

Requirements for Additional Traceability Records for Certain
Foods: Proposed Rule

Docket No.: FDA-2014-N-0053

Moderated by Kari Barrett

Friday, November 6, 2020

8:30 a.m. - 5:00 p.m.

Remote meeting

Food & Drug Administration (FDA)

White Oak Campus

10903 New Hampshire Avenue

Silver Spring, Maryland 20993

Reported by: Andrew Adams

JOB No.: 4263767

A P P E A R A N C E S

List of Attendees:

Kari Barrett, FDA Center for Food Safety and Applied
Nutrition, CFSAN

Frank Yiannas, FDA Food Policy and Response

Katherine Vierk, Office of Analytics and Outreach, FDA
CFSAN

Karen Blickenstaff, Coordinated Outbreak Response and
Evaluation Network (CORE), FDA CFSAN

Laura Gieraltowski, Division of Foodborne, Waterborne and
Environmental Diseases, Centers for Disease Control and
Prevention (CDC)

Brian Pendleton, FDA Office of Policy, Legislation, and
International Affairs

Yuhuan Chen, Division of Risk and Decision Analysis, FDA CFSAN

Christopher Waldrop, Office of Analytics and Outreach, FDA
CFSAN

Angela Fields, CORE, FDA CFSAN

Aliya Sassi, Office of Policy, Legislation, and International
Affairs, FDA Office of the Commissioner

Andrew Kennedy, FDA Office of Food Policy and Response

Erik Mettler, FDA Office of Regulatory Affairs (ORA)

A P P E A R A N C E S (continued)

Kyle Shannon, Center for Milk and Dairy Product Safety, Office

of Food Protection, Maryland Department of Health

Rebecca Buckner, FDA CFSAN

Jennifer McEntire, United Fresh Produce Association

Bryan Hitchcock Global Food Traceability Center, Institute of
Food Technologists

Hilary Thesmar, Food Safety Programs, FMI

Sarah Sorscher, Center for Science in the Public Interest

Susan Mayne, FDA CFSAN

Luis Saucedo, Trust Guardians

Donna Garren, American Frozen Food Institute

Rachel Gabato, Ripe Technology

Jeanne Duckett, Avery Dennison

Bill Ritcey, Blocksyste

Stephanie Harris, Food Marketing Institute

Dominique Mital, Fresh Food Factor

Ron Volpe, Persequor

Patrick O'Connor, International Warehouse Logistics Association

Scott Donachie, Companies for Zero Waste

Adam Brock, Dairy Farmers of Wisconsin

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P R O C E E D I N G S

MS. BARRETT: I hope you find today's meeting very helpful in evaluating the proposed rule as well as in facilitating the commenting process. So again, my name is Kari Barrett. I lead the Public Engagement Team for FDA Center for Food Safety and Applied Nutrition or CFSAN, and as Michael mentioned, I'll be hosting today along with Michael's help.

We are pleased that so many of you could join us for our first virtual CFSAN public meeting. This is also the first of a series of three public meetings on the traceability proposed rule. Over the course of the day, you're going to hear an overview of the rule. You're going to have some presentations on significant components of the rule. We'll hear from our state partners, external stake holders, and then at the end we'll have our public commenting process.

So a few quick notes, all of you should have access to the agenda and to the speaker bios from our website. So please, if you haven't already pulled those up, have those available to you, and also today's meeting will be transcribed. It will be recorded, and when ready, these materials will be posted onto our website.

So with that, at this point, I would like to turn it over to Mr. Frank Yiannas, our FDA Deputy Commissioner for Food Policy and Response, to give a warm welcome and some introductory remarks, so Frank, thank you.

MR. YIANNAS: Thank you, Kari. I want to make sure that I'm coming through. Can you hear me?

MS. BARRETT: Yes.

MR. YIANNAS: Great.

Well, good morning, everyone. Thank you for joining us today and for being a part of what is going to be a very, very critical conversation. We thank you. I recognize these are challenging times for everyone, and I appreciate that fact that you've taken time out of your busy schedule to look forward toward the future with us and working together to determine ways we can strengthen the protections for generations to come.

When we talk about food traceability today what we're really talking about is the ability to track a food at every step of its journey throughout the supply chain continuum. And by every step, we mean when a food leaves its origin our source all the way to where it lands on your dinner plate at the

restaurant that you consume it or at the retail location that you buy it. The draft rule we'll be talking about today is critical in my view. One can say that it's not only critical but it's foundational in our work to achieve the kind of end-to-end traceability that we envision being needed and inevitable in the future food system.

In the Food Safety Modernization Act, which we often refer to as FSMA, Congress anticipated the need for enhanced tracking and tracing of certain foods. We've used that framework provided to us by Congress to propose this new food traceability rule. In a draft list of foods for which additional record-keeping would apply, please note, and this is a very important distinction, that we're not calling it a high-risk foods list because the reality is any food can be risky if not handled appropriately or if the right steps aren't taken to ensure its safety. And we believe that calling it high-risk might be misleading to consumers. So instead, we're simply just calling it the food traceability list. And while it's limited to only certain foods, we're laying the foundation for the type of approach for traceability of record-keeping, paving the way for industry to adopt, harmonize, which is really important --

we'll talk more about harmonization -- to leverage, and very importantly for me is this concept of scaling more digital traceability systems in the future.

The proposed rule, which is under the offices of FSMA, is also part or a bridge to the new era of smarter food safety, the blueprint that the Commissioner and I, Dr. Steven Hahn, announced in July. In fact, tech-enabled traceability is one of the foundation pillars of our new-era initiative in which we plan to leverage new and emerging technologies, new tools and approaches to create a more digital, traceable, and safer food system. This track rule which we're talking about today is the first step in our work to harmonize the key data elements and critical tracking events. Two terms that you'll hear a lot about today needed for enhanced traceability. You'll be hearing from my colleagues today about the what of the new proposed food traceability, what's in the proposed rule, what are the certain key data elements, critical tracking events, what foods do we propose be covered.

So I thought I'd spend my few minutes with you this morning to start off with why this proposal is in my view so important and a game changer for food safety. I often like

to start off with the why because the why is critical. The why generally informs what we do. It serves as what I call a powerful antecedent to our behaviors and actions that I hope we will take together. Like I said, you'll be hearing about data and standards, but I want you to remember that at the end of the day, all of the discussion today is really about one thing. It's ultimately about protecting consumers from contaminated foods. It's also about creating a more transparent food system. In other words, it's about getting rid of the anonymity. The anonymity that exists and is often present as health officials try to investigate the cause of a foodborne illness and where the foods came from.

Everything we're doing is about bending the curve of foodborne illness in this country. Let me repeat because it's that important. Everything that we're doing is about bending the curve of foodborne illness in this country and giving consumers the confidence they deserve to have safety in the foods on their dinner tables and the foods they serve their families. So let me begin by elaborating on why this proposal is so important and why I genuinely believe it's a game changer for food safety.

First, we've made great strides in implementing FSMA. Most compliance dates as you know have arrived. There has been extensive training. Inspections are being conducted. Guidance documents and other resources to allow industry to comply have been provided, and in fact, while we're committed to educate before and while we regulate, enforcement actions have been taken. And today's food system is impressive when you think about the wide variety of foods available to you and many consumers. Wide variety meaning tens of millions of different food items in your typical grocery store and available to you for a fraction of your hard-earned dollar. In fact, one of the lessons for me from the COVID-19 pandemic is that despite the challenges it has and is presenting, the food system has remained amazingly resilient.

However, I've often been quoted as saying that I believe today's food system has one Achilles heel. This isn't just a soundbite. I genuinely have lived it, I've seen it, and believe it. That one Achilles heel is a lack of traceability and transparency. The records involved in moving food to the supply chain are still largely paper-based for food safety purposes. We must create a system which is necessary to take

one step forward to identify where the food has gone, one step back to identify the previous source. This concept, along with insufficient and a lack of standardized data for identifying the product, along that supply chain continuum creates an inability as we've all seen to rapidly track and trace foods to source during an outbreak. And during an outbreak, this can cost lives, millions of dollars in a abortable product loss and damage to consumer trust, which is very precious.

I cannot state this strongly enough. When there's an outbreak of foodborne illness, it's critical to rapidly identify where the contamination occurred. We all know we're getting really good because of the application of new ways of working and new technologies to identify these illnesses that are related across the country and often times associated with a certain food. We have to make the same types of dramatic improvements that we've made to make linkages of ill individuals to a food to where that food came from. We just have to do it. Having this information allows us to alert the public and the food industry about which food to avoid to rapidly and more promptly remove contaminated foods from the market and evaluate what may have caused that contamination in the first place so

that actions can be taken to prevent them from happening again.

So you see, food traceability is about foodborne prevention. All of this requires an extensive investigation working as necessary with our state and local partners, federal partners such as CDC and USDA. And these investigations simply cannot be effective and timely without being able to capture accurate information along the food supply chain's continuum. This is why this issue that we're talking about today is so important.

When we look at the current state of traceability across the food supply, we find that even though some companies and retail chains have stepped up, are modernizing, and creating more effective traceability systems, rarely are these systems compatible with each other. And even when they're digitized, it's hard to make connections because not all companies in the food continuum, which remember is a very large and decentralized food system, have adopted similar data attributes or similar technology. Simply put, we lack a harmonized system of tracing foods from farm to fork that is universally understood and utilized. And we can work together to change that.

The second part of the why for me is food safety,

as I think many of you know, has been my life's work for more than 30 years. First, in the private sector and now, what a privilege to be working in the public sector at FDA. And there's no question in my mind, zero, that there's a strong public health and a strong business case for better food traceability.

Some of you know I was once involved, not that very long ago, in a pilot involving blockchain technology to see if leveraging technology, and it's never about the technology, it's about the public health problem that we're trying to solve, but if by leveraging technology we could step up and do a better job with food traceability. The iconic example that I use that some of you have heard is worth repeating here for those that don't know the story. But I wanted to know if we could trace foods back to source using technology more quickly, more efficiently, more accurately, and I was interested in this new and emerging technology called blockchain.

Let me tell you the life story of a mango because it's pretty complicated. Mango is a particular, like many other foods, have a complicated supply chain. For mangoes in particular, it begins with planting mango seeds into the ground.

Mainly in this hemisphere, the mango that we consume are grown in Central and South America. It takes about five to eight years for those seedlings to mature into trees that are bearing fruit. Maybe eight years later, they're bearing these beautiful mangoes and they begin, but before the completely ripen small farmers in Central and South America send farms crews out to pick those mangoes. Those mangoes then go to a packing shed. They get washed and packed, a heat treatment process. They then will get shipped to exporters and importers to get, for those that are consumed in our country, across the U.S. Customs border.

Once in our country, in this particular instance, sliced mangoes, they went to a processor where it's further washed, peeled, sliced mangoes, and put them in clear clam shells. The mangoes then went to distribution centers, many of them across the country, and in this instance they ended up being distributed to about 6,000 retail outlets across the United States. You can just envision, I hoped you visualized the many steps that it takes for those mangoes to make their way to your dinner table.

So I wanted to see, well, if we want to trace

back these mangoes, how could we do it and how long would it take? So I literally took a package of sliced mangoes. I brought it into one of my staff meetings when I worked in the private sector, put them on the center of the conference room table, and I told my team at that time -- they didn't know this was going to happen that day at a staff meeting -- the traceback study starts right now. I said I want you to tell me from where these mangoes in this package of sliced mangoes came from. And I looked at my watch, noted the time and date, and said come back to me when you know.

I often like to ask how long do you think that took? And when I ask people, people will guess a variety of different time ranging in dates. It took our team then 18 hours and 26 minutes. Now some think, wow, that's a long time. The reality is that's pretty fast when you think about how traceability is done in this country. We then started to do a pilot where we were tracking using key data elements and critical tracking events, real simply user-friendly technology that people could use even if they didn't speak English as their primary language. And after 30 days, we did pilot. We scanned the package of mangoes to see where they came from, and we were

able to do it in 2.2 seconds. Now that's what I call food traceability at the speed of thought. An ability to deliver accurate real-time information about food, how it's produced, and how it flows from point of origin to consumption is a game changer for food safety.

The draft food traceability rule that we're talking about today is developed independently of any specific technology. I want to be clear. So that will remain relevant well into the future. We imagine that in the future methods for capturing, storing, and sharing traceability data will continue to evolve; however, these basic principles of traceability, data elements, tracking events, will remain consistent. We recognize there will be many solutions available, and while the FDA will remain technology agnostic, we'll let you choose if you so choose to comply with technology. You might choose to do it on paper, but we will be very focused on helping to ensure that the technologies that are out there in the marketplace and evolving can work well together. Paying attention to issues like interoperability, governance, the importance of common structured data and terminology such as the key data elements, KDE, and critical tracking events, CTE.

We'll also need to help ensure that food companies of all sizes, small included, can utilize new tracing technologies with costs we believe proportional to the benefits. But we also need to ensure that the lessons learned about food traceability through insights gathered by better traceability are shared with all in the continuum and even broader. We often say, and I hope that we all truly believe this, that food safety is not a competitive issue. That when it comes to food safety, we all win or lose together. We've all seen many examples of that. That's what we need. That's what I mean when I talk about democratizing data and information in the food system. We must create digital, traceable ecosystems that I believe create shared value for all involved and for organizations and companies of all sizes.

I see how these ecosystems when they create shared value can scale. Farmers participate because they know if they participate, if there's a food outbreak, they don't want to be falsely incriminated. This idea that everybody is guilty until proven innocent, and if they can clear their good name and continue to sell product, that's good for them. They want to be in those types of systems. Processors want to participate in

the case of sliced mangoes. This processor told me often times, Frank, when our products don't make shelf life, we get accused of being the problem, and we're not convinced of that. That maybe the temperature abuse occurred somewhere else in the food system. It creates shared value for the processor because they want to know the truth. And then certainly, retailers and food service organizations benefit from being in these types of systems, and ultimately, it's a big win for the consumer. That's what I mean by shared value.

We know that industry has already taken the lead in the quest for better traceability. You see these systems evolving at breakneck speed. Why? Well, primarily because their customers are demanding it, and it's good business practice. And there is already a lot of pilots and scaling of these technologies underway.

Let me give you the last why I think this is so important today. You don't have to look too far. I don't think I have to spend a lot of time persuading you this morning about the deadly outbreaks that have defined what a lack of better food traceability has cost us in society. Whether it was, and you can pick your example but I'll give you a few, the outbreak

of E. coli 0157:H7 inspections tied to bagged spinach in 2006. Do you remember that? More than a decade ago now. Illnesses of E. coli 0157, CDC tells us there's there's an association with bagged spinach. We don't know the brand of bagged spinach.

FDA investigators begin traceback exercises to try to determine the source. During that time CDC and FDA did what you would expect us to do which you put out a consumer advisory, and all spinach is wiped off grocery stores nationwide and off of restaurant menus overnight. All spinach. It took investigators almost two weeks to trace that back to source. When it was all said and done, there was one producer, one base production, one lot number. A lack of traceability.

How about the outbreak in infections tied to Peanut Corporation of America in 2009? A company that produced a very small percentage of peanut paste in this country, but that peanut paste had a way of making its way of an ingredient in literally over 1,000 food skewers. And the numerous ingredient recall that it resulted. At that time, I worked for a retailer. I could remember getting recall notices three months after -- three months, no exaggeration -- after the initial outbreak from food producers who were just getting around to figuring out that

that peanut paste was an ingredient that they used in their product. That's unacceptable. We can do better.

How about the multi-state outbreaks more recently of E. coli 0157:H7 infections tied to romaine lettuce and in particular, 2019. Better traceability will have the benefits of not only helping us solve outbreaks sooner and potentially preventing additional illnesses by shortening that epidemic curve. That's critical. That's a form of prevention, secondary prevention. But it will help us get back to source quicker to conduct the much-needed root cause analysis to prevent these outbreaks from happening again and again in the future. And that will lead to primary prevention.

You see, better traceability will result without question in better foodborne illness prevention. We need to all understand and agree to that, and it will also help prevent food producers from being unfairly impacted by contamination events that have nothing to do with them as I talked about. These outbreaks where there's these precautionary advisories, rightfully so. I'm not being critical of those. We will do that if the technology doesn't allow us to be more precise and granular. But the damage that that does when you have to pull

all product from shelves, the consumer trust is hard to measure.

Listen, food safety to me is first and foremost about protecting public health people, but it's also and we can and must do better. The need for modern traceability capabilities, in fact, is stressed in some of our recent work. Some of you are familiar with our 2020 Leafy Greens Action Plan we released in March to help prevent reoccurring natures of outbreaks due to Shiga-toxin producing E. coli in fresh leafy greens, and we're already getting a sense of how improved traceability can help in our response. In fact, in the outbreak of romaine lettuce that occurred in 2019, the fall of 2019, you saw the improvements that had been made in one short year as opposed to issuing a public health advisory to avoid romaine from anywhere across the U.S., based on some voluntary labeling that had been conducted by the industry as well as some companies adopting more tech-enabled traceability, we were able to limit the scope of that advisory to a geographic region. Not good enough, but you can see how progress has been made and how one day we might be able to limit that to a particular farm or ranch.

Traceability, I think I've persuaded you, is

critical, but let me just talk a little bit now about lessons learned. When you look at other industries and how they're able to track and trace through digital means -- digital means, the real movement of, for example, planes, ride sharing, packaged goods. Just think about when you order non-food, non-perishable packaged good how you know where it's at at every point in the destination and even what time it might arrive at your front door. We can leverage these same approaches and technologies with food. There's no question.

The benefits have been clear to me for a long time, but the need for better food traceability transparency have even been highlighted, believe it or not, during the pandemic. What we learned is that by potentially enhancing better traceability, these types of technologies and approaches might create the type of transparency needed to minimize disruptions in the food chain and get foods to where they need to be at the right time and at the right place. It's important during the normal course of events, and it should be an invaluable tool in a time of crisis.

And there are a lot of other benefits. Many of us have heard having better foot prints of where food comes from

and how it's produced could deter food fraud. We've all heard it said that there's more organic food sold in the world than is produced in the world. Having better traceability and transparency, do you think that might make a dent in deterrence? I think it could.

And lastly, we know consumers are demanding it more than ever. I've seen this firsthand over the course of the past 20 years. At one time, consumers really were interested in originatlity, and they still are. But more and more today what I've seen firsthand is consumers want to know more about their food. How is it produced? Where did it come from? This type of transparency is leading consumers to ask more questions.

