the implementation of this approach. We are also working on our compliance strategy and developing a compliance strategy in a similar manner that we use for the inspectional approach.

I want to move on to talk about the regulator training that we're developing for the food traceability rule. The goal of the training is to provide an understanding of the rule as well as inspectional considerations. We have already initiated development of this training with an aim to have it available several months before the rollout of the rule or the compliance day. The target audience is FDA investigators as well as SLTT regulators and other regulators.

The training will be web-based and it will be housed in a portal that will be accessible to our regulatory partners. It will be comprised of several self-paced modules that we considered in-person versus web-based, and this seemed to be the most effective way of being able to bring the training to more people. In addition to this training specifically for the FTR, we have reviewed existing FDA courses that incorporate elements of traceability or things related to the FTR. We have already updated some of these courses and we'll continue to work on updating the others as needed.

Next, I'd like to share our progress on industry training. We've been working with this with FSPCA, the Food Safety Prevented Controls Alliance. We have worked with them to develop curricula for other FSMA regulations as well. So they have a lot of expertise in this area. And the goals of this training are also to provide an understanding of the rule, but also for the participants to understand considerations for how to implement the rule and to build a food traceability program.

The target for this training is all persons covered by the rule, from farms, retail food establishments, restaurants, manufacturing, distributors, so the whole continuum of with the food chain that will be impacted by the rule. The modality is similar to the other FSPCA trainings where there is a train the trainer model where lead instructors can apply. Actually, the portal just opened today, so people can go ahead and apply if they have expertise in this area. The lead instructors will then deliver the training, and these trainings can be in person or virtual. The training will be available later this year. We're aiming to have our first courses in November of this year.

We have also been working on the PTS. Adam and Angela just talked about that, so I won't go into that today. We've also been working on a system for industry

and other regulators to send information to FDA, which I won't go into much detail today. I briefly wanted to touch on the resources, and I'm aware that many people may have seen these slides as well, but this is the FTR landing page. So the image on the left-hand side is the page that's devoted to the food traceability rule on FDA's website. There are many resources that are available on this website and we continue to update them.

These resources include access to our technical assistance network. So if you look at the menu on the left-hand side, on the main page, there's a tab here for the technical assistance network right at the bottom of the left-hand menu, so you can submit questions. We're already answering those questions. We have been answering them for a long time. You can access the final rule through the Federal Register, which includes the preamble which addresses the comments that we received, the proposed rule, and you can also access the codified language of the rule from the ECFR. There are translations from any of the documents, and we have a QR code available, so it can easily be shared.

Here's a snapshot of the available resources with links that are available. I wanted to point out that the At A Glance handout about halfway through the list on the left-hand side is a new resource which provides a short, concise synopsis of the requirements of the regulation so that this is a resource that could be shared by regulators or by companies with their suppliers or other people who may need some education on the rule, or just sort of a quick snapshot of the rule. All of these are accessed on the main page. There's a gray tabbed menu as you keep going down where you'll continue to find more information and more links and some specific examples for certain types of food products as well as resources for farms, retail food establishments and restaurants.

So I just wanted to acknowledge, again, that many people have been involved in these implementation efforts, including a very diligent team of people here with an FDA, too many to name, but just wanted to acknowledge and thank them for all the work that they've done, and also the people who have been working with us, like our regulatory partners in helping us review and refine our approach and the team who's been working on the FSPCA training. And I'll end there. Thank you.

Pilot Panel Discussion
Charles Leftwich, MBA, Sysco Corporation
Michael Lookup, Wegmans Food Markets
Takashi Nakamura, PhD, MBA, Del Monte Fresh Produce Company

Susan Winckler:

(38:34) Great. Thank you so much, Dr. Hayman. We routinely hear the importance of agency engagement with the broader community and are so pleased that you and your colleagues, Angela and Adam, could join us today, as well as Dr. Prater, to provide some of that important information. But now it's time in our program to pivot from the regulator perspective to hear from members of regulated industry about implementing this rule.

So we're going to say we'll turn to the perspective of the implementing industry. As our colleagues gather in the virtual discussion room, I want our attendees to transition as well. And in particular for our attendees to think about what steps you may be taking to implement the traceability requirements and what you might like to know from those who already have some experience in doing so. We have three panelists joining us today to share those implementation efforts, and I want to start the conversation.

So I'm going to start among our three with a panelist who is quite close to the beginning of the traceability efforts. So, Dr. Takashi Nakamura, you serve as vice president of Global Food Safety at Fresh Del Monte, where you're actively implementing the traceability requirements. If I recall those efforts accurately, you focused on the grower, processor and distributor settings, and particularly capturing, storing and sharing the key data elements across the critical tracking events like harvest, packing, shipping, and transformation.

I'm going to challenge you here. If you could distill those efforts and the accompanying insight gathered down to one thing, what would that be? What was the single most important thing that you and your colleagues at Fresh Del Monte learned in those early efforts?

Dr. Takashi Nakamura:

Wow, trying to distill that down to one thing. Well, first off, Susan, thank you for having me. Proud to represent a great organization with Fresh Del Monte. We'd like to add, we've made tremendous amount of progress on our journey for FSMA 204 compliance, and we only believe that it'll only complement our current traceability programs and processes.

The one thing that you just brought up... Let me start at that level and then probably work my way down from there. I'd say the biggest one for us is don't get paralyzed with all the different type of transactions that are executed on a daily basis by your organization. And that's going to come up during your mapping exercise as you start your journey on FSMA 204 compliance. What you're going to find is probably there's about 80% of the transactions that have commonality that you can focus on and develop the CTEs and KDEs on. Because what we find is that as you do your mapping exercise, you're going to find many subtle nuances, workarounds, exceptions. But like I said before, you will find a bulk of your transactions have significant commonality, and I would say focus on that. Don't get paralyzed by all the data. It can be quite daunting, especially in complex organizations such as ours. But if you focus on what are the bulk of the transactions, I think that's a great place to start.

The other thing I would add too, of the thing that came out of all of this is that as you look through your supply chain, understand all the different types of transactions, hundreds, thousands of them that happen every day, it's importance of technology. And we're not here to promote or advocate for any specific type of technology, but when you talk about suppliers, brokers, how that information comes into a supplier all the way through your organization, all the way to your customers, it's very apparent that technology is going to be a great enabler for those type of transactions.

So I gave you a bonus with 1B, but I'd say the one overarching thing is as you all of these organizations start mapping it is going to be quite daunting. You're going to go like, "Well, what about this and what about this?" If you kind of distill all that, you'll find that most of your transactions follow and have a significant amount of commonality, and then you focus on that. I mean, the other things will start migrating toward solutions too, but if you go after every little thing that comes up, you just won't get anywhere. And that's a great learning that we've had, and hopefully those on the call will be able to take advantage of.

Susan Winckler:

That's really helpful. And it makes sense, right? You could chase every last little thing, or you can, as you've said, kind of net out to the, "Okay, what's our commonality? What are we seeing most often?" And pursue that. Am I hearing you right?

Dr. Takashi Nakamura:

Yes, absolutely. Because what's going to happen is if you go down every little rabbit hole and every little nuance that you see in the organization, you'll find after a month or two, it's like, "Wow, I didn't really get anywhere." And it's quite daunting, and I'm not trying to underscore that. But if you look broadly at all the different type of transactions that happen in an organization every day, there will be commonalities. And you're like, "Oh, okay, this one, this one," and then start bundling them up and addressing that way, you'll get much farther ahead than stopping at every little thing that comes up. It's like, "Oh, hey, I heard by the way this happens." It's like, "Okay, I understand, but that's like 0.1% of all transactions. Let's focus on getting the big one done and then all the other ones can fall through."

Susan Winckler:

That's great. That makes a lot of sense. I'm even thinking that might apply to some life situations other than implementing the food traceability rule.

Dr. Takashi Nakamura:

Absolutely.

Susan Winckler:

So I might be bringing that home with me. So let's move. I want to bring another of our panelists up to the audio stage and note... So let's move to a different place in the implementation ecosystem and hear from our second panelist. So I'm going to turn to Charles Leftwich, who's Vice President of Food Safety and Quality Assurance for the Sysco Corporation.

Charles, I think in your efforts, Sysco focused on improving traceability for inbound and outbound shipments across your broad supplier network, and I know you learned a lot from those efforts. What would you highlight as the most important learning?