Now if you tally up the pros and the cons that we talked about this morning, it's clear to me that the pros far outweigh any cons. And so let me close. I'd like you to imagine, yeah, imagine a world in which you can scan a product before buying it at the grocery store and knowing immediately ad with certainty if it was produced in a certain region or if it was involved in a recall for that matter. Imagine if FDA could trace a food vehicle suspected to be the cause of an outbreak from shelf to source in minutes instead of days or weeks.

This draft rule that we will work on together is an important bridge between FSMA and the new era of smarter food safety. One that will bring us to full end to end traceability in our food system, which is inevitable. We should shape and create that type of future together. We are working towards that goal every day at FDA, but we realize we cannot do this alone. In fact, it won't happen if we have to do this alone. Some of you have heard me say I have learned from working with the FDA from the other side of the fence for many years that there is a lot the private sector and industry can do to advance food traceability. They're doing it, and they should continue to do that and accelerate it.

But what I've also learned now, two years in public service, is that there's a lot regulatory agencies can do to advance food traceability, and we're doing just that as we talk today. But what's crystal clear to me is that this concept of food traceability can scale if both the public and private sectors work together. And remember, I like to remind people of this, ultimately, it doesn't matter where you sit or where you are today as you listen into this webinar, whether you're in the private sector or you're in public service, federal, state, or

local. At the end of the day, it's important for all of us to remember we're working for the same boss. I really mean that. The American consumer. So let's get this food traceability work started. Consumers are counting on us.

Thank you for being with us today.

MS. BARRETT: All right. Thank you, Deputy Commissioner Yiannas for your remarks based on your deep knowledge and experience with this issue. It's really a great start to our day, and we appreciate your time and remarks again this morning.

So we'll now go ahead and we're going to go to our next speak which is Katy Vierk. She's our CFSAN Division Director, Office of Analytics and Outreach, and Katy will provide an overview of the proposed rule. So, Katy.

MS. VIERK: Good morning, everyone. I also want to thank everyone for being here today. We certainly appreciate the time you've taken to join us. It's a pleasure for me to give an overview of the requirements for additional traceability records for certain foods or what we are calling the Food Traceability Proposed Rule. We know many of you have looked forward to this proposed rule, and we're excited to publish it.

And we look forward to today's meeting and your comments. I'd like to thank the FDA staff who contributed to drafting the proposed rule for their hard work and commitment, considering it's a very intricate issue including the various challenges that come with proposing a rule that encompasses a variety of entity-type commodity and domestic as well as foreign firms. Everyone at FDA worked very hard to consider the diversity among the entire supply chain.

One of the goals of this proposed rule is flexibility. We want to maintain traceability throughout the supply chain making sure traceability information are unbroken, but we also want to be flexible and enable the requirements to work for various business models. As you listen to the presentations today you will likely have a lot of questions. There is a lot of information and many of you will be listening with an ear towards how it affects you, your business, and your role in the supply chain. An important part of the rule-making process is for us to hear your comments. What you think the proposed rule gets right in regards to what will work across various commodities, types of businesses and business models, and for food safety and traceability. In those areas where you

have questions or see challenges in the proposal, it is important for you to provide comments in writing and especially provide details about the specific scenarios and real-life examples for us to consider. It's very detailed but helps us understand your complexities and will help us to ensuring a safe and traceable food supply.

So a little bit, just quickly, background on how we got here. In September of 2011, the FDA asked IFT, The Institute for Food Technologists, to execute two pilot projects, tracing projects. IFT carried out those pilot projects at the direction of FDA, and we released a final report on the final projects and the subsequent report to Congress that describes these findings from the pilot projects and included the agency's recommendations for improving the tracking and tracing of food.

Also in 2014, the FDA issued a federal register notice to comment on our draft approach to developing a list of high-risk foods. In September of this year, we published the proposed rulemaking including the publication of the designated food for which additional record-keeping requirements would be required. Here we are today, the first of our three public meetings.

FSMA Section 204 has a number of considerations and limitations which required a lot of thought in order to craft a proposed rule to apply rapidly and effectively identify the recipients of a food, such as the requirement shall only apply to designated foods, not require a full pedigree, it should not describe the different technology for maintaining records, and the science phase. These are just a few examples of the things that were included in Section 204 that needed to be considered during the rule-making process.

As we sat to draft the proposed rule, we knew there was a better way for traceability. Better traceability can and need to be achieved individually as well as collectively. As Frank mentioned, there's a bigger picture here to consider. Transparency is in demand, and consumers want information through technologies and information technologies to help the way businesses are being introduced quicker. And businesses are pulled in many directions on what technology achieves especially for traceability, and we know that the ones stepped up and the ones stepped back is not enough.

We need data standards, common information, common terminology to clearly outline and follow consistently

across an industry and across all industries. We need that connecting information, the linkages throughout the supply chain. Information to know the scope of the problem and to understand how affected food moves through the supply chain, and we need technologies to be interoperable. There are new ideas popping up in traceability technology. Firms of all types and sizes need to be able to determine those technologies and what will work best for them. Information included in the proposed rule provides that foundation to allow for interoperability. And it's about interconnectivity. Taking it from a responsibility handled in its own way by each segment in the chain to a solution that connects the points in the supply chain and is based on a common set of goals and terminology.

FDA has a unique perspective, and we see so many diversified chains and how they converge. A consistent issue is linking the movement of product. The identifiers to link incoming product to outgoing product through the entire supply chain are just not consistently there, and it has a big effect. Lack of interconnectivity affects our timeliness, and investigations take longer and that affects public health. It affects specificity, and that can be so detrimental to

businesses if we're unable to narrow and scope recalls. FDA response is affected. Resources could be misdirected if we have a larger scope of potential product because the traceability information doesn't allow us to narrow it, and it means we have more suppliers to visit, perhaps spending time looking at products and firms that could've been scoped out. And it affects our communication. We have a difficult time determining appropriate communication because we are waiting for actionable information, and this is a harrowing detriment.

While limited to only certain foods, the proposed rule lays the foundation for a standardized approach to traceability record-keeping. We recognize that to fully realize the public health benefits envisioned by FSMA, we need to improve our ability to identify and trace foods that may be causing illness. We need to quickly and efficiently trace the movement of foods through the supply chain and identify and remove contaminated food from the marketplace.

So the food traceability proposed rule was published on September 23, 2020. We are currently accepting public comments for 120 days through January 21st of 2021. As I mentioned in the beginning, we do encourage you to provide

comments. Once the public comment period closes, we will view the comments and work to develop a final rule. We are under consent decree to submit a final rule to the Office of Federal Register by November 7, 2022.

As Frank mentioned and you'll hear throughout the day here, the proposed rule has a number of intended benefits such as being able to more quickly identify the source of contaminated food which will reduce the impact of foodborne illness. We have more accurate information. If you have more accurate information to help identify the source of contaminated food, we would be able to focus our recall efforts rather than to issue large public health alerts that implicate entire product categories or growing regions.

More efficient traceability is facilitated when each point in the chain is maintaining the same information. So harmonizing and standardizing that information helps establish those linkages, and we believe our approach is consistent with current industry approaches in terms of identifying critical points in the supply chain where essential traceability data should be maintained. This information will also help to form cause analyses to identify and apply lessons learned from

outbreaks and hopefully prevent similar problems from occurring in the future.

So here is an overview of some of the key concepts, and these will be discussed in much greater detail throughout the day. The proposed rule covers any person to manufacture, process, pack, or hold foods on the food traceability list. One benefit of the proposed rule is that touches the entire supply chain from farm to manufacturers, processors, to distribution centers, to retail food establishments like grocery stores and restaurants to retail food establishments like grocery stores and restaurants. The proposed rule only applies to certain designated foods which will be also presented in greater detail this morning, and the requirements apply to both foreign and domestic firms alike. There are some exceptions and partial exceptions and two options to we propose with regards to retail food establishments.

Our approach to learning in the proposed rule is one that's consistent with current best practices in the industry. We have identified key points along the supply chain where it is most important to collect traceability information. These are called critical tracking events or CTEs and includes

points where food is grown, created, transformed, shipped, and received. At each CTE, we are requiring traceability information essential to understanding what happened to the food at that point, either called key data elements or KDEs and will provide us with the data necessary to make linkages across a point in the supply chain and more quickly and accurately identify the foods movement through the supply chain. The KDEs required by each entity depends upon the critical tracking events such as growing, transforming, shipping, receiving that are being performed by each entity. Importantly, the records required at each CTE would need to contain a link, the traceability lock code of the food to the other relevant KDEs. By identifying the required KDEs, this will also help standardize the data the industry maintains for traceability.

An important concept in the proposed rule is on traceability and lock code. At every CTE, at every critical tracking event, key data elements must be linked to each traceability lock code of the food that is shipped. This will help make linkages within a firm and across the supply chain. The traceability lock code and the traceability lock code generator, KDEs, will help FDA to critically go back to the

entity within the supply chain that originated, created, or transformed the product. The traceability lock code stays the same as the product moves through the supply chain until a transformation occurs. The entity who originates or creates the food is the one who establishes and assigns the traceability and lock code. This enables FDA to skip points in the supply chain that minimally handle the product and quickly identify the points that can provide FDA with the information leading to the source of the product.

To illustrate this point and to visualize how the proposed rule can help and efficiently identify the source of a product, here is an example of the supply chain for fresh cut produce. Right now FDA must go to each point in the supply chain to obtain traceability information, asking questions about the product received at each point, gathering non-standardized information in paper and electronic format, resolving differences in terminology and lack of connectivity, asking the firm clarifying questions at each point. This takes a lot of time and requires a lot of resources.

On the proposed requirements, FDA would be asking for KDEs to be rated to an entity CTE for a certain time period,

gathering standardized information in paper and/or electronic format, obtaining the traceability lock code and traceability lock code generator in order to skip back to the source factor, going to the those points that handle the product, the effects to transform in order to get to the source efficiently, reducing clarifying questions while having access to traceability program records that explain traceability record-keeping processes.

This is the vision of the proposed rule and illustrates how industry regulators can work together to have more efficient and accurate traceability. So if you notice in the first example we were stopping at each point in the chain and the vision is to be able to skip some of those steps that handle the product minimally and save some time and be more efficient in getting back to the source.

I will wrap up by mentioning that we know that this proposed rule is only the first step towards our efforts in advancing traceability across the food supply chain. The proposed rule will help key data elements and critical tracking events across the industry so that anyone, regardless of whether they are covered by the rule, could use those same elements to enhance their traceability efforts. Many of you have heard

about our new era for smart food safety initiative. Much of our traceability work under that initiative will build upon the foundational work of this rule. Because ultimately we believe that end-to-end traceability is essential to track public health and ensure greater transparency throughout the food system.

So today you will hear from subject matter experts that were instrumental in developing the proposed rule as well as some of our federal, state, and industry partners. And then we look forward to hearing some comments from the public. Again, thank you for joining us today, and handing it back over to you, Kari.

MS. BARRETT: Great. Thank you so much, Katy for your remarks this morning. We are now going to have Karen Blickenstaff, who is Assistant Response Staff Director of our Coordinated Outbreak Response and Evaluation Network, and we also have Laura Gieraltowski from CDC. She is the lead of their Foodborne Outbreak Response Team of their Outbreak Response and Prevention Branch within their Division of Foodborne, Waterborne and Environmental Diseases. So the two of them will discuss the impact of traceability during foodborne illness outbreaks. We're going to start with Karen, and then we'll go onto Laura.

So Karen, over to you.

MS. BLICKENSTAFF: Great. Thank you, Kari, and good morning to everybody out there.

This morning my colleague, Dr. Laura Gieraltowski and I will be talking a bit more this morning on how traceability impacts foodborne outbreak investigations. So I'm going to start first by providing a little bit of background on my office, CORE, and some of the rules and responsibilities of federal agencies during foodborne outbreak investigations. The FDA's Coordinated Response and Evaluation Network was established in 2011 in order to manage the surveillance, response, and prevention activities related to incidents or outbreaks of illness linked to FDA-regulated products, specifically food, cosmetics, and dietary supplements.

CORE consists of several multidisciplinary teams, including three response teams. The response teams are charged with coordinating complex response activities across FDA, state partners, and the CDC, bringing all partners together with the ultimate goal of controlling and stopping the outbreak. Outbreaks that CORE responds to include ones where in-depth investigations are needed. This can include the coordination of

infections and investigations, sampling assignments, and traceback investigations. Specific to tracebacks CORE leads the traceback analysis from a national perspective in order to help identify the source and the distribution patterns of implicated foods.

There are multiple federal agencies at play when it comes to responding to foodborne illness outbreaks. We have the Center for Disease Control, the FDA, and USDA's Food Safety and Inspection Services. Our partners at CDC lead disease surveillance, outbreak detection and investigation, and additionally, they are involved in education and training of public health staff. You will hear a little bit more regarding CDC's role and outbreak investigation from my colleague, Dr. Laura Gieraltowski momentarily.

As for CFSAN, we are charged with establishing food safety policies for foods that fall under each agency's regulatory authority, inspecting these facilities to ensure they are in compliance with regulations. Coordinating product recalls when necessary, for example, when it was determined that a specific product may pose a hazard to consumers and coordinating traceback investigations to determination the

distribution and the source of the product. And finally, conduct investigations at farms and production facilities if there is an indication that they could be tied to an outbreak.

At this point, we're going to transition into a few more details surrounding the EFI and the traceback work that CDC and FDA carry out during the specific foodborne outbreak investigations and also provide some examples on how traceability impacts the overall investigation. So at this point, I'm going to turn it over to Dr. Laura Gieraltowski from CDC's Outbreak Response and Prevention Branch.

MS. GIERALTOWSKI: Thank you, Karen.

There are several challenges public health officials face when collecting epidemiologic data. Due to delays in surveillance, ill people are often interviewed about what they ate two to four weeks after their illness began and can be difficult for ill people to remember exactly what they ate and where they purchased their food. Also, it is difficult to determine if the proportion of ill people eating commonly-eaten foods such as leafy greens, chicken, and beef is higher than we would expect. We may not routinely ask about some new or uncommon foods on our standard patient questionnaires. Ill

people may not remember eating stealthy ingredients that are added to foods such as onions, peppers, herbs, and spices, and there is often a lack of brand or product information for produce, chicken, and beef. And this information is important for our regulatory partners to be able to trace foods to their source.

Finally, some clusters of illnesses where two or more ill people who don't live in the same household report eating at the same restaurant location or shopping at the same grocery store or attending a common event in the week before illness provides critical clues about the source of an outbreak. If several ill people ate or shopped at the same location within several days of each other, it suggests that the contaminated food was served or sold there.

Now I'll talk through two case studies that are examples of outbreaks where epidemiologic data collection was challenging and traceback data was necessary to identify the source. CDC, FDA, and state and local health departments investigated a multi-state outbreak of over 1,100 salmonella infections from 48 states linked to onions. Onions are a stealthy ingredient, and they're difficult to implicate with

patient recall alone. Initially, we identified nine illness subclusters and red onions were served at all nine subclusters. We utilized invoices from restaurants and other points of service to identify a common onion grower. Traceback evidence led to the company voluntarily recalling red, yellow, and white onions, and some of the investigation challenges I mentioned on the previous slide, onion are commonly eaten, they're stealthy, and it was difficult to traceback and recall the many food affected and provide clear public communication. We learned that it was critical to rapidly interview ill people to identify subclusters.

My next example is a multi-state outbreak of 425 salmonella infections, CDC, FDA, and state and local health departments investigated a few years ago linked to raw tuna. We utilized several methods to evaluate the association between tuna and illness and conducted a study to estimate the frequency of tuna consumption among sushi eaters. With the evidence pointing to spicy tuna, a traceback investigation was conducted by state and local health departments with FDA. The tracing efforts focused on fresh and frozen tuna supplied to four of the five restaurant subclusters. For each of these restaurants, the

traceback team collected invoices, receipts, bills of lading, and shipping documents for fresh and frozen tuna. Using these documents, all tuna was traced back to the producer level to identify if a common ingredient had been supplied to all the restaurant clusters. The common product was a frozen, raw, scrape yellowfin tuna from a single processing facility.

Again, the epidemiologic data alone could not identify a source of illness. Traceback was needed to confirm spicy tuna was the single ingredient in common among the sushi items ill people reported eating and to determine the source of the raw tuna. This led to actions to protect public health, such as an FDA info alert, product recall, and public communications to consumers and retailers.

Karen, back to you.

MS. BLICKENSTAFF: Thank you very much, Dr. Gieraltowski.

I'm going to dig a little bit into traceback now. So when a traceback investigation is initiated, it means that we have an ongoing foodborne illness outbreak. And at this point, time is of the essence, and we must move swiftly to prevent additional illnesses. Tracebacks do come with a variety of

challenges that we must navigate while trying to move as quick as we can.

So an upfront challenge which Dr. Gieraltowski just a little bit about is poor consumer recollection of consumption history and a lack of specific product information. Understanding consumer's exposure is the critical first step that needs to happen in order for us to initiate a traceback investigation. At times, multiple varieties of a certain product or multiple ingredient items are identified which makes it hard to determine which exposures or ingredients should be prioritized for a traceback, and at times, we may trace multiple products to help piece out what could be causing illness as previously discussed by Dr. Gieraltowski.

Additionally, points of sale can and usually do have multiple sources of the same product. Additionally, poor record-keeping at firms is a challenge that we often face during our traceback investigation. In some instances, we have received handwritten records or records that are difficult or at times even impossible to read.

But one of the biggest overall challenges I want to highlight that we do face when doing tracebacks is the lack

of a rapid and rigorous mechanism to link shipments all the way from farm to fork. Currently, there is varying amounts of tracing data across the supply chain which means we must piece together information from numerous types of documents in order to extract the most useful data point to follow the product throughout the supply chain. And this can be a very time consuming step. So each of these challenges greatly impact the efficiency and the effectiveness of a traceback investigation.

I'm going to highlight the traceback findings specific to the E. coli 0157:H7 outbreak linked to romaine lettuce from the fall of 2019. This particular traceback investigation was initiated on November 18th in conjunction with our state partners, and in total, the traceback investigation included 15 points of sale where ill persons shopped and purchased varying degrees of products that contained different romaine items. For the majority of the points of sale, we did not have any lot code data available for the products purchased, and because of this we needed to request tracing data to identify all growers who could've supplied any romaine lettuce used in the product reported by consumers and available for sale during the time period of September 15th to November 18th. So

we were looking across romaine that was supplied across a two-month period.

For the 13 out of 15 points of sale without lot code data available, it took FDA approximately one month to collect, analyze, and identify the growers that supplied lettuce to the points of sale during this time frame. Now on the other hand, there were two points of sale where we did have lot code data available for the specific product purchased by consumers, and in those instances, a much narrower scope of data could be requested and the growers were identified within 24 hours or less. I do want to note that it's not typical for us to have the lot codes at the point of sale during an outbreak investigation, and I'll go into a bit more detail momentarily regarding how we did obtain the lot code data in this situation. I just want to note that while this traceback was ongoing, case counts were increasing. So a broad public advisory targeting a regional area was issued on November 22nd as it was the most efficient way to ensure that contaminated product was off the market while we continued to work through the traceback.

So here we emphasize the difference in timing when lot code is available versus not available. So looking at

this table, you see on the very top we have points of sale locations where no lot code data was available. Those tracebacks were initiated on November 18th, and it wasn't until December 13th that we had a handle on all of the growers that could have supplied romaine during the time frame that we were looking at. So that was 25 days later after the traceback was initiated. Now we have a Maryland point of sale location where we did have lot code data. And that information request for the grower level details was initiated on November 18th, and had those growers identified later that same day. For the Wisconsin point of sale location, again, we have lot code data available. That information request was initiated on December 4th, and we have the grower level data the following day on December 5th.

So in these situations, how did we get the lot code data? So as our investigation was starting on November 18th, our partners in the state of Maryland informed FDA of an E. coli 0157:H7 contamination in an unopened packaged salad collected from a consumer's home. With the availability of the lot code on the product packaging, Maryland partners were able to provide FDA with the corresponding grower level information later on that very same day on November 18th. Similarly, for

the second instance on December 4th, our partners in Wisconsin reported there was an E. coli 0157:H7 contamination that had been detected in an unopened bag again of a leafy green romaine product this time collected from an ill person's home in their state, and for this situation, the corresponding growing information was obtained the next day on December 5th. So for two separate products which were of separate brands, FDA was able to obtain grower level data within 24 hours or less compared to 25 days when no lot code data was available.

What are the benefits of better traceability? As shown in the case study, access to specific key data elements creates efficiencies in our tracing process. Now this situation was unique in that we had product packaging containing the lot code, but it clearly demonstrates how quickly grower level data can be obtained when we do have that information in hand. Based on combined years of experience at CORE doing traceback investigations, we feel that if lot code data and other key data elements are available throughout the supply chain, it would likely enable FDA to identify common product sources in five to seven days. This time would account for the time necessary to request, obtain, and analyze tracing data across the supply

chain in the absence of the actual packaging that has the lot code data.

Having this data readily available could result in swifter product action and better scoped product action. Additionally, we'll be able to have more refined record requests, avoiding the need to ask for large quantities of records spanning weeks or months. These large requests are both time consuming for the firms involved and time consuming for FDA to analyze.

To summarize, by requiring lot code and other key data elements to be kept within the record through the supply chain, authorities will be able to reliably obtain the information needed to swiftly identify the source of the product, remove that product from the marketplace, reduce exposures and subsequent illnesses, and investigate the reason for contamination in a timely manner.

That concludes my presentation. I'll turn it back over to you, Kari.

MS. BARRETT: Great. Thank you, both Karen and Laura. I appreciate your remarks. We are now going to go to our next presenters who is Brian Pendleton. He's a Senior

Policy Advisor, Policy Engagement and Coordination Staff in FDA Office of Policy, Legislation, and International Affairs. Brian will discuss the scope of the proposed rule and exemptions.
Brian.

And Brian, we need your audio.

REPORTER: You're still muted, Brian. Make sure your phone is unmuted. Brian, make sure your phone is unmuted.

MR. PENDLETON: Yeah, it takes me a long time.
Sorry about that.

REPORTER: There you go. You're in now.

MR. PENDLETON: Okay. Thank you, Kari, so much, and good morning, everyone, and thank you for the opportunity to talk with you today about the -- am I able to advance the slides? I'm not sure where that goes. Down at the bottom?

REPORTER: Yes, you can at the bottom of your slide there by the two arrows. Bottom left corner.

MR. PENDLETON: There we go. There we go.
Sorry.

So we've had an excellent overview of the need for the regulation, and now we'll begin to talk about some of the details of the proposed rule starting with the scope of the

proposal. That is the farms and firms that would be subject to the regulation as well as some exemptions from the proposed requirements that we have proposed.

So who would be covered under the rule? The rule would apply to persons who manufacture, process, pack, or hold foods on the food traceability list or the FTL. And remember that the FTL includes the foods that are specifically listed that actually appear on the list as well as food that contains listed foods as ingredients. And this would cover all of the entities throughout the supply chain from the farms and manufacturers and processors to distributors and wholesalers and to retail food establishments, including grocery stores, convenient stores, vending machine locations, restaurants, online food retailers, meal kit delivery companies. There are many types of food establishments. And this would apply to both domestic and foreign entities.

This slide presents an overview of the exemptions that we are proposing. Several of them are set forth in the statute, Section 204 of FSMA, including for farms that sell food directly to consumers, food that's produced, packaged, and labeled on a farm. And some of the exemptions we are proposing

on our initiative for certain smaller food originators for produce and shell egg that receive certain processing or food that is designated as rarely consumed raw under the produce safety regulation, food transporters, non-profit food establishments, and those who manufacture, process, pack, or hold food for personal consumption.

Some of our exemptions are partial, and these include certain statutory exemptions who are commingled raw egg or cultural commodities, although importantly, it doesn't include most fruits and vegetables that are subject to produce safety regulations, fishing vessels and farm to school programs. One of the partial exemptions that was in the statute, we're proposing to broaden to cover not just grocery stores that receive food directly from a farm but for all retail food establishments.

It's also important to note an additional partial exemption for food on the food traceability list. That receives a kill step. Under the proposed rule, if a person applies a kill step it is processing that significantly minimizes the pathogens such as by cooking or pasteurizing the food, then they wouldn't be required to maintain the records that would

otherwise be required under the proposed rule as long as they document the application of that kill step. In addition, subsequent recipients of a food to which a kill step has been applied would not be subject to the requirements under the proposed rule.

The first exemption I'll talk about is for certain small originators of food, and by originators, the proposed rule defines them as a person who grows, raises, or catches a food, or harvesting non-produce commodity, and that would include things like egg collection as well as taking seafood in an aquaculture operation. So these are all certain types of originators. So farms or farm activities of farm mix-type facilities which is tied to the produce they grow would be exempt when the farm is in a covered farm under the produce safety regulation at Section 112.4(a). And basically that refers to farms with no more than \$25,000 in average annual monetary value of produce sold.

Also exempt would be small shell-like producers with fewer than 3,000 laying hens at a particular farm and originators of other food that have no more than \$25,000 in average annual food sales. And this would include small

aquaculture farms and potentially small farms that grow non-produce food if such foods were added to the food traceability list at some future time. Another exemption is for farms when the food is sold directly to consumers. So this exemption would apply to a farm with respect to the food that's produced on the farm including food that's also packaged there that's sold directly to a consumer by the owner/operator/agent in charge of the farm. This would include things such as sales at farmers markets, roadside stands, internet food sales, and sales through community-supported agriculture programs.

Also exempt, the rule wouldn't apply to food that's produced and packaged on a farm provided certain conditions are met with respect to the food's packaging. The packaging would have to remain in place until the food reaches the consumer, and the packaging would have to maintain the integrity of the product to prevent subsequent contamination or alteration. In addition, the foods labeling that gets to the consumer would have to specify the name, complete address, and business phone number of the farm, although we would waive the requirement to include a business phone number to accommodate a religious belief of a farm owner.

An example of such an exemption applying would be iceberg whole head lettuce that's harvested and packaged for the consumer in the field with individual non-vented cellophane wrapping that maintains the integrity of the lettuce and prevents subsequent contamination or alteration. Not eligible for this exemption would be things such as produce that's packaged or in containers such as clamshells with holes, cardboard boxes, vented crates, plastic bags with holes, or netted bags. So those are some foods that would not be eligible for this exemption.

Foods that receive certain types of processing would be exempt under the proposed rule. So this would mean that the rule wouldn't apply to produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, provided that the requirements in the safety regulation at Section 112.2(b) are met, and that includes things such as the application of the commercial processing, a disclosure that the food isn't processed to adequately reduce the presence of microorganisms of public health significance, and written assurance from the customer that it or a subsequent entity in the supply chain

actually performed the commercial processing. I note that this exemption would apply to all of that manufacture, process, pack, or hold such produce. Not just the farm that grew it. And it would apply both before and after the processing takes place.

Another exemption would be that the rule wouldn't apply to shell eggs and all the eggs that are produced at a farm receive a treatment in accordance with the regulation on the production, storage, and transportation of shell eggs. And this kind of treatment would have to be a technology or process that achieve at least a 5-log destruction of salmonella and -- for the shell eggs, or the shell eggs would need to be processed in accordance with the egg products in the inspection act.

Also exempt under the proposal would be produce rarely consumed raw. The produce safety regulation subsidizes several types of produce that are designated as being rarely consumed raw. I'm not going to mention all of them, but examples would be beets, sweet corn, potatoes, and several kinds of beans. So produce rarely consumed raw would be exempt from this rule.

I want to talk about certain partial exemptions from the requirements that we have proposed. Several of them

are consistent with the statute. So the rule wouldn't apply to a commingled raw agricultural commodity, and that's defined in the statute in our regulations as any commodity that's combined or mixed after harvesting but before the processing. Very importantly, it would not include fruits or vegetables are such raw agricultural commodities when they're subject to the produce safety regulation.

In fact, shell eggs right now are the only potentially commingled raw agricultural commodity that is on our proposed food traceability list. So that would be the general exemption, but if a person who manufactures, processes, packs, or holds such a commingled raw agricultural commodity has to register with the FDA the food facility with respect to that commodity, then the person would have to keep records identifying the immediate previous source and the immediate subsequent recipient of such commodity consistent with the existing food traceability regulations in Subpart J of our regulations. So some of the facilities are already subject to these existing traceability requirements. Those who aren't would now need to keep these what's called one up, one back records under the Subpart J structure.

Another exemption we are proposing is for small retail food establishments which we propose to define as establishments having 10 or fewer full-time equivalent employees, and this is actually a co-proposal where we have set forth two options that could apply to these establishments. Under option one there would be full exemption from the proposed rule. Under option two, the smaller retail food establishments would be exempt from the requirement to make available to FDA in certain circumstances an electronic sortable spreadsheet that sets forth the information that we would be requesting for specific foods and date ranges. We'll talk about later today about when we would request such a spreadsheet, but this would include when we are investigating to help prevent or mitigate a foodborne illness outbreak, for assisting in recall implementation, or otherwise addressing a threat to public health such as when there's a reasonable belief that a food poses a risk of serious to adverse health consequences or death.

Now some of the pros and cons if you will of these two options, for the full exemption, because of the lesser volume of food from these smaller establishments, the compliance cost for these establishments could outweigh the public health

benefits, and we might be able to obtain the information we would need from larger firms that sold the same food using the same distributor. But whole exemption, these establishments from the rule could delay our ability to obtain the information we need in investigating outbreak and as well as hinder our ability to narrow the scope of implicated products during an investigation.

Regarding option two, it could be that smaller firms might be less likely to have the resources to easily produce this electronic spreadsheet under the circumstances when they might be asked for it. So exempting them from that requirement could ease their burden. At the same time, that would retain the traceability benefits of keeping these smaller entities within the scope of the other rule. So we request comment on these two options for small retail food establishments as well as if you think there's an alternative approach that we should use for these entities under the rule.

There's also a partial exemption proposed for all retail food establishments, large or small, and that would mean that the rule wouldn't apply to the retail food establishments regarding the food that's produced on a farm, including food

that's produced and packaged there and sold directly to the establishment by the farm's owner, operator, or agent in charge. The establishment would have to keep a record for 180 days just of the name and address of the farm that was the source of the food.

Similarly, there is a proposed exemption for farm to school programs. The rule generally wouldn't apply to an institution operating a child nutrition program authorized under the Richard B. Russell National School Lunch Act or Section 4 of the Child Nutrition Act of 1966 or any other entity conducting a farm to school or farm to institution program regarding the food that's produced on a farm and sold directly to the school or institution. But as with the previous exemption, the school food authority or relevant food procurement entity would have to keep a record just of the name and address of the farm that was the source of the food.

Another partial exemption set forth in the statute and we have incorporated in the proposal is for fishing vessels. So the rule generally wouldn't apply to the owner, operator, or agent in charge of a fishing vessel with respect to the food that's produced through the use of that vessel. But if

that owner, operator, or agent in charge has to register with the FDA as a food facility with respect to that fish that's produced through the use of the vessel, such as the vessel not only caught the food but it was processed on that vessel, then the person would have to keep the one up, one back records that are required under the existing regulations in Subpart J.

Now some other exemptions that we are proposing for transporters. We think that for the types of information that we are requesting under the proposed rule, that we could probably get this information from others in the food supply chain in the supply chain for our food. So we think we can exempt transporters from this proposed rule. Other exemptions would be for non-profit food establishments, for persons who manufacture, process, pack, or hold food for personal consumption, and for persons who hold food on behalf of individual consumers if they aren't a party to the transaction involving the food they hold, and they're not in the business of distributing food. Some examples of this could be a hotel concierge reception desk, reception staff, desk staff at an apartment building, and staff at an office complex who receive and store food on the food traceability list for a consumer, but

they're not parties to the purchase of the food, and they're not in the food distribution business.

So that is an overview of the farms and firms that would be subject to the proposed rule and exemptions that we have proposed, and I look forward to any questions you might have on these provisions later this morning. Thank you.

MS. BARRETT: Great. Thank you so much, Brian.

And at this point, we're going to conclude our first group of subject matter expert presentations. We have Yuhuan Chen who is the CFSAN Interdisciplinary Scientist, Division of Risk and Decision Analysis as well as Christopher Waldrop who's the CFSAN Senior Health Scientist in our Office of Analytics and Outreach. They will speak in more detail on the food traceability list, and we're going to start with Yuhuan and then we'll go to Chris.

So, Yuhuan, I'm going to turn it over to you.

MS. CHEN: Thank you. Thank you, Kari. Can you hear me okay?

MS. BARRETT: Yes, we hear you great. Thank you.

MS. CHEN: Thank you very much.

Greetings, everyone. To inform the designation

of the food traceability list, we developed a risk ranking auto form food tracing. This overview of the model highlights the development process, model criteria, and how we classify foods and school commodity as it pairs. I'll begin with the food requirement, talk about the methodology and these result examples. In FSMA Section 204(d)(2)(A), Congress lays out the requirements on which the designation on high risk foods must be based. It must be based on -- the known for safety risks including the history of outbreaks, the likelihood of microbial and chemical contamination and whether the food would support pathogen growth, the point in the manufacturing process where contamination is most likely to occur, the steps taken during manufacturing to reduce contamination, the consumption of the food, and the likely or known severity, including health and economic impact of a foodborne illness attributed to a particular food. They are specific in these requirements which we have considered.

In developing the model, we took a systematic approach and strive to have a transparent process that engaged stakeholders and a broad range of subject matter experts. We put together a project advisory group and developed a draft

approach which was published in 2014 for comment. We then revised the approach, collected data, and developed a model. As is the case for our risk assessment, we conducted peer reviews of the model and the underpinning data. Throughout this process, the project advisory group helped decide how to address public comments and peer review comments to refine the model. The overall modeling approach to designating a list of foods which we convey as food traceability list was to create a data-driven model, use it to score food hazard pair factors based on the risk factors specified in FSMA and every day scores appropriately to create a ranked list of foods such as commodity and for commodity category. So designating the list is a policy deliberation. My colleague, Chris Waldrop, will talk about the risk management decision shortly.

So the risk ranking model has seven criteria. To address the statutory factors we created these criteria using -- in decision analysis. This feature shows the alignment of the model criteria and the FSMA factors. As indicated by the arrows, each FSMA factor is represented in the model by one or two criteria. The model is operationalized based on data across the seven criteria, C1 through C7, which are frequency of

outbreaks and occurrence of illnesses, severity of illness, likelihood of contamination, growth potential with consideration of shelf life, manufacturing process contamination probability, and industry-wide intervention, consumption, and cause of illness. This is a multi-criteria decision analysis for food hazard pairs on the public health criteria.

So how do we classify food? We consider both the food characteristics and the manufacturing process and classify FDA-regulated human food into 47 commodity categories, such as low -- canned food and fresh produce. Though commodity categories are adapted from similar categories in the reportable food registry or FR programs and the facility registration program. Within each commodity category, we identify commodity and overall a comprehensive list of commodity hazard pairs based on data and expert knowledge. The model then scores each pair independently. To do that, we need scoring definitions.

Let me take a moment to go over a couple of examples. Here is the scoring definition for criteria one. It's a matrix with the frequency of outbreaks on the X-axis and the occurrence of illnesses on the Y-axis. For each food hazard pair based on data, a score of 1, 3, or 9 is assigned. For

example, 10 outbreaks in 1,000 cases will be a score of 9. On the other hand, if 1 outbreak in 100 cases, the score would be 1. The number of outbreaks and cases are rated by the year for relevance. Data rating is explained in detail in the methodology report which is reference 16 in the proposal.

And here is the scoring definition for criterion 3, the likelihood of contamination of the hazard in the food. The definition is based on sampling data for other data such as RFR and recall data. For example, if the contamination rate is greater than one percent, the score would be 9. Sampling data are also rated for relevance. We developed scoring definitions for all seven criteria and have the definitions peer-reviewed.

The model utilizes data from a wide range of sources including the published scientific literature, government surveys and investigations, and multiple expert solicitations to fill data gaps. We also use data and information submitted by stakeholders. The model draws on a vast amount of data to score many commodity hazard pairs. Here is a quick look at how the model details all the data for the seven criteria for each commodity hazard pair and eventually generates a ranked list of commodity. Considering microbial and

acute chemical hazards, we identified approximately 770 commodity hazard pairs that involved 210 commodities and 60 hazards. The model uses over 10,000 data points.

So let me draw your attention to the left side of the slide and walk through the scoring process. These circles represent data points, and C1 through C7 on a branch indicate the seven criteria. Remember each of the criteria is scored using data and well-defined definitions. The branch shows how the model calculates a risk for a commodity hazard pair. For example, commodity A has one. It's by summing the seven criteria scores. The model evaluates each commodity hazard pair independently so it does this evaluation multiple times for commodity A because it's associated with multiple pairs. From there, the model aggregates the score for the pairs to calculate a risk score for the commodity. So that's how it generates commodity A risk score.

Now there are about 210 commodities in the model so this data evaluation and scoring process is repeated 210 times. That's how the model generates results, and we see two examples here. The figure in the middle is a ranked list of commodity hazard pairs. This is the subset of the overall 770

pairs in the model. The color block indicates the contributions from the criteria scores. The figure on the right is a ranked list of commodities. The longer the bar, the higher the score.