Charles Leftwich:

Thanks for having me, Susan. So to start, I want to set the stage a little bit. I think at Sysco we believe that we have a very robust traceability processes that we're routinely testing. And I think we have a demonstrated track record of effectiveness with those processes. On average at Sysco, we execute over 200 market actions, things like holds, product retrievals, withdrawals, recalls on an annual basis. And we've supported the regulatory agencies in many different outbreak traceback events and have routinely been able to provide them with the information that they need to support those traceback events.

By utilizing our traceability tools that we have and also our relationships with our suppliers, we are almost always able to get the regulatory agencies back to the manufacturing location or even the farm who produce the product. And I say that not to brag or anything, but to give some context to the background to my first thought here. And the most important thing is that while we as an industry have traceability processes in place today, we still have a long way to go to be able to efficiently and effectively meet the FSMA 204 requirements.

And the reason for this is while the rule doesn't necessitate a technology solution to be able to comply with the regulation, at scale there's just no other way to do that without a significant investment in technology. The rule requires trading at a granular transaction level of data that's massive and that the industry has not had to do in the past. And the biggest hurdle isn't the traceability portion of the rule. The biggest hurdle is aligning the industry to leverage common standards, common processes and common technologies that'll enable compliance with the rule. When we conducted our pilot, we were able to see this firsthand, and I'll provide a few examples.

The first was there was instances in our master data that we pulled from the global data synchronization network that was either incorrect or maybe wasn't updated by suppliers, and that creates complexities whenever we ingest that data. At the time, the GS1, they didn't have a field to capture whether a product was on the food traceability list or not. And since then, GS1 has added the ability to capture that attribution of the product. But I think other downstream entities, such as other distributors or retailers, would agree that it's been a real challenge even to get suppliers to inform us if their products are on the FTL or not, much less be able to trade that transaction level of data that's needed to comply with the rule.

The next one is advanced shipment notices. We notice that they're not as widely utilized in the industry as we originally thought. ASNs can have data inaccuracies and they can be sent late, which causes issues at receiving, and these issues create a need for a new redundant verification process to ensure the accuracy of the data that is sent to us. There's also inconsistencies when it comes to barcoding of products. We saw that some suppliers thought they had a GS-128 barcode, but really they didn't, they had another type of barcode.Or maybe a supplier did have a GS-128 barcode, but that barcode wasn't properly encoded with the right information.

And then there's always the issue of barcode legibility and them being damaged in the supply chain, which also creates issues when you rely upon them to capture the information throughout the supply chain. The last point I would like to make is that there's a lot of technology systems that are going to need to be aligned both internally and externally to enable compliance. Suppliers and customers are going to need to leverage an array of different technology solutions to meet the requirements of the rule.

We're going to have to figure out how do we seamlessly connect these hundreds or potentially maybe even thousands of different technology solutions to enable us to effectively trade data both up and down the supply chain. We're also going to have to look at how do we figure out how do we align internal systems as well, whether it's our PO generation systems to cut POs to our suppliers, or our ERP systems, or warehouse management systems, or our customer order management systems, or how we communicate that information back out to our customers. There's a lot of work that we're going to have to do to align systems both internally and externally, especially for companies who have grown through acquisitions and are continuing to utilize those legacy systems that they have when they made those acquisitions.

And then to add to this complexity, we're going to have to figure out how do we do business with entities at all levels of technical sophistication, both on the inbound side and the outbound side? We're going to have to figure out how do we meet suppliers and customers where they are on their own technology journey so that we can make sure that we can effectively and efficiently trade data to meet the requirements of the rule. And so, again, I think the most important thing is we have good processes in place, but we still have a long way to go to meet the requirements of the rule.

Susan Winckler:

Mm-hmm. Well, and I appreciate you built on the technology acknowledgement that Takashi made and saying, "We'll need the technology component too." But I also heard in your comments the importance for some of the standards development as well as the movement that was already made on the standards development even to just track that elements that food items weren't on the list and would need to be captured to comply with the rule. So there's some forward movement there.

But let me, before I let too much time pass, I want to make sure we call on our third panelist today. So we've heard everybody's voice at least once and then

we can continue the conversation. So, Michael, I'm going to turn to you. Michael Lookup is joining us from Wegmans Food Markets where he serves as the traceability lead. And certainly food markets like Wegmans are another key note of activity for this work.