To facilitate the understanding of the model we have created a user-friendly tool, a web page. It's interactive. It allows you to view the results as tables and figures by commodity, by commodity category, or as a whole. It also facilitates the review of the methodology and walks you through a calculation example.

In summary, to inform the designation of the food traceability list, FDA developed a risk ranking model that is aligned with the FSMA requirement that is systematic -- and data-driven, and it has been peer-reviewed to ensure credibility.

With that, I will hand it over to Chris.

MR. WALDROP: Thank you, Yuhuan, and hello, everybody. Good morning.

There are a few other aspects of the food traceability list we wanted to highlight. So first, in using the data from the model and developing the food traceability list, FDA focused on the results from the model for which

traceability would be most beneficial. In terms of hazards, FDA focused on biological and acute chemical toxins as these pose an immediate public health risk. For example, leafy greens contaminated with E. coli 0157:H7 or finfish potentially contaminated with shiga toxin. In both cases, traceability would be necessary to rapidly identify the source of contamination and prevent additional illnesses. In contrast, enhanced record-keeping for traceability would not be as useful for addressing adverse health effects from other hazards such as chronic exposure to chemical hazards like lead or other toxic elements.

Second, FDA decided not to include results from the model related to food allergens. Typically, consumers with food allergies can identify the food or ingredient that most likely caused the allergic reaction, including the brand and packaging of the food in most cases. FDA can then rapidly identify the source of the allergen-containing food, and take appropriate regulatory action. Therefore, enhanced record-keeping for traceability would not greatly enhance FDA's ability to identify and respond to undeclared allergens in food.

Third, as we reviewed data used for the model to

generate the food traceability list, we decided to not include results for certain food hazard pairs that were attributed to contamination at retail or point of service. Examples include perfringens in fresh soup and norovirus in cakes. Such contamination is generally due to unsafe food practices at retail or point of service such as lack of time, temperature control, ill food workers, or improper cleaning and sanitizing of food services. Once the retail or point of service location was identified as the source of contamination, there's really no need to further trace the source of the food. As such, enhanced record-keeping requirements would not significantly improve traceability in these situations.

FDA considered different levels of granularity in categorizing food for the food traceability list, such as commodity or commodity category, and you hear Yuhuan use those terms. An example of food at the commodity level would be tomatoes while food at the commodity category level would be the broader produce or cultural commodity. We determine that commodity was the appropriate level of granularity for the food traceability list. Food items within the same commodity level designation generally have similar characteristics, associated

hazards, and production and supply practices and conditions.

This approach results in a more targeted food traceability list than one based on a broader commodity category level.

To identify commodities for the food traceability list, the commodities and associated food hazard pairs produced by the model were ranked. A commodity was included if there was sufficient evidence of a significant public health risk based on the data in the model as Yuhuan has described. More information about how this was done is available in a memo that accompanied the proposed rule and is included in the docket. Using the results of the food traceability model, we tentatively identified foods for the food traceability list as you can see here. Foods on this list are considered covered under the proposed rule. For most foods listed here, it would include all varieties or types, such as all varieties of tomatoes including Roma, beefsteak, cherry, et cetera, or all varieties of peppers, such as sweet peppers, poblano peppers, jalapeno peppers, et cetera. For some foods, there are a few exceptions. For example, the category of finfish would not include some other forms of fish such as catfish as those are regulated by USDA.

We have additional detail available in a memo

about how we did this which accompanies the proposed rule and is included in the docket. In addition, the food traceability list includes not only the foods specifically listed here, but also any foods that contain listed foods as ingredients. For example, peanut butter is on the food traceability list. So crackers with peanut butter filling that do not undergo a kill step would also be covered by the proposed rule. And then each proposed requirement in the rule would pertain to all such foods unless an exemption applies.

Comments may be submitted on the food traceability list as well as comments on the proposed rule, and we will publish a final version of the food traceability list when we publish a final rule. We do intend to periodically review relevant data and information to determine if we need to update the food traceability list; however, we do not anticipate updates to the list will happen very often. But if we do determine we should update the list, we will do so via notice in the federal register providing the public with an opportunity to comment. We will then review those comments and post a notice on the federal register identifying any changes we decide to make. Any addition to the list would become effective one year

after the date we publish any final changes to the list unless otherwise stated in the notice.

So with that, thank you very much for your time, and I'll turn it back over to Kari for the next part of our agenda. Thanks.

MS. BARRETT: Great. Thank you so much, Yuhuan and Chris. I really appreciate your remarks, and we'll do sort of a silent round of applause for all of our morning speakers.

We are now at a point where we're going to do the first Q&A, and so please if you haven't already, you can submit your questions to the chat as Michael instructed at the beginning of our meeting this morning. I will read questions out loud to our earlier presenters, and I also understand we have a couple of additional FDA team members who are joining for this particular segment in case they're needed for a response, so we'll welcome them. They'll all be joining us here momentarily, and they'll turn on their cameras, and then we'll begin. We will give ourselves a full 15 minutes for the Q&A. I know we're a couple of minutes over our expected time. We may shorten our breaks. I just want to let people know that in advance.

Okay. We have a couple of our folks up for the Q&A if others can join.

MR. KAWCZYNSKI: All presenters from that first series, there we go. I think we're ready.

MS. BARRETT: Okay. All right. Fantastic. Let's begin then.

It looks like we have a question for Yuhuan and Chris. The question is would a single outbreak cause a food to be added to the food traceability list.

MS. CHEN: Thank you for the question. I can answer first. In terms of a single outbreak, it depends. It would depend on the magnitude of the outbreak and the characteristic of the food and the hazard implicated. I think that other similar outbreaks would also play a role. In the risk ranking model, outbreaks are considered in criterion one. There are six other criteria, so the risk score for the food hazard pair is affected by data across all seven criteria, as is the risk score for the food. The model is flexible. It can accommodate new data to update the risk score, and as you have heard, there is a process to decide when to update the model. There is also a risk management process to decide, given updated

risk score whether a food would now be included on the list. So maybe Chris can comment further on that.

MR. WALDROP: Yes, thanks, Yuhuan.

So just to add that we won't be revising the list after every single outbreak that occurs. It'll be part of a periodic review that FDA does as I mentioned. And again, when we do decide, if we do decide to add a food to the list, we will go through a public process, and the public will have an opportunity to comment on that. So thanks for the question.

MS. BARRETT: Great. Okay. We're going to go to our second question. It looks like it's for Brian.

Brian, is the exemption for farms when food is sold directly to the consumer, is the agent in charge of the farm any employee who is selling the food on behalf of the farmer?

Brian, we can't hear you.

MR. PENDLETON: Did it again. I'm sorry. What was the question about?

MS. BARRETT: So it's saying is the exemption for farms when food is sold directly to the consumer, so the question is is the agent in charge of the farm any employee who

is selling the food on behalf of the farmer. So defining the agent in charge of the --

MR. PENDLETON: We did not define what an agent in charge is, so I don't know that we have discussed that at length as to exactly what persons are going to be the agent in charge or whether there's a commonly understood meaning for that term. So I don't know if other folks here have thoughts on that, but if not, I guess we would appreciate your comments on who that could be in terms of the agent in charge of such a farm.

Katy or Chris, do you have thoughts?

MS. BUCKNER: This is Rebecca. I'm not Katy or Chris, but I think the question included the phrase on behalf of the farm. So as Brian said we welcome your comments on this but I think if what was behind the question is does it actually have to be, like, the owner of the farm selling at a farm stand or something. I think we would be thinking it's broader than that, but as Brian said, please submit specific examples to us in question or comments. Thank you.

MS. GOLDBERG: This is Katy. Can you guys hear me?

MS. BARRETT: Yes, we can.

Thank you, Becky.

MS. GOLDBERG: Yes, I mean, I can add to that a little bit. First of all, if there are parts of this that are confusing or if they're unique business situations as everyone has said, please submit comments and questions, but certainly, I don't think it's envisioned -- it's not envisioned that the owner has to physically be standing at the farmers market all day long and be the only person who stands there, right, you know, for something to be sold. Presumably, there's some designation of authority there when a sale takes place. So again, if there's unusual circumstances, let us know, but the intent was not to be so narrow that the person had to be standing right there.

MR. WALDROP: Right. Yes. It would seem to be someone that the person who is responsible for the farm or owns the farm or operates it has said that this person is standing for me in terms of the sales directly to consumers so ...

MS. BARRETT: All right. Well, let's move onto our next question. And Katy, it looks like this is for you.

Katy, can you discuss the key difference between

traceability lot code and lot?

MS. VIERK: Sure. So businesses can maintain their own lot codes that are separate from traceability lot codes, the same lot, as long as they also maintain the traceability lot code. So once a traceability lot code has been assigned, it can only be changed when a food is transformed. So let me explain a little more. We're proposing to require the assignment of a traceability lot code when a firm originates, transforms, or creates a food on the food traceability list. So it's not -- we're not prescribing how you create your traceability lot code or lot codes, similar to how firms create their own lot codes using their own methodologies or their own ways, and so that is not changing. We're just saying that -- we're using the term traceability lot code to be clear when a firm -- that needs to be assigned, the traceability lot code, when a firm originates, transforms, or creates a food on the food traceability list.

So some firms assign lot codes to foods they receive even though they don't transform the food or use the food to create a new product. And we believe the assignment of new lot codes to foods in those circumstances can create

confusion that can hinder traceback and trace forward efforts during an investigation of a foodborne illness outbreak or a recall. Therefore, the proposed rule generally would prohibit the establishment of a traceability lot code for the purposes of this proposed rule and this requirement for a listed food except for originating, transforming, or created a listed food. So you can still have your own lot codes if you want to in addition to having traceability lot codes where you're supposed to. If you also want to create your own internal lot codes for whatever reasons that you may want you can, but the traceability lot code is what needs to be assigned and shared with the supply partners when a firm originates, transforms, or creates a food.

I hope that helps a little bit. We're not saying you have to be -- we're not telling you how to assign that lot code. You can use the same procedures that you do right now. We're just using the term traceability lot code to be clear.

MS. BARRETT: Great. Thank you so much, Katy.

And now we're going to go, Brian, back to you. What would the small RFEs need to supply if not a sortable spreadsheet? What would be an acceptable submission? What would an acceptable submission look like?

MR. PENDLETON: Well, if they were -- if we adopted that option two in the final rule and then they would be -- these smaller establishments would be exempt from the requirement to present the sortable electronic spreadsheet and the circumstances that we would be required to ask for it, you know, we would request that they -- we would request the information in the most helpful form that they could provide it to us. Perhaps, I mean, some folks might want to in their comments suggest what that should be as an alternative to an electronic sortable spreadsheet, but if that requirement did not apply to those smaller entities, then we would expect or hope to see the best that they had, best information they could provide for us. If it was electronic, not fully sortable, I think that perhaps that's something that may be -- if that option is adopted, I think maybe that would be a good thing for people to comment on what could be provided as an alternative to help us get the information that we would need when a fully electronic sortable spreadsheet can't be provided.

MS. BARRETT: Great.

MR. PENDLETON: I know, Katy, you're --

MS. GOLDBERG: This is Becky Goldberg from FDA.

I can jump in a little more there. I think that's right, and in terms of how it stands now in the proposed rule, you know, if option two were adopted, then they would be exempt from that specific requirement. The other requirements would still apply, right?

MR. PENDLETON: Right.

MS. GOLDBERG: And the other requirements would have to do with producing records.

MR. PENDLETON: Right.

MS. GOLDBERG: So they would still need to produce all of the key data elements that they're required to maintain the same way that anyone would in any situation. The difference is that in these particular situations of a threat to public health with an outbreak or something like that, if they were exempt then we still would not be able to request this particular format of a sortable spreadsheet, but we would still be able to request all of the key data elements. There would just from a legal perspective be more flexibility in terms of how they provided those on paper or whatever they had, but they would still have to provide the key data elements.

MS. BARRETT: Okay. Great. Thank you, both,

Brian and Becky. We now have another question.

Karen, this one is for you. How does the rule improve the traceback process when the lot code is not available from ill consumers?

MS. BLICKENSTAFF: Thanks, Kari. Yes, that's a great question.

So when a consumer does not know a lot code is most times we don't expect the consumer to have that lot code. We will need to turn to the record to obtain that data. Currently, this information is not always readily available so we are piecing together varying amounts of tracing data in order to track the product that would've been available to the consumer through the supply chain. As Katy just previously mentioned, oftentimes firms assign their own lot, but there's no consistent way to kind of link those codes together through the chain. So in the proposed rule, we would have the traceability lot code, and that would be readily available in records in order to quickly get back to the source.

MS. BARRETT: Great. Thank you so much. Let's see. We have another question here.

This one, Chris, are dried spices like chili

pepper or tomato powder covered by this rule?

MR. WALDROP: Yes, thanks. Good question.

So I want to direct your attention to the methodology documents that was put out as part of the proposed rule as one of the memos, and in that document, if you look in Appendix, I think it's A2, there's a list of all the different commodities and the grouping that were considered as part of the model. And so there's a separate category for spices and seasonings. That's where something like dried chili powder would fall, so chili powder is not on the list because it falls in that separate category. Thanks.

MS. BARRETT: All right. Well, thank you so much. I know that went very quickly, and we have a lot of questions this morning. We do need to go ahead and take a break and stick with our schedule today. I would ask anyone who submitted a question we were not able to answer, please submit your question if you would like to our can. You can find that link available on the FDA website. That is a way to get your question into a subject matter expert. Also too, please submit all your comments to the docket, and our SMEs have asked too that when you submit comments, please include specific examples

of how your supply chain works. Really our goal with this rule is to be as flexible as possible to work in a variety of situations so please keep that in mind.

I do want to thank everybody for this morning. We are now going to go to a 15-minute break, and we'll pick up our agenda once we get back. So thank you. Enjoy the break, and we'll be back with you shortly.

(Off the record.)

MS. BARRETT: Welcome back, everybody, from the break. I hope you had a good one. We are going to continue with our second group of subject matter expert presentations at this time, and first up we have Angela Fields. She is the CFSAN Senior Consumer Safety Officer within CORE, and she's going to discuss the requirements of the proposed rule.

So, Angela, I'm going to turn it over to you.

MS. FIELDS: Thanks, Kari. Good morning, everyone.

So today I'll be discussing the proposed codified provisions. I'll be covering what records will be necessary for the traceability program records, what the key data elements, or KDEs, that would be required for each critical tracking event or

CTE, and how we are proposing to qualify for an exemption or a waiver. Additionally, I will be discussing how records would need to be maintained.

The records for the traceability program information is usually maintained in varying ways across the food industry. As a result, there can be a significant impact on the time needed to analyze and tracing data is collected from each farm during a traceback investigation. Obtaining as much detail from firms regarding interpretation of their records can assist in alleviating time delays that result as a lack of understanding.

The proposed rule would require every person who manufacture, process, pack, or hold foods on the food tracing list to establish and maintain traceability program records. These records would be intended to help FDA understand a firm's record-keeping process which is significantly valuable especially in foodborne illness outbreak investigations. All firms that would be covered by the rule would be required to maintain traceability program records. Additionally, a person that would be subject to these requirements may enter into agreement with individuals or firms to create and keep the

records that would be required for this rule on their behalf to accommodate the varying business relationships and constructs for these and all other records that would be required under Subpart F.

While most of the proposed records would need to be maintained for two years from creation, all traceability program records will be required to be maintained for two years following their discontinuance. Maintenance of these historical records would be helpful during retrospective outbreak investigations where historical cases are associated with an ongoing outbreak investigation.

Here we have listed the components that would be required for a firm's traceability program records. You have a description of relevant reference records, which while it is encouraged that these required traceability information be maintained in a single electronic system, FDA recognizes that there are firms that currently do not have product tracing systems that enable them to do this. As a result, a firm's KDEs might be kept on various types of reference records, such as bills of lading, purchase orders, or production logs.

A firm's traceability program records would need

to include a description of the reference record on which the firm maintains the required KDE. This description would explain where on the requisite records the traceability information appears and, if applicable, a description of how reference records for different tracing events for a food are unique. Linkages of incoming to outgoing products, such as product descriptions and to the next firm. We also would propose a requirement for a list of foods on the food tracing required shift.

This proposed rule would require anyone who ships food on the FTL to keep a list of foods which they ship, including the traceability product identifier and traceability product description for each food. In situations where product tracing or product action are necessary, access to a firm's FTL food list can help FDA and the firm more quickly identify associated foods potentially save up time on product action. This list can also assist the firm when identifying foods that will be subject to this rule. The list of foods would indicate which food on the FTL a firm generally ships even if there are gaps in those shipments. Also a description of traceability codes and how they are assigned. The traceability code allows a

food to be uniquely identified throughout the supply chain. As part of the firm's traceability program records, firms would be required to describe how they establish and assign traceability codes. Because of this crucial role that traceability codes play in the proposed rule, it is important that regulators know how a firm created and assigned those codes so that they can better understand the scope of the records they are reviewing.

Other information needed such as classification, glossaries, and abbreviations that are provided within the required records. The proposed rule would require a firm's traceability program records to include any other information needed to understand the data within their traceability records. These include internal and external coding systems, classification, and glossaries, and abbreviations. This would help regulators understand the terminology, methods, and systems a firm uses in its traceability operation.

A traceability lot code is proposed to be descriptive and alphanumeric used to identify a traceability lot and would be assigned by the traceability lot code generator. Currently, industry specifically refers to this term as lap or lot code. As mentioned, traceability lot codes are an essential

part of this proposed rule and should only be manipulated in certain situations to avoid creating confusion that can hinder a traceback or trace forward efforts. Therefore, the traceability lot code would only be able to be established or assigned if a firm originates, creates, or transforms a food on the food tracing list and would be linked to the records containing the required KDE.

In situations where a first receiver receives a listed food where the originator has not assigned a traceability lot code, the first receiver would be required to establish and maintain a record of a traceability lot code for that food. Prohibiting when a traceability lot code can be changed would potentially expedite the amount of time needed to trace a product. This could create an ability to skip steps or avoid unnecessary record collections from firms where the contamination did not likely occur.

For example, if an originator establishes a traceability lot code for a product and its packaging is not manipulated prior to arrival at the point of sale, it is not necessary to collect records from a distributor that may only change the label on an unopened box. Depending on the handling

and supply chain of a product, skipping steps can reduce time necessary to review records from multiple firms. Additionally, by limiting when a traceability lot code can be changed, there would be better tracking of traceability lot codes across the supply chain as well as to the firm.