So if I recall your implementation work correctly, you explored how to implement the requirements for the reprocessor repackager role, and particularly how that plays out with ingredient transformation, which I was intrigued that it was the creation of store prepared sushi. I know it can be challenging, already been acknowledged by our first two panelists, but I'm going to ask you to do the same thing. What would you distill as your primary learning from that work?

Michael Lookup:

Yeah, thanks. Thanks, Susan, for having me today. Yeah, at Wegmans, our mission is to help people live healthier, better lives through exceptional food. This is guided in our high standards for food safety and really which is at the heart of everything we do, kind of building on everything we do today. Our goal was to pilot, was to really better understand the process, changes the needs, and then in some cases kind of kitchen design changes that would be required to scale this transformation process to meet the requirements of the rule. So our pilot was primarily focused on an in-store transformation event at one store that is producing a spicy tuna roll with three ingredients on the food traceability list. That is then shipping that product to another store nearby, in their division. So really what our goals when we were trying to learn, like I said, was really to better understand this process and how we would scale it.

So that's pretty much our first learning is really just the complexities and understanding the scaling of these processes. For a lot of our supply chain, the product moves on pallets and in cases and boxes. When we get into in-store transformation, we start removing that product from its case. So for instance, it's really important for us as we continue to produce products through several intro steps to really understand those key data elements through that whole transformation process. For instance, it's really highlighted the needs for us to better understand GS-128 case labels and the industry standards that go beyond those. So those are really important for us. And that's really highlighted in the fact that the more uniqueness or differences we were identifying those labels, the harder it is to train folks on the floor to better understand, "How do I capture a lot so that I can take that ingredient lot and move it into a transformation lot?"

So really just highlighted the importance of industry standards and them being a pathway to success for meeting the requirements of the rule. We certainly, as we embarked, we learned a lot and it guided our, I'll say, strategy and our requirements. And those requirements, our goal was never to be unique in our requirements, and we really just wanted to align to those standards. And to build off of, Charles, data accuracy and alignment across your supplier base, super important in order to be successful. So I would say that's the biggest learning we had from our early stages of that pilot.

Susan Winckler:

Yeah, that's really helpful. And I hear you, even though I didn't hear Takashi say the word standards, in looking for what the common elements are in some of those other components, clearly there's a component of that. And then hearing both from Charles and Michael, the importance of the standards, I'm struck that I've heard folks in speaking about implementation efforts like this, that standards help you move with more speed, that they allow you to have that common approach. So I'm struck that that's kind of a distilled out learning of each of yours.

So that helps all of our attendees to be thinking about they're beginning with that baseline level of awareness, focus on the commonalities, and then thinking about the technology and recognizing the complexity, the importance of standards. So let's pivot to a bit... something beyond the practical awareness. I'm interested if any of your implementation efforts allowed you to illustrate any value that your organization might gain from enhancing traceability as outlined by the regulation, or is it too early to be thinking about that return on investment? So, Charles, I'm going to turn to you first with that one.

Charles Leftwich:

Yeah, thanks. To be honest, when we conducted our pilot though, Susan, we were really focused on how we could comply with the rule. With that, I mean, we really weren't focused on effectively tracking the operational benefits for what we were doing. But irregardless you, we didn't see many substantial operational benefits during the pilot that made us quickly begin to implement changes. In fact, it was more the opposite where it appeared it would increase costs.

But I think there's two important things to consider on the topic of operational value. And the first is, if a company has very little technology in place to support the rule, then they probably are going to see huge operational benefits for the company. For example, if a company is not currently date tracking perishable products, then they'll probably see an appreciable benefit in the shrink due to spoilage, because often the traceability lot code may be the best by date or a similar type of date.

Or if a company does have technology to address some of these potential benefits, they may not see a substantial operational benefit. For example, many ERP systems today are set up to date track products by capturing a single lot code for a pallet. And by earning the oldest date on the pallet, a company could manage the potential for shrink or spoilage without tracking every single possible lot code that was shipped on that pallet.

Second, some of these traceability enhancements could create additional unintended consequences or other issues that would require additional costs that need to be evaluated for the business. For example, we believe that there's operational benefit in utilizing advanced shipment notices. We believe that ASNs have the potential to speed up our receiving and inbound logistics processes. However, as I mentioned earlier, the data that's sent through ASNs can frequently be inaccurate and it can be delayed substantially, which causes

major issues if an entity is solely reliant upon those advanced shipment notices for receiving.

In fact, we've heard from several companies who are heavily invested in ASNs, they've had to create new supplier compliance teams just to manage discrepancies and other issues related to the ASNs. So, again, we need to make sure that when we're looking at the overall impact to the business created by these changes in our processes and technologies to get a true assessment of the impact to the business from an economic standpoint.

Susan Winckler:

Mm-hmm. So it depends a bit on where you are both in your traceability work, but then also in some other components of where you may have implemented technology or not in the other pieces. Michael, I'm going to turn to you and then we'll turn to Takashi. But, Michael, does the value question look different from the Wegmans angle?

Michael Lookup:

I would say it's pretty similar. What our original focus was heavily on the compliance of the rule and developing MVP or minimum viable product type solutions. But when you think beyond compliance, improving traceability through a better digital relationship with your supplier partners can certainly have benefits for Wegmans, our suppliers, our customers. Really building on what Charles said, there's benefits to ASN receiving and using EDI as a mechanism to transact information across the supply chain.

But it is really important to see those benefits really understanding if you don't want to deviate from those standards and you also want to make sure your data is not misaligned. Because the more misalignment of data, the more deviation from standards you drive yourself into operational impacts and certainly can have an impact there. Certainly we continue to work through and understanding the impact of, I'll say, some of the more complicated supply chain scenarios, but really do really heavily focus on it bringing forward that kind of EDI framework and working with our suppliers to onboard. So we're heavily involved in that right now and excited about all the benefits it'll bring. But like I said, it's certainly a work in progress and continue to kind of learn as we go.

Susan Winckler:

Yeah, yeah, very helpful. But I think also acknowledging it's in those kind of cranking up stages, which has... You feel those bumps a little more. Dr. Nakamura, I want to turn it back to you. So is value a different calculation for your place in the supply chain, or is there some resonance with what Michael and Charles are sharing?

Dr. Takashi Nakamura:

Yeah, I mean certainly there's overlap with what Michael and Charles described. But I would say when we first started this and started our mapping exercise, we quickly found areas of opportunity for unlocking efficiencies in the organization.

And I'm going to talk broadly in two areas. One very specifically on our unique product identifiers, so GTINs. So every organization has it probably throughout their whole product skew, but over the years it can take a life of its own.

And there have been several great articles by very reputable food and beverage companies over the last couple of years on when those product identifiers are properly generated, managed, and there's oversight of it, the potential for an organization to be more efficient with their supply chain can potentially be in the millions. That's just an example. So as we went on this journey of FSMA 204 compliance, we were able to see a lot of different opportunities for unlocking efficiency, which the company is right now taking advantage of.

I'd say the other area that there's a lot of value, and I think my two partners have also commented on this, is harmonization and standardization. So we use a very extensive international supply chain base, and even more so now than what it was maybe 5, 10 years ago. And that pace will probably keep increasing over the next couple of years. What does that mean? Well, education, training, making sure that food safety is on a common place among all of our supply chain, regardless of where their locations are. And what that really does, it unlocks opportunity and value for our own internal supply chain as well as commercial opportunities for our business. So one, going back, value? Absolutely. We saw that pretty early on in our efforts here and we probably will continue to tease out some of those as we work in the next year or two on compliance.

Susan Winckler:

Great. And I'm glad you mentioned the international dynamic here as well. And it strikes me that as you acknowledged... But I want to ask, did you find your company doing some of the education for your international suppliers so that they understood?

Dr. Takashi Nakamura:

Oh yeah, absolutely. I mean, numerous. And in addition to all these numerous, very educational webinars that organizations like Reagan would all do, it's probably hundreds in the last two, three years. So, yes, we do actively involve our own training to supplement anything that industry or institutes have. So we have a pretty extensive one on that too.

Susan Winckler:

Mm-hmm. Mm-hmm. Okay, very, very helpful. So there are... as we get through the cranking upstage, seeing some opportunities for value there.