The term traceability, as envisioned by the proposed rule, would allow the FDA to more quickly identify the source of a contaminated product, reduce the scope of product recalls, and conduct timely recall investigations to learn more about how contamination occurred in order to prevent future outbreaks. At the heart of the proposal, a requirement for those who manufacture, process, pack, or hold a food on the food traceability list. To establish and maintain records associated with specific critical tracking events or CTEs, entities would be required to establish and maintain records containing KDEs. The CTEs include the point where food would be grown which is a subset of origin, transformation either by changing a food on the FTL, its package and/or its label, regarding the traceability lot code or traceability product identifier, creation where food on the food tracing list would first be created, and it should be noted that the definition further

states that creating does not include originating or transforming foods, and then where the food would either be shipped or received from one point in the supply chain to another. The proposed record-keeping requirements would apply to all foods on the food traceability list, which includes products that contain listed foods as ingredients. Firms elect how they would like to maintain their KDEs; however, they would be required to be linked to the traceability lot code.

Our first provision covers the grower KDE. Many farms in rural locations lack a street address. In addition, many farms have multiple fields in which the same commodity is grown. Therefore, for a person to grow FTL foods, the grower would need to keep a record of the growing area coordinates of their farm and the shipment record information and name of the transporter. The grower would also need to provide certain KDEs to the next point in the supply linking these data points to the lot code of the product. This would also include information about the harvest, cooling, and packing of the foods which will be discussed later in the presentation during the proposed shipping KDE requirement.

It should also be noted that the growing area

coordinates would not be required 21055 unless the grower chooses to do so. The only requirement would be to maintain a record and provide the information to FDA when necessary. This sprouts posed unique food safety concerns as reflected in the special provision for sprouts in the produce safety regulation. Additional KDEs would be required for growers of sprouts. These KDEs would create linkages between sprouts and the seeds used to produce them. Requiring sprout growers to keep records on seed lots assigned by seed harvesters, conditioners, processors, and re-packers along with the dates of seed harvesting, conditioning, processing, and repacking could help to better scope a sprout recall event and identify the seed lot used to grow the sprout involved in that contamination event.

Our next provision covers the first receiver KDE. A first receiver of a food would be the first person other than a farm who purchases and takes physical possession of a listed food. Examples of first receivers could include manufacturers, processors, buyers of seafood from fishing vessels, and distribution centers. Only listed foods that are originated (i.e. grown, harvested for non-produce commodity, raised, or caught) would be a first receiver. It would have its first

receiver.

The concept of the first receiver was created because the foods on the food traceability list include foods in several different types of commodities with varying growing and production practices and associated business relationships. Because of this, the first receiver would be the first person who's in the best position to maintain comprehensive information about the origination and subsequent handling of a food. This includes information identifying the person who originated, harvested, cooled, and packed the food. Identifying the first receiver and defining it in this way would then ensure that comprehensive records relating to the origination and handling of the food were maintained by a single person who both owns and possesses the food. First receiver -- includes information about farms, maintenance of these -- by first receivers of a listed food would likely help prevent delays in determining who grew and physically held a product by alleviating the initial need to visit each entity performing farm activities.

Additionally, if you were the first receiver of a food on the FTL to which the originator of that food has not assigned a traceability lot code, you would then need to

establish a traceability lot code for the food and maintain a record of the traceability lot code linked to the KDE. However, in situations where an FTL food is made exclusively from non-FTL ingredients, which is a CTE identified at creation, there would not be a first receiver.

Since unique tracking information is relevant for seafood products obtained from fishing vessels, we are proposing to adopt separate record-keeping requirements for first receivers of listed seafood products obtained from fishing vessels. These KDEs would give FDA a better sense of the general harvesting trip a fishing vessel made for the identified seafood.

Now I would like to spend some time to review some examples that would help show how this first receiver concept would be assigned. In this example, a farm grows cantaloupe which is on the food tracing list. The farm sends the cantaloupe to an on-farm cooler who in this case solely cools the product and does not purchase it. It is then sent to a distributor. Since the distributor is the first person other than a farm who purchases and takes physical possession of the cantaloupe, the distributor would be considered the first

receiver and would therefore be required to maintain the corresponding KDEs.

In this next example, we have mangoes. Farm number one grows mangoes which are on the food tracing list. Farm number two then purchases and takes physical possession of the mangoes from farm number one. Farm number two send the mangoes to an on-farm packer who sends them to an on-farm cooler. The mangoes are then sent to an importer or wholesaler. The importer/wholesaler is the first person other than the farm who purchases and takes physical possession of the mangoes. The importer/wholesaler would be considered the first receiver and again would be required to maintain the corresponding KDE.

In this example, we have shell eggs. Shell eggs are on the food tracing list. The farm that harvests the shell eggs and then sends them to an inline washer/packer who would then further send them to a distributor. As illustrated in the previous examples, the distributor is the first person other than the farm who purchases and takes physical possession of the shell eggs. Therefore, the distributor would then be considered the first receiver and be required to maintain the corresponding

KDE.

The receiving KDE is one of the CTEs in that all firms in the supply chain will be responsible for maintaining with the exception of the originator or creator of the food. A retail food establishment, especially smaller RFEs that would be covered by the proposal, we recognize that this may find record-keeping requirements to be challenging. We are therefore proposing to require leading suppliers to send in most of the records that the RCs would need to meet the requirements so that these establishments would not have to generate these records but only maintain them.

It should also be noted that if an imported food was subsequently transformed, another CTE which is documented, the resulting food would not be regarded as imported. The receiver of the food product through transformation would not be required to keep a record of the entry number for any imported food that is a component of the transformed food.

Transformation of a food on the food traceability list would involve taking a listed food and changing the food or its packaging and/or labeling such as by processing it, combining it with other ingredients, commingling or repackaging

it. There are two important points to consider. One, transformation only applies to FTL food. And also this requirement would not apply to retail food establishments with respect to the listed food they sell directly to consumers.

Creation of a food on the food traceability list would involve making or producing a listed food such as through manufacturing or processing using only ingredients that are not on the FTL. Similar to the transformation KDEs, RFEs would not be required to be maintained for creation records for foods that are shipped directly to consumers. There is some multi-ingredient foods on the current draft of the food tracing list. As a result, it was necessary to make requirements for ingredients that are not on the FTL.

Unlike with transformation, there would be no Subpart F records available for the immediate previous sources of any of the ingredients as they would not be on the food tracing list; therefore, a firm would not be able to satisfy proposed KDEs for transformation. Because of this, this concept of creation was made to serve as a starting point for Subpart F record requirements.

Shipping is another CTE that all firms in the

supply chain would generally be responsible for with the exception of most RFEs. The records we propose to require a shipper of listed foods to keep are similar to the records that receivers of foods would have to keep as well. By requiring that most of the records be passed along from the shipper to the recipient, the rule would avoid duplication of effort and ensure that the requirement for the receiving CTE can be met. As with the requirements for receivers of food, if an imported food product was subsequently transformed, a shipper of this food produced through transformation would not be required to keep or send forward a record of the entry number for any imported food that is a component of said food.

As referenced in the proposed grower CTEs, farms would be required to send certain KDEs to the immediate subsequent shipper. To help ensure that those who receive the listed foods would be able to obtain the information they would be required to keep under the proposed rule, we propose to require a person to ship listed foods to provide their customers with certain information related to the foods they ship, as this information may not always be provided under current commercial practices.

Now I would like to spend some time going through some supply chain examples. This specific example represents the supply chain of fresh-cut romaine. Romaine is on the list so it would be covered under the proposed rule. This slide highlights the relevant CTEs for each point in the supply chain and the KDEs that would be required at each point. As you can see to the left, you have the grower who would be required to keep the grower KDEs. Next, we have an on-farm cooler. The cooler would need to keep receiving KDEs based on what they received from the grower, and the cooler would also need to keep and send shipping KDEs to the next point in the chain. Our next point is an on-farm packer who would keep receiving KDEs based on what they receive from the cooler. The packer would also need to keep and send shipping KDEs to the next point in the supply chain.

Because the grower, cooler, and packer are all farms, each one of them would have to send certain information forward to the next point in the supply chain. Specifically, a statement that the shipper is a farm, the location identifier and descriptions of the originator, the business name, POC, and lot number of the harvester of the food if not the shipper, and

the date and time of harvesting. Also, the location identifier and location description of the place where the food was cooled and/or packed if not by the shipper if cooling or packing has occurred. Also, the date and time of cooling and/or packing if cooling or packing has already occurred.

Next, you have a produce processor. The produce processor would consist of first receiver and the specific supply chain because again they are the first person other than the farm who purchases and takes physical possession of the listed food. The produce processor would need to maintain receiving KDEs as well as the specific first receiver KDEs based on what they received from the on-farm packer. Since the produce processor is transforming these romaine heads into fresh cut romaine, they would have to maintain transformation KDEs as well. Finally, the produce processor would need to keep and send shipping KDEs to the next point in the supply chain.

Next in the supply chain, we have a distributor who again would be keeping/receiving KDEs based on what they received from the produce processor. The distributor would also need to keep and send shipping KDEs to the next point in the supply chain. And then finally, we have our retailer, who the

retailer would then be keeping receiving KDEs based on what they received from the distributor.

Our next supply chain example relates to soft cheese. This diagram shows soft cheese which is on the food tracing list. The diagram shows the creation event because the ingredients of this particular soft cheese are milk and salt and would not be on the food tracing list. So requirements under the proposed rule would begin at the point of creation. Since soft cheese is on the food tracing list, the record-keeping requirements would apply throughout the remainder of the supply chain all the way to the retail food establishment.

Our next example is a supply chain related to seafood. This example relates to finfish. Finfish is on the food tracing list, but the proposed rule establishes modified requirements for the fishing vessel which catches the fish. The purchaser of the finfish would be the first receiver and would have to maintain specific KDEs related to seafood obtained from the fishing vessel. The record-keeping requirements would apply throughout the remainder of the supply chain all the way to the retail food establishment.

The proposed rule establishes procedures for

requesting modified requirements or for an extension for a food or a type of entity. FDA will consider whether to modify requirements or grant exemptions based on our own initiatives or based on the citizen's position by an interested party. Based on the information petition, FDA will determine whether application of the identified requirements is not necessary to protect the public health. Requests should meet the requirements listed provision in 21 C.F.R. 10.30 and would need to include to specify the food or type of entity to which the modified requirements or exemption would apply, if the petition request modified requirement specified the proposed modifications to the Subpart F requirements, and prevent information demonstrating why application of the requirements request to be modified, or from which exemption is requested is not necessary to protect public health.

The proposed rule also establishes procedures for requesting a waiver for requirements for an individual entity or type of entity. FDA will consider whether to modify requirements or grant exemptions on our own initiative or based on a written request from an individual entity or a citizen's petition or a type of entity. Based on the information in the

petition, FDA will determine whether application of the identified requirements would result in an economic hardship due to the unique circumstances of the individual entity or the type of entity, and the waiver will not significantly impair our ability to rapidly and effectively identify a recipient of a food to prevent an outbreak or address credible threats of serious adverse health consequences or death to humans, and the waiver will otherwise not be contrary to public interest.

Examples are unique and circumstances might include but are not limited to issues related to unique business operations or geographical factors. Waiver requests should include the name, address, and point of contact of the individual entity to which the waiver would apply or the individual entity waiver, or the type of entity to which the waiver would apply. The requirements of this Subpart F to which the waiver would apply, information demonstrating why application of the requirements requested to be waived would result in an economic hardship, information demonstrating why the waiver will not significantly impair FDA's ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak, and information

demonstrating why the waiver would not otherwise be contrary to the public interest.

The proposed rule would also require that records be maintained as either original paper records, electronic records, or true copies. They all must be legible and stored to prevent deterioration or loss. Records must be kept for two years from the date they were created. Traceability records must be provided to FDA as soon as possible but no later than 24 hours after a request is made. Firms must also provide FDA with an electronic sortable spreadsheet containing relevant traceability information within 24 hours of a request when necessary to assist FDA during an outbreak, recall, or other threat to public health.

Thank you, Kari. I'll turn it back over to you.

MS. BARRETT: Wonderful. Thank you so much, Angela. That was a lot of content to work through, and I know we've got a number of questions that hopefully we can get to when we get to the Q&A. But for now, we're going to go to our next speaker which is Aliya Sassi. She is a Senior Economist, Office of Policy, Legislation, and International Affairs in the FDA Office of the Commissioner, and Aliya will provide us with

an overview of the regulatory impact analysis of the proposed rule.

So Aliya, I'll go to you.

MS. SASSI: Good afternoon, everyone. Glad to be here to talk about our preliminary -- . This is an outline of today's -- go over the estimated number of entities covered by this rule, then discuss the estimated benefits impacting small businesses and international affairs. There are two -- options when it comes to -- of food establishment or RFT. Under option one of the code proposal, -- establishment -- will be -- . Under option two, these -- establishment will be exempt only from the requirement to provide FDA -- circumstances with an electronic sortable spreadsheet containing the requested information. During this talk, I'll present the estimates to both options side by side.

Entities that would be exempted by this rule not only include retail food establishments. Overall, this rule covers entities that manufacture, process, pack, or hold foods that FDA has placed on the food traceability list and that are not subject to any exemption discussed in the preamble. Here you can see both the estimated number of -- and the number of

establishments -- by type. One firm can operate several establishments.

Under option two, the rule that's currently proposed would cover approximately 422,000 firms operating at 566,000 establishments. Under option one, the total number of -- would be lower at 188,000 firms operating 332,000 establishments. This is a summary of quantified costs and benefits of the rule. The cost and the benefits are analyzed over 10 years at seven percent discount rate and presented in 2018 dollars --. This proposed rule is an economically -- action -- by executive order on 2866. We estimate that annual cost of the rule under -- option one would be \$411 million per year. Annualized health benefits would be 667 million per year based on an estimated 84 percent traceback time improvement.

Under code proposal option two, the annualized cost of the rule would be \$535 million per year. And annualized health benefit would be 626 million per year. In addition, the estimated cost to foreign entities at about \$295 million per year, a portion of which could be passed through to the -- and consumers via price increase. Using examples from three product recalls, we estimate that additional non-health benefits for

both options one and two -- from \$1.7 billion to -- billion per year. -- complete information on other benefits and -- .

This slide shows the breakdown of cost by option and industry -- . Compared to option one, costs for option two are greater by \$124 million and the benefits are greater by \$60 million. This is -- under option one -- establishment would need to comply with this rule, however, by exempting RFTs with 10 or fewer full-time equivalent employees. And that's our option one. The time limit, precision, and accuracy of the -- can be impacted. Under option one, FDA has the ability to narrow the number -- and the ability of these RFEs to have data to quickly identify and remove -- products from shelves will be lessened. We believe that non-quantified benefits will also be left under option one compared to option two. The required record-keeping by RFTs regardless of their size allows the -- organized and specific information that covers the entire supply chain of listed food.

This proposed rule -- in public health benefits of foodborne illness is directly related to outbreaks from listed food -- . The primary health benefits are the value from the reduction of the foodborne illness and death, the --

required by -- are likely to reduce the time that -- listed food products is on the market. This public health benefit could be generated if the following two conditions of first, a foodborne outbreak occurs, and second, the traceability record required by this proposal helps FDA to quickly and accurately locate the -- product and ensure it is removed from the market.

This may also lead to more efficient use of FDA and industry sources needed for outbreak investigation that potentially result in more precise recall and also by avoiding overly broad market withdrawal and -- . Additional known health benefits may include increase to supply -- such as improvements in supply chain management and inventory control, more expedient initiation and completion of recall, avoidance of cost due to unnecessary preventive actions by consumers, and other -- from a standardized approach to traceability, including an increase in transparency and trust and potential -- of product. Without complete information that would enable to quantify these benefits or to quantify the difference between the two options. In the -- we -- .

With new public health benefits based on the model provided in the 2012 pilot study report by the Institute

for Food Technologists, we included five of the eight case studies from the IFT report plus 10 additional case studies using data from the statistics along with investigation and intervention data from FDA as explained in Appendix B of our analysis. We focused our analysis on four pathogens, Cyclospora, E. coli, listeria monocytogenes, and -- Outbreaks from these four pathogens present over 90 percent of all illnesses associated with the listed food. According to the -- and other key data elements throughout the supply chain would likely enable -- to identify common product sources in about five to seven days. That's an average of six days as opposed to 37 days that it takes now based on the studies that we looked at. We used this information to estimate -- percent of improvement based on the reduced time to trace implicated products.

In sum, we estimated the burden of foodborne illnesses attributed to listed foods by multiplying the estimated number, total number of illnesses that would be prevented by the weighted average -- illness -- from the FDA -- . This slide shows our upper and lower case estimates of public health benefits. Both options one and two estimate the value by

a wide range. We estimate that annualized benefits -- under code proposal option one would range from approximately \$33 million to \$1.4 billion per year with the primary estimate of \$567 million per year. Under option two of the code proposal, the annualized benefits of the rule would range from approximately \$36 million to \$1.5 billion per year with a primary estimate of \$626 million per year.

In addition to the public health benefits, documentation of more precise food recall -- and social benefits from avoiding -- . The recalls -- product -- the necessary cost, -- that involve closely related or unrelated product can be unnecessarily costly. There are no benefits from removing unimplicated products from the market; therefore, avoiding the - - unimplicated food products is a benefit.

Using three case studies and supermarket data, we estimate the social benefits as the value of -- sales during each -- recall event. -- time periods -- the shortest length of a -- recall and as our best case scenario and -- is the longest length of a cross -- recall or worst-case scenario. The -- on this slide represent estimated low and high of -- sale. This proposed rule is finalized with the compliance cost on covered

entities by increasing the number of records that are required for -- . Public entities would incur the current cost to establish and maintain traceability records. In -- terms, -- investment and training costs and systems that would enable them to establish, maintain, sort, and make available upon request the traceability records. -- firms would incur a one-time cost of -- .

This slide shows our upper and lower estimates of costs. We estimate that annualized costs of the rule and the code proposal option one would range from approximately \$34 million to \$2.4 billion per year for the time of the estimate of \$411 million per year, and under option two of the code proposal, the annualized cost of the rule would range from approximately \$43 million to \$3.2 billion per year with the primary estimate of \$535 million per year.

Here are the estimated costs for the entire industry by provision -- between the two options. The highest cost would be customer investment costs, especially for option two and shipping -- costs. This slide shows our upper and lower down costs from small business by industry type. This cost is similar to the two code proposal options, and we used the --

definition that small business administration -- of a small business and U.S. Census data to estimate that about 90 percent of firms covered by this -- are small businesses.

Because small businesses may have annualized costs that exceed one percent of their annual revenue, we find that this proposed rule will have -- economic impact on a substantial number of small entities but not on all small entities. We estimate that this -- about 212,000 foreign entities and that the annualized costs to foreign entities would be about \$259 million per year. A portion of this cost will -- entities and consumers see price increases so they may experience higher costs. -- concerning the portion that they -- through. However, requirements of this rule apply to all domestic entities in the same manner regardless of -- . -- cost on the proposal on foreign entities we extrapolate from the main cost estimates by comparing the number of foreign entities in FDA food facility -- model and primary estimated number of domestic establishments minus retail food establishments. We assume that the number of -- retail food establishments affected by this rule is manageable.

Overall, there are several areas where we are

seeking comments and information to help us improve our estimates and model ranges. For example, the number of governed entities that -- of which entities already satisfy the requirements. The percentage of -- and additional expenses. They expect the health benefits due to complexity of -- health benefits -- outbreaks. The current number of foodborne illnesses caused by listed food and overall our estimates of cost and benefit and the extent of which cost will already be internalized by a covered entity.

Thank you very much. Turning it back to you, Kari.

MS. BARRETT: Yes, thank you so much. All right. Well, now we're going to conclude our morning segment of SME presentations with Andrew Kennedy. He's our New Era Technology Team Leader in the FDA Office of Food Policy and Response, and Andrew is going to walk us through a real-world application of the proposed traceability rule.

So, Andrew, I'm going to turn it over to you.

MR. KENNEDY: Great. Thank you and thanks, everyone, for joining today. Again, my name's Andrew Kennedy with the Office of Food Policy and Response.

So it's my honor to be able to take this rule and actually put it together into a real-world example for you today. So what we're going to do is walk through a salad kit that's prepared with tomatoes and iceberg lettuce, but the focus will be on the tomato grower, the salad maker, distributor, and retail store. In this presentation, I've abbreviated some of the data due to time constraints, but if you're interested in the full detail, when we post these presentations online, I'll also attach a sortable spreadsheet with the data so you can see how I constructed this example.

The following example is intended to illustrate how several types of firms in a supply chain might meet the requirements of the proposed food traceability rule and how that information can be used by investigators to trace backwards from a retail food establishment to a farm. The finished product is a salad kit made from cherry tomatoes, iceberg lettuce, and non-FTL ingredients that won't be shown here. For the purposes of this scenario, it's assumed that the tomatoes are the commodity of interest in the traceback so the iceberg lettuce farming information will not be shown.

This chart provides a quick snapshot of the data

I'll be walking through. Specifically, I'll show the farm's program records and shipping KDEs, including the originator, harvester, cooling, packing, KDEs to be sent to the first receiver and how those might be included in an extended bill of lading. Due to time constraints, I'll abbreviate program records and receiving KDEs for the processor, distributor, and retailer. I'll represent the information in a technology-agnostic manner, but I developed the examples based on what I imagine the sortable spreadsheets might look like for each actor in the supply chain.

For discussion purposes, let's imagine that the farm is providing paper records to the produce processor who then digitizes the information upon receipt. The processor then captures the ingredients and finished production in their manufacturing software which is used to produce an electronic advanced ship notice for the distributor incorporating the shipping KDEs. The distributor receives and verifies the information into their warehouse management system then shares their shipping KDEs to the retail food establishment via their proof of delivery system. Please note this is only one example and by no means is intended to be the only way data can be kept

and shared.

So here's our scenario overview. Tom's Produce is a large produce growing company that contracts with several companies to grow, harvest, pack, and ship fresh produce, including cherry tomatoes. They retain ownership of the crop from planning to shipment to customers. The organizations they work with are Tom's Tomato Farm, number one, owned by Tom Jr., Aries Harvesting that harvests the tomatoes, Patty's Packers, who cools and packs the tomatoes, and Johnson Storage stores and ships the packed tomatoes for Tom's Produce. These slides do not focus on the iceberg lettuce and the salad kits which is sourced from a different company.

So first off, we have the program records, and this is the description of the records. So program records are critically important for an understanding of traceability KDEs. The first type of required program record is a reference record description. This example shows a bill of lading, and that's listed under the first column that says reference record. The second column is a listing of rule KDEs. So you can see those beginning -- the first one is reference record number, transporter name, traceability lot code, et cetera. The third

column, you can see the field name on the actual record. So this is what it would look like on the bill of lading. So a good example is the cross-reference between the rule KDE called transporter name and carrier which is the name on the record. So when we look at the record, we would look for carrier, but we would know that means transporter name. And then the next couple of columns shows the linkage between other records, so in this example, we used the traceability lot code to link to the growing KDEs, and that's linked by the traceability lot code. So you can see that in the final two columns.

The next step of the required program record is a list of FTL foods the organization shipped. Please don't confuse this with the shipping CTE. This is a master listing of traceability product identifiers and associate KDEs including category, brand, commodity, variety, --, and style. If the products shipped are multi-ingredient, the product name KDE would be used instead of the commodity and variety KDEs, and you can see in this example I put N/A under the product name because these are single ingredient commodities.

The point of this program record is two-fold. First, this enables firms to reference the traceability product

identifier in critical tracking events instead of incorporating all of these KDEs in every line of your shipment records, receiving records, and transformation records. So it's like a shortcut. You can just reference the traceability product ID in those records and it points to this table, and we can look up the additional information from this table. And then the second thing is if we want to get an idea of what products and what categories the products that you ship, this is a quick and easy way that we can find out what kind of commodity. So if this grower grows things other than tomatoes, we can quickly go through and see, oh, they grow tomatoes and carrots and peas and a couple of other things. So from this list, that would give us an idea of what they grow and ship.

So the next one is -- this is a complicated conversation. We'll try to cover it here quickly in this slide. This is a traceability lot code assignment method. It's important for investigators to understand how lot codes are determined and assigned by the traceability lot code generator. Because this gives us a sense of the scope of a lot code, the example shown here is very specific, including the commodity, variety, packing location, and pack date. Other lot code

assignment methods are less specific. The important thing to consider is how the traceability lot code combined with other KDEs can be used to identify a certain quantity and type of food and narrow the scope of the investigation. So we see many different kinds of traceability lot code formats and just as long as it gets us to where we need to go, where it's produced, what was produced, when it was produced. That's the important thing with a lot code.

So next up we've got the location master. Although this is not required, and it falls under the category of other information that's optionally provided, to simplify your CTEs, if you want to create a master listing similar to the way we did in the product listing, you can reference the location by the location identifier. So in other words, you don't have to list a primary phone number and street address, et cetera in every line of shipping records and receiving records. Again, it's the same principle applied with the product identifier.

Growing KDEs. In this example I tried to represent for each FTL food grown, the grower of the food would be required to establish and maintain records linking the

traceability lot code of the food to the growing area coordinates. So that's shown here on this slide. Your actual records may include more information that is important to understand this. So, for example, I've seen records that include ranch, field, block, sub-block, et cetera that are meaningful to the grower and help kind of explain where this growing area is. So the main idea here is that we can physically identify where the food was grown, especially as we're doing a traceback investigation. That helps us to determine where the area is so we can determine if it was contaminated in the field. So again, it's not required that the grower sends this information to the trading partner, but oftentimes we see it's common practice to do so.

Shipping KDEs, product information that needs to be kept, this is the starting point of the shipping information the farmer would need to keep and send to the processor. So imagine all of the orange boxes that you'll see on the next few slides are part of the same tab of a spreadsheet. To begin with, the farmer would provide product information including the traceability product ID, the quantity and unit measured, a link to the traceability lot code. To make the critical tracking

event easier to read, I've included an abbreviated traceability product description. The full traceability product description was shown before in the program records and is referenced in this example by the traceability product ID. The next three columns in our spreadsheet tab include the traceability lot code generator information. In this case, Tom's Produce assigned the lot codes, so they're listed as the traceability lot code generator, and Tom is listed as the point of contact.

Continuing onto the ship to information, the ID for the fresh processor plant, number 16, in this case, an abbreviated location description, are kept and sent. The location ID references the location master information shown in the program records, so I only included a short description on this slide. In a similar way, the location from where the product was shipped along with the shipment date and time are kept and sent to the processor. I abbreviated the ship from location description, Johnson's Storage Warehouse number four, and referenced the detail location information in program records using the location identifier. The last component of the farmer's shipping KDEs, so this is -- you're imagining that spreadsheet tab, this is the last part of that tab. The KDEs

are intended to be kept only, so these include the reference record type and number. In this case, it's a bill of lading number and the transporter name.

The following five slides illustrate the data that should be sent from the farmer to a first receiver. So you've heard a lot about first receiver. This is an actual example of what that data would really look like. Step one is to let the processor know that the shipper is a farm. This alerts them that they're a first receiver because if you don't tell them, there's no way they're going to know they're first receiver. So next is the originator. The farmer communicates the originator's location identifier and description for each traceability lot code sent to the processor. In this case, I've referenced the location master list and program records. So you can see the location identifier refers to Tom's Tomato Farm number one. Under harvesting, the harvester's business name, contact information, and harvest date and time are sent. Next up we have cooling. In this example the same packing company provides cooling and packing, so the information shown here is basically the same as the next slide except for the date and time. So we have the cooling date and time. On this one, we

have the packing date and time, but both of them are done at Patty's Packing Shed.

So that kind of wraps up on the farm side. Now we're moving to the fresh processor. A quick reminder of what this part of the scenario looks like. The fresh processor receives the ingredients and processes them into salad kits, and the organizations they work with are Tom's Produce, who provides the cherry tomatoes. Lizzy's lettuce provides the iceberg lettuce. The food distributors are kind of next in the chain, so they receive the salad kits from fresh processor, then they, in turn, distribute the salad kits to the retailer. So again, Tom's provides the tomatoes, Lizzy's, the lettuce, then we send it off to the food distributor.

So for the sake of time, I've abbreviated the processor's traceability program records. They're pretty similar to the farmers but will include reference record descriptions for work orders used to process ingredients into finished products. The list of foods shipped will include the salad kit in this example, and the location master list will include the distribution center the processor ships to. So since the processor's been alerted that they are a first

receiver these are some of the KDEs that they would receive as part of that and capture. So this information provided by the farm basically mirrors what I'm showing here. So we just walked through that detail on the farm side. So you have the originator, the harvesting, the cooling, the packing. That's all linked to a traceability lot code. So that information would be stored, and really you only have to have that listed once per traceability lot code. You don't have to list the first receiving information for every single line of product that you receive. It's just for that individual lot code.

Next, the receiving information, the receiving KDEs. The processor captures this information. Again, this kind of mirrors what you saw in the outbound shipment side. So you have the product information, the source, the recipient, the traceability lot code generator, the reference record information, other information. The key difference is you're going to have the receiving date and time. On the outbound shipment, you have the shipping date and time.

So this is a new CTE that we haven't covered before. So this is the processor's transformation CTE. So the first step, and there's just two slides on this one, we show the

foods used in the transformation process. So that information is shown here, so we have the new traceability lot code. It is shown on the next record. What we have on this record are the ingredients. So we have the traceability lot code information for the cherry tomatoes and the iceberg lettuce. We have the quantity, how many cases of each product, their traceability product identifier, and then a short description of those ingredient products. This is where we create the new traceability lot code. So on the left, you can see the new traceability lot code that we generated, the location where that transformation took place, description of that location, which again is shortened in reference to our location list, the transformation date when it was completed, the quantity and unit measure, so how much we produced, and the new traceability product identifier and new traceability product description. In this case, I've included a UPC code on there just to give you an idea, you know, from a common business practice standpoint how a product that's typically in a case would also represent what's in that case. So in this case I put the UPC in parentheses under the product description. Then we also have the reference record type and number. In this case, it's a work order number

on the far right.

The next five slides show the shipping KDEs for the salad kit that was produced in the prior step. So similar to the farmer's shipping KDEs, we have the product information which is shown here, the traceability lot code generator which is now the fresh processor. So I put in the fresh processor information, their contact information, and the person who should be contacted with regard to that traceability lot code. Then we have the food distributor's ship-to location which is identified here, so we're sending to D.C. 100, and then the ship from location, fresh processor's plant 16, and we also capture the shipping date and time. Finally, we have the reference record, so this shows the new bill of lading that I'm shipping outbound on and the new transporter name.

Okay. So we are halfway there. We've made it to the food distributors, so this is the -- the food distributors receive the salad kits from the fresh processor that we just produced. The organization they work with, again, the fresh processor and the retail food establishment that they ship to. So under the distributor's program records, these are pretty simple because in this case, they're not assigning any sort of

lot codes. So lot code assignment method would probably be blank in this situation. Then under the receiving KDEs, this mirrors the outbound shipping KDEs so you can see the product information, the source, the recipient, the traceability lot code generator, reference record information, and other, and again, the receiving date and time for these records, so very similar.

And then the distributor's shipping KDEs, so kind of walking through these, you can see -- you know, the shipping KDEs are going to be about the same as you go through the supply chain. The only difference between a distributor and manufacturer and a grower is you don't have the first receiver outbound KDEs. So the processor and the distributor shipping KDEs look very similar. So we have the traceability lot code, the quantity, and unit of measure, traceability product ID, and description. And this is the information that was assigned by the processor, so this is carried through the distributor onto the retail food establishment. So they pass the exact same traceability lot code product ID and name that they got from the processor, and they also provide the traceability lot code generator information which points back to our fresh processor,

plant number 16 and the point of contact, Bob Brown. So it's important that that information is passed through along with the lot code so then the retail food establishment has the information.

In the next step, you'll see what the retailer can do with that. We also have the immediate subsequent recipient, so who it's being shipped to. In this case, we have the store number, the retail food establishment store number, 1052, and then where it came from. In this case, it's a distribution center, and then we have the shipment date and time. And by prior shipping records, you can see we're capturing the new bill of lading number and who provided the transportation into the retail food establishment.

So the last step in the supply chain --

MS. BARRETT: Andrew.

MR. KENNEDY: Yes?

MS. BARRETT: This is Kari. I'm not seeing the slide content right now. I'm just seeing a white slide.

MS. GOLDBERG: I'm seeing it here.

MS. BARRETT: You are? Okay. Fantastic. Sorry for the interruption.

MR. KENNEDY: Yes, it's up. Okay.

So this is the last step in the supply chain. So the retailer receives the product from the distributor, and what's important is the lot code generator information. So what's important is that the retailer is receiving the lot code generator information for that salad kit and the retail KDEs. So you'll see these. So the traceability program records are even simpler. They're basically just a description of the locations and any reference records that they have in their operation. But again, they're not going to be assigning lot codes, and they're probably not going to be shipping to any further locations because they're the end of the supply chain. So the list of who's on the food traceability list will be very simple. So the retail receiving KDEs look very similar to the processors and the distributors. So we have the product information, the source, the recipient, the traceability lot code generator, the receiving date and time, their reference record information, and other information. So at this point, they've gotten the traceability lot code generator, the traceability lot code, the product information from the distributor that was passed to the distributor by the processor.

So they have all of that original information passed through.

So then you go to the overview of how we use this information in a traceback. So to kind of understand how this simplifies it, imagine the investigators know the location, UPC, and date of purchase. From the retail food establishment, they can request information on traceability lot codes and traceability lot code generators related to products received at the time of purchase. The investigators can then use that information to contact the processors directly and ask them about the ingredients and the ingredient lots used to produce the salad kits of interest. So in this example, investigators have determined that tomatoes are the likely cause, so they can use the first receiver information to contact the farm regarding the physical location or locations where the tomatoes were grown. Along with the packing, cooling, and harvesting information, the investigators are starting with a pretty good idea of where to look for possible contamination. If contamination is discovered at the growing location, cooler, packing shed, or processor, the same type of traceability records used in the traceback investigation can also enable the supply chain to initiate and complete a quick and effective

trace word and recall using the exact same records.

So hopefully that gives you a good idea of how we can take this role and create our records and share those with trading partners and then also how those would be used in a real-life investigation. And I look forward to Q&A coming up and any questions. And again, thank you. Andy Kennedy with OFPR.

MS. BARRETT: Great, Andy. Thank you so much.

At this time, we'll go to our Q&A.

MR. KAWCZYNSKI: Okay, presenters, please turn on your cameras. Let's see. There we go.

All right, Kari, I'll let you take it away.

MS. BARRETT: Okay. Great. Can you hear me?

MR. KAWCZYNSKI: Yes, we can. Okay.

MS. BARRETT: Okay. I'm getting a little feedback on my end, but you're not hearing it?

MR. KAWCZYNSKI: No. I'll be off in a second here.

MS. BARRETT: Oh. Okay. I'm still having it, but if it's not bothering you then we'll keep going.

Thank you, Andy, for your remarks, and we'll get

started with our Q&A.

MR. KAWCZYNSKI: I'm going to be joining. Just keep going, Kari. We'll fix it in one second.

MS. BARRETT: Okay. Thank you.

All right. Well, again, if people have questions, please put them into the chat. We'll run through this Q&A just as we did the last time, and we do have a number of questions. So we'll begin.

Andy, this one looks like it's for you. Do I need blockchain to do this?

MR. KENNEDY: Yes, great question. So lots of questions about blockchain and traceability. The way we designed this rule is to be technology agnostic, so you don't need any specific technology to meet the requirements of this rule. You can use blockchain, but there are many other technologies for sharing data between trading partners. And in terms of generating a sortable spreadsheet, blockchain traceability applications can certainly generate those, but it's not the only way to do it.

MS. BARRETT: Great. Thank you. Okay.

Now, Angela, we have one for you. Would the KDEs

need to be provided to the next entity in the food supply chain for foods on the food traceability list?

MS. FIELDS: Yes, thank you for that question. So distributors would need to keep and send any shipping KDEs to the next point in the supply chain.

MS. BARRETT: Okay. Let's see what else we're going to go to here. There's quite a few.

Aliya, this one is for you. Does the number of affected entities include foreign facilities?

MS. SASSI: So the number of affected entities that I had presented in the summary does not include foreign entities, but the number of affected entities that I presented on the slides in the last group. That slide was completely dedicated to foreign and the number of entities.

MS. BARRETT: Okay. Great. Thank you.

This one is going back to Andy's presentation. He showed the traceability product identifier being 99999 for the processor and the same identifier as the distributor. Is it a requirement that the distributor use the same traceability product identifier through the entire supply chain?

MR. KENNEDY: Yes, that's a great question. So I

think the important thing is the traceability lot code and traceability lot code generator remains the same through that step. If a product is relabeled with a different product identifier and linked back to the original product identifier, I mean, not 100 percent positive. Maybe I'll kick it off to the legal folks that are online. I don't know that that's an issue, but certainly, a question that one of the folks, maybe Katy or Rebecca or Becky, could delve into.