Dr. Takashi Nakamura:

Definitely.

Susan Winckler:

Yeah. Okay, so let me turn then to think about a really practical point on the learnings that each of you has had. Let's imagine that one of our listeners, one of the webinar attendees is going to start a pilot or implementation efforts in four weeks. Michael, what would you tell them?

Michael Lookup:

No, that's a great question. Honestly, I think it's still a kind of two themes, right? First is collaboration and communication across stakeholders is paramount. Second, it's keep it simple, right? So when you talk about a pilot and collaboration, it's really making sure... Don't be afraid to start small and learn and be... Adjusted as you learn. So certainly it doesn't have to be the world's biggest pilot.

We spent a lot of time with our folks on the front lines making sushi, understanding the importance around the processes, the current state, but also helping them understand the why. Not, "We're just changing these processes," why? So I think that's really important and it went a long way. And then at the end of the pilot, we spent a lot of time learning from them, talking through it and better understanding where there was opportunities, where things we could introduce and really just support them along the way, making sure that you're there, you're supporting.

In terms of implementation and keeping it simple, I think Takashi had mentioned this a little bit earlier, prioritize and understand those highest volume scenarios. First, take that 80/20 principle, looking for ways to move forward in a forward manner, but also keeping the momentum and understand, don't let a lot of the different varying scenarios or edge cases distract you from getting things done. So certainly look to do that. And look for ways to remove some of the noise from the implementation. You can use to a lot of the points today of getting ahead with master data. Can you take a look at your master data? Is there alignment between you and your supplier partners? So certainly like I said, just kind of keep it simple and then communicate and collaborate along the way.

Susan Winckler:

Yeah, I heard communication, the communication, the communication. Not just the practical, but the why and helping folks to understand. Takashi, what would you add to Michael's thoughts for that person who's kicking something off in four weeks?

Dr. Takashi Nakamura:

Yeah. No, I'd feel overwhelmed initially. But, no, I'm going to echo a lot what Michael said. I mean, one of the most important things that we did from the very beginning is you put together a multifunctional team. I'm talking sales, operations, procurement, data management, quality, food safety. Now, like any project, they come in and out depending on the need of where they're at. But I can't stress enough the importance of having a truly cross-functional team addressing this pilot that this organizations are looking at doing in the short

time. Because you just can't do it all. And there's just nuances of every different function that have input into FSMA 204 compliance that you're going to find are really critical and you're not going to know that unless they're on the team. So that's one.

The second one is get mapping your supply chain as soon as possible. And that seems like a simple exercise, but again, it's more rigorous when you do have that cross-functional team. So I get this in, where are they in the supply chain? Are they direct to us? Do they sell whole? Does it go to fresh cut? All of that needs to be taken into account. And then I go back to when you're doing that mapping exercise, especially if you're on a very short timeline, want to accelerate that, you're going to have to, with this team, really prioritize those transactions that happen in any organization on a daily basis to go, "Let's go after the big chunk," the 80/20 rule that I described earlier.

But again, echoing a lot what Michael said, I mean, you got to communicate, you got to have the right people on the team, and you got to have the focus of what are the priorities of the project. Because with that short of a time window, if you have those elements, I think you have a pretty high level of success. Because, again, if you start going down every little mole hole, rabbit hole, it just won't work. But that only comes when you have a team that represents many different functions engaged in talking. And I'll be honest, some of those discussions are pretty tough. But when you break through those tough discussions is when you find like, "Oh, okay," the aha moment, and hopefully that helps. But map, prioritize and make sure you have a good cross-functional team.

Susan Winckler:

Yeah. Great. And you're right, it's better to have those difficult conversations with the right people around the table-

Dr. Takashi Nakamura:

Absolutely.

Susan Winckler:

... than folks who are leaning back and being like, "Okay, let's see where that goes."

Dr. Takashi Nakamura:

See where this goes. Yeah.

Susan Winckler:

Yeah. Charles, I want to turn to you on this. What would you emphasize in that attendee who's like, "Yep, we're going to start doing some of this in four weeks," or four days, but we'll give them four weeks.