MS. GOLDBERG: Yes, I can take a shot at it.

This is Becky Goldberg. If I understood correctly, it's about the traceability product identifier. So that's something that I'm not quite sure I understood what the question was asking, but I think in Andy's slides different entities were using the same identifier. And I guess the question was whether that has to be the case. Like, does the distributor have to use the same one that was used by the manufacturer. That is not the case for traceability identifier. You can create your traceability identifier in different ways, but your records are going to link up, you know, because if you look at the way the records are constructed where you have the incoming and the outgoing, and you're linking it all by traceability lot code, will be able to

link up and therefore not get confused about that and have full traceability. But there are different ways to create traceability identifier. You don't have to do it the same way as other people in the supply chain. I don't know if others have other thoughts on that or if that answers the question.

MS. BARRETT: Great. Thank you very much.

All right. Andy, we're going to come back to you again. We have another question for you and that is why include a traceability location ID and description. Isn't that redundant? Same with the traceability product ID and description?

MR. KENNEDY: Yes, great question. And for the purposes of this example that I provided, it's easier to see that short description next to the ID if you're not necessarily aware of what that ID represents. So just for the purpose of these slides, I show that abbreviated product and location description, but if you have the ID and you have that listing, it would not be required to have that shortened description. It was mainly just for readability as we did this presentation so you knew what the product ID and location ID was.

MS. BARRETT: Great. Thank you, Andy.

Angela, we're going to go to you. Is packing fresh-cut herbs transformation, and if the packhouse receives the herbs from an external supplier grower, will the traceability lot code assigned by the grower have to be maintained or can it be changed at the packing step?

MS. FIELDS: Yes, thank you for that question. So we propose to define transformation as an event in the food supply chain that involves changing a food, its packaging, and/or its labeling. So in the instance where the initial packing is happening, that would not be considered transformation, and so the traceability lot code would be maintained from the internal supplier. Now in the situation where that packaging or those herbs would be repacked, in that case, the traceability lot code could be changed.

MS. BARRETT: Great. Thank you, Angela.

Aliya, this one is for you, and the question is where do the capital investment cost estimates come from? What assumptions go into that estimate?

MS. SASSI: Thank you. Good question. So considering variation across firms by -- size and existing -- basically -- recent industry reports and -- estimates with the

input from subject data experts, and we assume that covered firms would spend between 500 and 25,000 for additional -- investments to comply with this proposal with our primary estimate of \$7.5 thousand. So because the majority of -- entities that would be covered by this rule with the small and medium-size firms, we assume that basically this estimate is skewed towards the lower end. However, we recognize that there is essential variability and we request information on these assumptions. And specifically, we request information on the capital investment costs by firm size, --, and existing -- . Overall, we think that some firms may be able to comply without additional customer investments and others would need to invest the -- related capital and that's the incremental cost of complying with the proposed rule that we're looking for, the information we're looking for. And we believe that if maybe -- agree to -- then the cost of the total system upgrade of things like that.

MS. BARRETT: Great. Thank you.

Angela, we're going to come back to you, and the question is do originators, for example, growers of produce on the FTL have to meet the traceability program requirements

listed in Section 1.1315 and that's the traceability program records?

Angela, you are on mute I think.

MS. FIELDS: Can you hear me now?

MS. BARRETT: Yes, thank you.

MS. FIELDS: All firms that would be required by the rule would be -- or covered by the rule would be required to maintain traceability program records, but I do want note that again persons that are subject to the rule can enter into agreements with individuals or firms to create and keep these records that are required for the rule on their behalf because again, we acknowledge that there are a lot of varying business relationships and constructs that are happening across the commodity.

MS. BARRETT: Great. Thank you. All right. Now we're going to go to our next question.

And Aliya, this one is for you, and it's a little bit long so I'm happy to repeat any portion of it if that's helpful. But the question is in the regulatory impact analysis, is the number of retail food establishments the number of stores selling to consumers, for example, restaurants, grocery stores,

et cetera, or is it the number of corporations, brands, for example, restaurant chain that may have 200 stores. Does the rule apply at the store level or the corporate level?

MS. SASSI: So in the REAL ID Act, we present numbers to both firms, the number of firms and the number of establishments, and I said that one firm can operate several establishments. And some of these -- for some of the provisions we estimate a cost on the firm level, for example, customer investments or training and for record-keeping made on establishment level. I hope I answered your question.

MS. BARRETT: Thank you.

And Andy, we're going to come back to you. There's still confusion. I'm still confused with the difference between a traceability lot code and lot code identifier. Can they be the same?

MR. KENNEDY: Yes, I just want to clarify, there's the traceability product identifier and then there's the traceability lot code. And so the product identifier identifies the product. The traceability lot code is the lot code. So it's two different concepts. One is what type of produce it is, so that would be askew or a G10 or something like that which

identifies the type of product, the pack size, the pack style. And then the other component is the lot code, and that, you know -- during the course of the day or week or month or whatever, as you're making different products, you segment your production by lot code. So the lot code really determines, you know, where something is produced, when it was produced, who produced it, and then the product ID is more around the product characteristics. So it's like two different pieces. Together, you know, it's the product ID with the lot code, provides the complete picture.

MS. BARRETT: Great. Thank you, Andy.

Becky, we have a question for you. It says for the location of a quick-service restaurant typically would have less than 10 FTEs. Are they exempted?

MS. GOLDBERG: Right. So the number -- so that's for the code proposal, right. So it's not clear at all -- there's two different options, and that exemption would only take place at all under option one of the code proposal. But assuming that you were under option one of the code proposal, the number of full-time equivalent employees is based on the number of such employees at each retail food establishment and

not the entire business. So if I'm understanding the question correctly, you know, it's not the whole chain or whatever. It's just the specific retail food establishment. If they have 10 or fewer full-time equivalent employees, they would be exempt under option one.

MS. BARRETT: Great. Thank you very much.

Angela, is repacking vegetables that are kept whole fresh into clamshells or bags considered a transformation?

MS. FIELDS: Thank you, Kari.

So yes, again, any event that requires -- transformation is defined by anything that is cut, cooked, commingled, repacked, or repackaged.

MS. BARRETT: All right. Very distinct. Let's go to the next question. This is Andy.

Do traceability lot codes need to contain hierarchal information such as the example, or can it be a random alphanumeric code?

MR. KENNEDY: Yes, great question, and again, for simplicity on the slides I created a very explicit sort of simplified idea of what a lot code would look like. But yes, in operations I see all kinds of different lot codes, schemes, or

methods. The important thing is you think about when you have a traceability lot code and the traceability lot code generator, if you're in a traceability lot code generator and you get the phone call and someone says can you tell me about this lot code, you have to have enough information in that lot code either stored in a process or system where you can look at lot code up and find out, you know, what does that lot code mean. So you have to be able to find out where something is processed, what was processed, when was it processed from that lot code. So it's got to be specific enough for you to be able to provide that information. And then when you provide the explanation of how your lot code is created, everyone's going to have a different methodology for lot codes. Just as long as it makes sense when you get that phone call to track a product that you can link that lot code to the appropriate information that we need. So that's kind of the key thing you have to ask yourself with the lot code assignment methodology.

MS. BARRETT: Excellent. Thank you.

Andy, this one may be for you or for Angela. I'm not sure. The question is the harvest location coordinate is a very specific single site. What would be required for a seafood

harvest area that might span a broad area?

MS. GOLDBERG: And I can jump in on that if it would be helpful.

MS. BARRETT: Sure. Please.

MS. GOLDBERG: So --

MR. KENNEDY: You win. You got it.

MS. GOLDBERG: Yes. It's different. It's not supposed to be precise for seafood. It's the location for the trip during which the seafood was caught. So we're not looking to know where each fish actually came out of the water. We're looking for the whole trip during which the seafood was caught. So it's suggested in the proposal that that could be given through National Marine Fishery Service ocean geographic code or through geographical coordinates. I don't know how those NMFS geocodes work precisely, you know, in terms of if you did it by geographical coordinates, it would not be a single point. It would be, you know -- and it's a date range as well. So it'd be I caught this fish. It's actually not the boat that needs to maintain it. It's the first receiver. But it would be if they caught this fish, you know, during the week of November 1st to November 8th while they were in this general area.

MR. KAWCZYNSKI: Let's hold on a second here.

Are you there?

MS. BARRETT: Yes, I do see we're getting some messages.

MR. KAWCZYNSKI: Yes, I saw that, too. So it looks like we had a disconnect here. I just want to double-check real quick. Here's what I want to do. I'm going to -- we're going to take a quick 30-second pause. Like, a one-minute pause. Here's what I'm going to have to do. I'm going to kill the audio for a second and reconnect us. So to my presenters, nobody else has to do anything, just my presenters, you're going to have to come back in again real quick. Okay. So you know how to do that, to reconnect to your audio. I'm just going to kill it, come back in to make sure it resets. Does that sound fair?

MS. BARRETT: Sure. Thank you.

MR. KAWCZYNSKI: You know how to do it, right? You don't need to leave the room or anything, but here we go. We're going to stop it here for a second.

(Off the record.)

MS. BARRETT: I'm going to turn it over to you.

MR. METTLER: Thank you. Fantastic. Thank you, guys, for the time for this. What we really wanted to do as part of a new era in the food traceability proposal that's going out there is really sort of acknowledge all the people that are working as part of this, not only FDA but also industry and the states. And as part of the new era, one of the key pieces is actually -- reliance, and so we're really sort of relying and looking at one workforce between FDA and the state.

And so thank you very much for joining us, Kyle. And for those who don't know Kyle, Kyle is the Chief of the Center for Milk and Dairy and Product Safety, the Office of Food Protection in the Maryland Department of Health. So he is going to join us, and I do want to note that we were also supposed to have Anita MacMullan, the Director of the Food and Drug Protection Division in North Carolina Department of Agriculture and Consumer Services, but she was unfortunately in a car wreck this morning. And she was not able to join us, so our thoughts are out with her and everyone else who was involved in that. So I just wanted to put that out there.

So, Kyle, thank you for joining. This has a profound impact I think on all of us, and so one of the

questions I wanted to ask you is you guys are really sort of the boots on the ground. So would a more harmonized traceability enhance your ability to improve your role in outbreak investigations and product tracing of listed foods?

MR. SHANNON: Right. Thank you, Erik. So just real quickly, I'd just like to thank Erik and the FDA for inviting me to speak on this topic. From the State's perspective, particularly with the Maryland Department of Health, we are currently one of 20 states that have an active rapid response team which is a cooperative agreement with the FDA. So since 2012 when that cooperative agreement began, we started working very closely along with our partners at FDA to respond to food emergencies, including foodborne outbreak investigations, recalls, and other events involving the potential contamination of the food supply. Communication, coordination, and consistency, and action have been key to our agencies working together as well as working with our industry partners during these events.

So efficiency and coordination during traceback investigations and recall events have really been core proficiencies that we worked on, you know, with the rapid

response team program beginning in 2012. This included coordination during events as well as information sharing and really trying not to duplicate efforts. I think that's really important during these investigations because we certainly don't want to become more burdensome to industry that are also working with us to respond to these events. So I know sometimes that additional record-keeping requirements may be sometimes viewed as burdensome, but I really think this rule will help standardize and allow for better communication during these events with our state FDA and industry partners, particularly during traceback investigations that will allow us to become quicker and more efficient and accurate during the record analysis process.

MR. METTLER: That's fantastic. So just another question. Do you see the difference in size of retailers? Does that make a major difference in this tracing of investigations? Is there a difference you see within the size of the retailers with the way that they are collecting the records and sort of holding onto it or is it pretty much the same across the board at least from your experience?

MR. SHANNON: I'm not sure that the size of the

retailer matters, but I certainly think there are retailers that have really good systems in place already and that we were able to work with them and understand their process. And then like anything else, there's others that we had a little bit more of a difficult time understanding what the process is and how they're keeping track of records. That's really important for us, too, because during some of these events, particularly at point of service, we fall back on our local health department partners, so it's important for us to be able to communicate with them efficiently as well. So we're taking that information and bringing it down to their level and telling them, hey, can you go check this facility out? These are the records we're interested in. So I think trying to standardize and harmonize this might help with that communication.

MR. METTLER: That's great. I forgot to mention the local level as well. Is there anything that you think as we're sort of going through this rule how we could actually sort of work better together, both FDA, the states, as well as local?

MR. SHANNON: Again, I think really it just falls back on communication. I think in Maryland we have a really good partnership with FDA, particularly our district office, and

also with the coordinated outbreak response and evaluation network. We work with them very closely during some of these multi-state outbreaks. So I really just think communication is key. I think one of the items in the rule that I like is the fact that the retail or the firms have to have kind of an explanation of what their process is for traceability, and I think that will help us as investigators coming in and understanding their process so we can ask the relevant questions.

MR. METTLER: Sounds great. How about anything to your other state counterparts about how the states could work closer together in these events? Is there any sort of insight that you have there where it's worked better than others?

MR. SHANNON: Certainly. And I think the rapid response teams, you know, they kind of have a network of their own. So the states that have rapid response teams, they know who to go to. They know who the key contact person is, but sometimes there is a little bit of a disconnect when you're going over state borders. So I think there's certainly some work to do on our end for that for sure.

MR. METTLER: That's great. Well, I think that

was sort of more of it. We were hoping to have more of a dialogue with Anita here as well. Anything else that you sort of want to let everyone know or just sort of insights or thoughts?

MR. SHANNON: I think one of the things is moving forward it's important for our agency to certainly understand the role and what our role will be moving forward. You know, everybody kind of knows, again, I think Erik, you said it, we're boots on the ground so we're in the firms and facilities, you know, quite a bit and we get to know our firms pretty well. So a lot of times they come to us for guidance so it's important for us to keep up with the rule and again understand what our role is in the rule so we can provide guidance that's accurate and consistent with what's being put out there.

MR. METTLER: Thank you. And let me just say again that we truly appreciate everything and our partnerships together. So just thank you and thank all the other states for everything that you guys do in working with us. Thank you.

So back over to you, Kari.

MR. SHANNON: Thank you.

MS. BARRETT: All right. Yes, thank you, Erik.

Thank you, Kyle.

Appreciate the remarks, and we are now at a point in our agenda where we're going to take our lunch break. It'll be a little bit longer so for all of our participants, we're going to adjourn for now. We're going to reconvene back at 1:35 as noted on the agenda. So please enjoy your lunch, and we'll be talking to you this afternoon. Thanks so much.

(Off the record.)

MS. BARRETT: I sure will. Thank you so much, Michael. And welcome back, everybody, after lunch. We are now going to go into a session. It will be about an hour-long as Michael mentioned, and it's really an opportunity for us to hear external perspectives from our stakeholders. And to moderate this panel we have Rebecca Buckner. She's our Senior Science Advisor to the Center Director.

So at this point, Rebecca, I'm just going to hand it right over to you.

MS. BUCKNER: Okay. Great. Thank you so much. And it is my pleasure to be moderating this panel this afternoon. If the other -- if the panelist could join that would be great. We have four panelists with us this afternoon,

and it's my pleasure to moderate this time with them. This is the afternoon panel. It's perspectives on the food traceability for proposed rulemaking, and these are four very accomplished panel members and we appreciate them taking the time to participate and share their knowledge.

Our panelists for this afternoon are Bryan Hitchcock. Bryan is with the Institute for Food Technologist and is the Senior Director for the Food Chain and Executive Director of the Global Food Traceability Center. In this role, he's responsible for managing and directing the Global Food Traceability Center including overall leadership, strategy and government, sales and marketing, and their relationships with the government and others. He also has extensive product and process development expertise in the food and beverage industry.

Next, joining us is Jennifer McEntire. Dr. McEntire is Senior Vice President for Food Safety and Technology at United Fresh Produce Association. She is trained as a food microbiologist and note that she has spent the last 20 years bringing the science to Food Safety Policy discussions. She has a history with traceability working on an IFT project on behalf of FDA on traceability back in 2008. She also led for the

Acheson Group, the traceability pilot project which helped form the foundation of the 3:47:11 that were talking about here today.

Our third panelist is Sarah Sorscher. Ms. Sorscher is Deputy Director of Regulatory Affairs at the Center for Science and the Public Interest where she works on initiatives that improve consumers' access to information about the food they eat and addresses food additives and contaminants in our supply. Previously, she worked on health and safety issues at Public Citizen's Health Research Group.

Finally, we have with us this afternoon Hilary Thesmar. Dr. Thesmar is the Chief Food and Product Safety Officer and Senior Vice President of Food Safety Programs at FMI. In this role, she provides leadership for all safety programs for FMI's retail and wholesale members and provides support for members in areas including safety 3:48:01 training, crisis management, and overall safety and sanitation programs. She also works with the FMI Foundation on Food Safety Education and Research Project. As you can tell this panel has a wealth -

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MR. KAWCZYNSKI: Rebecca, Rebecca. I'm going to

check something here. Somebody said no audio, and I want to make sure we're broadcasting. We were a second ago. It looks like somebody needed us so hold on a minute. I don't want to have that mess up. Can someone else -- you have audio? I just want to make sure we have audio. I apologize. Everyone can still hear?

All right. We just wanted to make sure when we got those in we weren't going to have the same problem as last time.

All right. Sorry about that, Rebecca. Take it away.

MS. BARRETT: That's all right. If I was going to have to do that again I was just going to say all their first name and be like, you're on your own.

No, anyway, as you can tell this panel has a wealth of food safety and tracing experience, and again, we're just very appreciative of their time this afternoon in joining us.

The format for today is we're going to start with an overarching question that you will each speak to and then we'll move onto follow up questions that you guys can just jump

in on as you want to. If nobody jumps in, I'll call on you.

So to start with the overarching question, I would ask each of you to briefly discuss your experiences with traceability and your perspective on why from a high level, traceability is important and maybe we can just go in the order that I introduced you. So that means we would start with Bryan.

MR. HITCHCOCK: All right. Well, good afternoon, everyone. I'm so glad to be here today with this wonderful group of people that have this conversation. You know as Rebecca introduced me, I'm from the Institute of Food Technologist, and we heard from several speakers earlier today on the role that IFT has played in this journey, including with some folks, well, your fellow participants on the panel today.