Charles Leftwich:

I'll give them four weeks. It's funny, I was sitting here thinking about what are the three things I would say. And I think they've kind of already been said what I was thinking. The other thing I would add that maybe wasn't said that I would add is our technology team has a saying, fail small, fail fast. I mean this rule and the compliance for this is so complex and so massive, if you try to build an end-to-end solution and then start to implement that, my opinion is you're going to have a lot of problems.

And so how do you start to quickly eat away of the elephant one bite at a time and start to slowly make those changes? And that's why we started doing the pilots on the inbound receiving side, is we started with a small trunk started there, we moved to the next step in the process, tried that, fix that, move to the next step of the process, try that, fix that. We realized we have to go back now and fix something at the very beginning and redo that. And then that way you're not trying to deploy a whole big solution at once.

The other thing I would echo a hundred percent is the cross-functional stakeholder engagement. You're going to need all aspects of your company to come together to support the initiative. And so you may want to consider having your FSQA teams and your legal teams to assess the impact of the rule, your procurement teams to understand which products are on the FTL, which ones aren't, and how they're going to engage suppliers and hold them accountable to however your compliance plans look, your operations team to understand how are you going to capture this information throughout the process. Even your HR teams, there's going to be roles and responsibility changes and how are you going to communicate those to those impacted individuals and is there other changes that need to be made?

Or obviously your technology team, I think everybody's gotten that message loud and clear, but also your sales team, they're going to need to make sure that they're talking to the customers and understanding how the customers, what their expectations are going to be and how you're going to meet those. Your finance teams. I think one of the reason these conversations are difficult is because they cost money. And so having those financial people in the room as well to understand, "How do we need to plan for these financial investments into the future? What's this going to do to our cost structure by having to scan cases," and things like that. So I think that's probably the most critical one, is making sure that you're not trying to do this alone as a compliance group or as an FSQA group or whatever. I mean, making sure that you have a good, well-rounded functional team to help support you is going to be critical.

Susan Winckler:

Excellent. So I think that builds on... I was building the list that Michael started out with, collaboration, communication, the commonality. You've got now the cross-functional broad team. I did have to lose the alliteration there, but when we get into some of the other elements about prioritizing and working with the map, but really helpful insights from each of you on trying to piece that together and how to move forward.

I'll note we have time for one final thought from each of you. I would love a kind of rapid fire observation, but you can take a minute or two. We've covered the most important things, some of the value, the what to think about first. Would love to hear you share what surprised you in your early implementation efforts? So was there something... of course, these things and your business, so there's a lot that was probably expected. But what would you observe was surprising or unexpected? And now I'll go to Takashi, Charles and close out with Michael. So Takashi turn to you.

Dr. Takashi Nakamura:

Yeah, so thanks, Susan. I say the one that I look back on, where we were with where we're at now, is our current traceability programs and processes essentially capture most or if not all of the critical tracking events and KDE's specified by FSMA 204. I think the big one for us is how do you aggregate that, make it more seamlessly communicate with each other, the different systems, so that you can get a report out in the time that is being requested? So that's probably like one is we have that information, we have that data. It's just making sure that you can route that and assimilate that in a manner that is quick and accurate, which is a big part of why technology is such an enabler for this.

But the other thing too, when I think about this traceability and FSMA 204, I think even beyond just as an organization or an industry above and beyond what we're trying to do here is that it really addresses the three pillars like food security, food defense, and food safety. All of this is about transparency, getting a global ecosystem which is even expanding as we speak into a more standard harmonized state of supplying all of us with safe, reliable food. And when looked at that lens, I think people in the organization, our consumer base, I think will better understand and embrace what this ruling really is. It's not just about making sure that I can track something from A to Z and do it within a certain time window. It's much more than that. It's just making sure that we have... In many areas we have food crisis and I think having initiatives like this, which will I'm sure be picked up by other regions too, is that we're ensuring food security, food safety, and food defense.

Susan Winckler:

Great. So you see that broader effect and impact on those?

Dr. Takashi Nakamura:

Absolutely, yeah.

Susan Winckler:

Okay. Charles, I said I'd come to you next.

Charles Leftwich:

Yeah, so I think I'd start with almost where I began. I think one thing I hear routinely, both internally and externally is that we have the ability to trace our

products today. And so complying with the rules shouldn't be an issue. But, again, like I started the conversation with, many entities in the supply chain can trace their products up and down the supply chain. The thing that makes this rule extremely complicated is how you effectively and efficiently share that transactional level data up down the supply chain with each shipment in a standardized manner. And the key word there is standardized. And what makes it difficult is because we don't have interoperability across the supply chain. Each player in the supply chain has a different way of receiving data, a different way of tracking data throughout their process, in a different way of sending that data to their customers.

And so trying to standardize that across the industry is, in an economical manner, is what really makes this rule difficult to comply with. The other thing I would say is the de facto case level tracking requirements that the rule necessitates for downstream entities and the supply chain. Product isn't bought and sold at a lot level, and lots are often combined and mixed on loads and pallets and so forth. And so products may be sold at the case level or even the sub-case level throughout the supply chain. And so to ensure that entities know specifically and definitively which lot is sold to which customer will require that case level tracking for many entities in the supply chain, especially those who are downstream of the manufacturing facility. So those are the two things I would quickly say that were kind of a surprise.

Susan Winckler:

Okay. So that, yes, there was an awareness and then there is the how to do that efficiently and effectively and broadly? All right, Michael, let's turn to you.

Michael Lookup:

Yeah, no, kind of similar to what you said earlier, Susan, around there was an expectation, but what surprised us I spent a lot of time in my supply chain in my career and certainly expected a great deal of coordination, but I still very much so, as we've kind of began our implementation working with our suppliers, just really am surprised at some of the coordination it really does take to share information across partners, both accurately and timely. I know Charles kind of alluded to that a little bit earlier, just the coordination of transacting data across the supply chain up and down.

But certainly, like I said, it really does emphasize the importance of us working together as an industry and collaborating. At Wegmans, we see this as a shared responsibility between Wegmans and our suppliers, and we'll continue to collaborate and partner and improve traceability for us and our customers. So yeah, I think it's just continuing to focus our energy and our efforts on the right focuses and continuing to focus on how we continue to improve the traceability.

So I would say it's that great deal of coordination. Also throw in the number of mangoes on a pallet, sometimes lot codes on a pallet of mango. So I always throw that one out there. That's something that surprised me early on in this endeavor.

Susan Winckler:

So you were expecting... I might imagine you were missing some smaller number and it was much larger?

Michael Lookup:

A little bit larger. Yes, yes, yes.

Susan Winckler:

Yeah. Yeah, that is a great visual. Michael might've given us, no offense, Takashi and Charles, but Michael's visualization from the... Was it spicy tuna?

Michael Lookup:

Spicy tuna roll, yeah

Susan Winckler:

Yeah, yeah. Spicy tuna roll. Because I could actually see your team members doing the work then be like, "Oh, we have something to do with traceability here when we probably think our primary..." Well, their primary role is making good sushi, but then thinking about what the traceability dynamic of that is and how to carry the information forward. Well, I'll just note it's been really helpful for me to have this front seat and hear from each of you about what you've learned and the observations you've had.

I'm concerned if I turn to you with one more question that will go well past our time, but it's really helpful, and I appreciate sometimes in conversations like this it can be challenging or there can be a competitive dynamic that comes in. And each of you has just been so refreshingly candid and sharing your insights that I just want to thank you for doing that. And so for pursuing the efforts, obviously this coordination and everything, we'll have to continue in order to see the benefits.

I think, Takashi, you said in food security, food safety, and there was a third pillar that-

Dr. Takashi Nakamura:

Food defense.

Susan Winckler:

... food defense, to see the improvements there.

Closing Remarks and Adjourn
Susan C. Winckler, RPh, Esq., Reagan-Udall Foundation for the FDA

Susan Winckler:

So thank you so much to each of you for investing your time in these efforts every day. But then in particular in sharing those efforts with us today. What I'm going to suggest that we do is that we give our attendees a little bit of time to internalize and think about what it is that you've shared before they run off to the meeting that they have scheduled at the top of the hour. And so allow me to say thank you to each of you, as well as to our colleagues from FDA and to all who are listening to the webinar.

I'll note we will be posting the recording and the transcript from today's meeting on our website, reaganudall.org, if not late this week, early next. And on behalf of the Foundation and FDA, we appreciate you joining us and contributing to the discussion. Take care and be well.