So this is a small world but we've been on quite a journey over the last decade-plus driving a traceability space. Whether that, you know, interfacing with small-scale producers upstream around the world all the way down to Hilary's space with the retail side of it, this is a community, and everyone has a role to play. And so when we think about the role that traceability does, having the importance of it, its food safety, its sustainability, its authenticity, there's so

many different 3:50:24 cases that traceability can provide. This is a backbone in a foundational component of our food system, and we're just so excited to see it continue to advance. In the end, consumers are really looking for this, you know, as we've been looking at the food system and what they've been telling us. They're looking for transparency in their food. They want to be able to trust that their food is safe. They want to know where it's coming from. Where historically that was information that was more behind the scenes and now it's coming more and more to the forefront. So we're excited to see that happen and participate in that journey so I'm looking forward to the conversation along with the rest of the panel.

So I think I'm handing it over to Jennifer then.

MS. MCENTIRE: Thanks, Brian. And, yes, it has been quite a journey. I remember December 2009, there was a joint USDA, FDA public meeting on traceability. So this is before FSMA. There, I had the opportunity to speak about the initial work that IFT had done where our group coined the terms critical tracking events, key data elements, described the concepts, and it is really quite satisfying to see how they've taken on and helped contribute to a common understanding.

I did have the privilege of working on the FSMA pilots. In my experience in traceability, I've seen the varying interpretations, definitions, understandings of what traceability actually is. Every company feels that they have great traceability and yet we still have this struggle where we can't always connect the dots. I joined United Fresh Produce Association just over four years ago, and produce certainly has had more than its fair share of outbreaks. That said, not all products are equal. It's not all commodities, not even all fresh-cut items, are equal, but nevertheless, we know that things happen. And regardless of regulations, products should be traceable.

I think it's critical that we focus on the outbreak investigation and the traceback, not the consumer packaged, in most cases where perishable products, the packaging is gone. The traceability in this context and what this rule is really about the records that remain. Even I think earlier today as Karen Blickenstaff talked about the romaine-associated outbreaks from last fall, having those lot codes at the point of sale I think that that's because the packaging was there. If you have the lot code, it makes it easy, but rarely are we in

that situation. So we need to see that product pathway and why it is about that root cause investigation that Frank Yiannas mentioned earlier today. Figuring out where is that product coming from? And I used to be a big believer in convergence. That even if it wasn't clear, if it wasn't product A or product B, that if you had enough traceback leg that and you kept on seeing product A, you go, oh boy, it's probably product A. But now it's not clear in every outbreak that contamination is limited to one lot, one brand, or even one field, one ranch, one orchard. And that ambiguity in our current traceback system results in a lot of noise. And we need to be able to tease out that signal.

So I see it finalized that this rule would do that, that it would help. It would not address all of the issues. This rule is about record keeping, and traceability is more than just record-keeping, so outbreak investigations, also about more than traceback. So the EPI side that was discussed earlier today, so I think we need to be realistic about what this rule would, what this rule may not do. But waiting on this rule has served as an excuse, in some cases, for parts of the industry to delay in advancing their traceability. So for me,

12 years into this, I feel like given consumer expectations, more transparency, FDA's enthusiasm in issuing advisories, the acceptability of technology options, I feel like it's finally time to stop talking and start doing. And I'm excited to see where we go with this and very much want to thank you for having me on this panel.

I think it's up to Sarah now, right.

MS. BARRETT: Yes. Over to Sarah. Thank you.

MS. SORSCHER: All right. Thank you. And I want to thank Frank Yiannas, the team at FDA also for organizing this event. We know organizing a diverse group of stakeholders is challenging under any circumstances, and it's particularly challenging during a pandemic and with everything that's been going on this week. So I just want shout out and give appreciation to FDA for being proactive and creating these opportunities for questions and feedback on a rule that are more informal.

I'm here representing Center for Science in the Public Interest. We are America's food and health watchdog. Consumer Group founded in 1971 with a dual mission of research-based advocacy and consumer education. We've long focused on

food safety and nutrition in our work, and our primary vehicle for our consumer education is the nutrition action health letter which is the nation's largest circulation nutrition newsletter. We don't take advertising for that publication and we don't take gifts from industry or grants from the government, and so that allows us to speak independently and really come representing the perspective of our consumer membership. TSO [ph.] was a huge component behind the Food Safety Modernization Act. We're really eager to see FDA finally building out the traceability provisions of that legislation. We're nearing now close to the 10-year anniversary of FSMA, and certainly, it's a rule that's long overdue.

Traceability is really important for consumers for two core reasons. One is first and foremost, that we want our food to be safe. You know, traceability is not only going to allow us to ensure that when food is tied to an illness outbreak that's identified and removed quickly from the food system. But also more fundamentally, it informs prevention efforts because it's not possible to design solutions to prevent further contamination without understanding where and when, and how the contamination occurred. So we're really looking forward

to seeing a safer food system as a result of this rule.

The second reason is that 3:56:49 separately from the food actually being safe, we need to have confidence that it's safe. And if you look at the list of food the FDA has identified that has had these repeated issues of traceability and outbreak, it's dominated by fresh produce and seafood. And these are the foods that from public health perspective, we're constantly trying to get ourselves to eat more of, right? American's chronically under consume these foods and having widespread deadly repeated outbreaks in fresh foods like spinach and romaine lettuce, it really undermines that effort. So in order to restore that confidence and undo the public health 3:57:32 associated with those outbreaks, we're looking forward to seeing a rule that keeps the widespread public warnings out of the public eye. I think also we've talked a little about additional benefits that are going to flow from this rule, and I think we have yet to see all the ways it's going to transform our food system.

As other speakers have said, consumers are really seeking greater transparency. We want to know where our food comes from, and so we're really looking forward to how this is

going to build for the future in addition to having these great benefits for food safety.

MS. BARRETT: Thank you.

Hilary.

MS. THESMAR: I'm Hilary Thesmar with SFI. We are an association right outside of Washington D.C. that represents retailers, wholesalers, and product suppliers. I would like to echo what Sarah said and thanking the FDA for holding these meetings and also having such an open, collaborative process during the rulemaking. It really helps us to educate our members in the industry. It helps with understanding, and you've really gone above and beyond with making information available, accessible, and including stakeholders. So we thank you very much for that.

We agree with the FDA and the others speakers today that the goal is to protect consumers from foodborne illness.

This is a -- we are a public health agency. This is a public health initiative. We've got to make sure that consumers have access to safe food. Consumers expect their food to be safe. They also expect transparency and want to know more

about their food, where it's from, and what's in the food. The industry has taken steps to make this information available through industry programs such as smart label which you might have heard of. But it's an industry with an initiative to allow for more information to be shared with consumers. This is just one example.

But the safety and transparency are two priorities for the industry, to respond to customer inquiries and their questions and their needs. So FMI numbers are often the point of contact in the food industry during a foodborne illness investigation. So they're the first ones that the public health officials, state, local, federal, would go to and kind of start their investigation. So we know the importance of sharing information to speed up the process and also to make the necessary information available about the products during the investigation process. Together we've been involved in discussions on traceability for many years, going back to the pilots and work with the Global Food Traceability Center, and we look forward to working with the agency and the food industry and other stakeholders on coming up with something that's practical and actionable and commendable in the industry. Thank

you.

MS. BUCKNER: All right. Thank you so much to all four of our panelists for those statements. I think there's a lot of good information in there. Some of which will be relevant to some other questions I want to ask you because the first question I'm going to throw out there is almost all of you just talked about the importance of safer food, et cetera. I would love to hear your thoughts on how traceability, you know, more specifically, can improve food safety and also improve another area that we didn't hear -- I didn't hear you all mention which is recall which definitely affects consumers. So thoughts on that. Open it up to whoever wants to fight to be the first person to respond.

MS. MCENTIRE: So this is Jennifer. I'll take the first stab. You know, you mentioned recalls through the most part for our members in the produce industry. Unfortunately, I don't think we often have a lot of opportunities to recall products because it's perishable, not when it's a public health outbreak investigation type of scenario. I think conventionally traceability is viewed as being reactive, but there absolutely is that opportunity, I

think a tremendous opportunity to improve public health and transition traceability to be more proactive if we can get to the root of that issue in that traceback. So, you know, this rule would not require tracing to the individual consumer as Hilary said. The investigations generally start at that point of sales, point of service but we still don't know exactly what somebody ate. So just getting to that point is a challenge from the epidemiological logical side where do we begin. But once FDA starts that traceback, finding that root cause, Frank Yiannas mentioned it this morning, that is critical.

And I think it's the combination of requesting records but also evaluating business information, understanding which records should be requested, what's the scope of that records request so that we can really focus in quickly and expeditiously on the origin of that product.

I was encouraged to hear FDA earlier today say that they would be willing as long as the information is there and sufficient to skip steps in the supply chain, to be able to go back more quickly. This would allow the onsite investigation to occur more quickly, hopefully increasing the likelihood that we do figure out where and how contamination is occurring. And

that's critical to protecting public health.

We, on the produce side, have suffered from recurring outbreaks. So we need to put an end to this, and I do believe that traceability will help. Again, recognizing that this rule is about record keeping and it doesn't take into account the mixing of lots that may occur as product is manufactured, processed through the supply chain. So there will be some other, I think, some other complicating factors that are also part of traceability. But this rule as proposed in the record-keeping requirements will certainly go a long way.

I think on the recall side, we have UPCs the universal products code which is a standardized bar code on a lot of packages that really helps in terms of a recall. I'll let Hilary talk about from her members' perspective, how recalls are executed today. But I feel like that process is usually pretty good. It's when you add the ingredient-driven recalls where things do become more complicated, TCA being I think the poster child for that sort of an issue.

But I don't know that it's always the lack of traceability when we see issues on the recall side or if it's a lack of execution, lack of proper scoping of the recall by the

recalling firm, lack of clear communication within the supply chain. So there are other complicating factors that I think we should be mindful of and also tackle. But this rule will certainly go a long way on being the record-keeping where there are some real opportunities for improvement today.4:05:06

MS. BUCKNER: Bryan, anything to add?

MR. HITCHCOCK: Go ahead.

MS. BUCKNER: Bryan?

MR. HITCHCOCK: Yes, I was going to build on that. So when I look at the traceability systems and, you know, I talked about it being a foundational backbone to food safety, I think it has a role to play across the entire life cycle when we create food systems, the safety systems, and manage them. From evaluating risks, identifying what those are, creating preventative controls and engineering controls for them, bringing recalls and root cause investigations.

You know, when we create traceability systems, we're going through process steps just like those, and they can interact with each other and cross-fertilize those different systems. I think it's --

MS. BUCKNER: This is great.

MR. HITCHCOCK: It's broader than recalls but yet certainly we classically think about traceability as the primary thing in recall. But I think it's a universal construct within food safety.

MS. THESMAR: Those are excellent points. Thank you, Bryan and Jennifer.

So the question as I remember it, Rebecca, is, you know, will traceability -- where does it fall into safety and will help food safety? I also see it, I think Jennifer mentioned, that it was reactionary. It's kind of that last step that we have to go through when there is a foodborne illness outbreak and to stop that outbreak as quickly as possible. And to solve the investigation basically, traceability is the tool that we have at that point, and I encourage our members to spend a lot more time and resources on the prevention side of the industry.

The industry has a responsibility for selling safe products, and we should not have a contamination in the first place. So we spend a lot of our time and effort on prevention of contamination and basically controlling those hazards. And then, you know, but the systems all through the

supply chain, all the way until that investigation is closed, are super important. So not to minimize the role of traceability, but just keep in mind, it's reactionary.

So related to recalls, we think of recalls a little bit differently. Our numbers deal with a lot of recalls. It's multiple recalls per month and per week even and hundreds per year. From both FDA and USD regulated products. And with the recall, you have a product that you're trying to remove from commerce, but the way I think of recalls, it's more of the trace forward is more important than the traceback because you're trying to trace that step through the market and every single customer that that product went to in the supply chain and to consumers. So if one is traced forward, traceability we think of traceback being the more important, so can you identify the product throughout the supply chain both forwards and backward? And I think that's the challenge to put all of the pieces of the puzzle together.

MS. SORSCHER: Yes, and I'll say that one of our hopes for the rule is that it will facilitate both trace forward and traceback. That having uniform systems and having a way to communicate consistently between the different players in the

supply chain is going to facilitate both getting to that recall sooner by having that traceback and identifying where the contamination occurred, being able to point out the products that need to be recalled, but then also being able to follow those products moving back up through the supply chain.

We've had a number of examples of large recalls that involve ingredients like the onions most recently, peanut butter in the past, where you have these repeated notices. New products being recalled on a daily basis, and that takes time. It means more consumers are getting exposed. There's cases where nut butters stayed on the shelves for months after the recall, and it also, it undermines that confidence because it keeps the issue in the news. It makes consumers concerned when they wouldn't have to be if it was done more quickly and efficiently.

MS. BUCKNER: Thank you so much, everybody, for those great comments. Yes. No, we totally agree. I mean, we think obviously the measures in this rule play a part in both traceback and trace forward. I know one of the things the rule talked about are the benefits of avoiding overly fraud recalls, which we hope, you know, this rulemaking can do, as well as, you

know, increasing the efficiency and actually tracing those products, pulling the products once it's been identified. So I think we see multiple sort of benefits on that, on that front.

And as Sarah just mentioned and this leads to my next question, I mean, all of this feeds into consumers and kind of how they are impacted by recalls and outbreaks, et cetera, and that talked about the benefits to consumers. But I would ask you all to speak to what do you think are the specific benefits of traceability to consumers in terms of how, you know, how they live their lives et cetera.

MS. THESMAR: We try --

MS. BUCKNER: Oh, go ahead. Anybody. It's hard to tell which of you are talking.

MS. THESMAR: We track consumer trends at FMI, and transparency is something that's been raising higher and higher every year. So consumers expect to know more about their food, about where it's from. And I think that where it's from ties in perfectly with traceability. They expect us to know where their products are coming from and kind of, you know, if they don't need visibility in the supply chain but they want awareness and confidence in the supply chain. And I think, you

know, everything our members do is for that consumer that's coming into the store every day eating the products that our members are making.

At the food industry, we're responsible for making it safe and keeping our customers safe and making sure that they get the products that they want and need when they need them. So I think that's kind of core to the industry and it's in all of our job responsibilities to make sure and guide the industry to make sure that they have the tools they need to make that happen, whether it's food safety programs or latest research coming out or government regulations. That's what we do is facilitate that and kind of help them to continuously improve their systems.

MS. SORSCHER: Yes, I would concur with that. I think, you know, obvious to the primary focus of this rule is food safety and solving outbreaks. And we expected to have a huge number of benefits for consumers just for those reasons. But I do think that as we, you know, are craving knowing more about our food, where it came from, how it was grown, we want to get to know the people along the supply chain. And this framework that's getting created by the rule, it's going to have

a host of additional benefits for consumers in that regard and producers because they'll be able to communicate that information more easily to us as well.

And I just want to highlight how food safety does drive these consumer trends. You know, after the 2006 spinach outbreaks we saw permanent declines in consumers being interested in spinach, you know, because they had seen the empty shelves and listened to the message that spinach was not safe. And because of that outbreak, during that outbreak, they shifted to other leafy greens. Fortunately, there wasn't a decline overall in leafy green sales as a result of that. They just shifted their practices, but, you know, someone said they shifted to romaine and then we had a series of outbreaks of romaine in 2018. And what we don't want is for consumers to get the message that they can't trust any category of product, particularly the categories of products that we're talking about today. The fresh produce, the whole foods, seafood.

And so really having that transparency and accountability in place and being able to make sure you're not being overbroad in your recalls, not overbroad in your warnings is really going to be a key benefit from a consumer perspective,

and I can't emphasize enough how important that will be for all of us.

MS. MCENTIRE: Yes, I agree with Sarah. The broad advisories are devastating, obviously, to the entirety of the industry, you know, the vast majority of whom had nothing to do with the issue, but also clearly erodes consumer confidence in the entirety of the food industry and the entirety of the supply chain. So to the extent that traceability can enable us to get back to wherever the root of the problem was, execute a recall where the product, the supplier of that product is known, extract that product, that specific product from the distribution system, that's where I think it will give consumers the confidence that if there is a problem which, you know, to Hilary's point, we do need to focus on prevention and ensure that there isn't. But if there is a problem, that it's rapidly addressed and minimizes the exposure, minimizes the risk to consumers.

I would also add that while the emphasis I think on the part of the industry should always be on prevention, we don't want to live in a reactionary mode. Traceability is that feedback loop. Traceability is that feedback mechanism that

points us, hopefully, illuminates why our preventive measure didn't work. So we need that insight from the traceback to put the improvements in place, to increased prevention, protect consumers moving forward.

MR. HITCHCOCK: Yes, I think the part -- I agree with my fellow panelist and everything that they've said. I think the build I would make on this is your consumers are constantly bombarded with all kinds of information, and they are trying to process it, what they should -- you know, how they should use it, what's real, what's not real. And the more that we can do as an industry builds on traceability, you know, data to educate them, communicate with them around what makes their food tick, where it comes from, that it's safe. We continually and constantly build that trust. Trust is very hard to obtain and is very easily broken. And so we as a broader industry have to constantly be working on that. And they're looking for -- they need us to do it and we need to do it for them.

MS. BUCKNER: Great. Thank you all so much. Those were perfect observations.

I mean, I think we all have hopes and expectations that this rule will improve efficiency so we can

get to issues faster, have less impact on consumers, both in terms of their health and inconvenience and with products that they have on their shelves needing to be recalled. And also and as someone said, Jennifer, the feedback loop, greater prevention because we are getting better information about the kind of issues that are out there and are able to funnel that information into how we prevent another similar outbreak from happening in the future. So yes, this is all very very exciting, and it's wonderful to hear you all talk about some of these benefits and opportunities that we see also flowing from this rule-making.

Moving to some discussion about kind of where we are with tracing, the work that's been done so far, et cetera, I'd like to ask you all what steps that you're aware of that industry has already taken to implement systems. Do you see the proposed rule and its measures in it as enhancing? What has already been done, et cetera or I guess from the opposite perspective, sort of needing to rebuild stuff that's already been done, et cetera. So I welcome your thoughts on that.

MR. HITCHCOCK: Well, there's a lot in that question.

MS. BUCKNER: Yes.

MR. HITCHCOCK: And since it's been a long journey as Jennifer mentioned earlier, that's a lot that's been done, and we still have a lot to do. And so let me try to chunk some of those portions of those.

Yes, there's an industry being formed around, you know, solution providers, software providers, you know, sensor providers to enable capturing this information, being able to label products more consistently. You know, a lot of different conversations that, you know, association, industry, group level, pre-competitive platforms and trying to standardize information to be captured, how labels should be applied. You know, a lot of that type of foundational work has been happening in pockets and there are different components, and I don't know that we want to go through all the various different parts of it today. But I do think there's a lot there. I do think there are folks that have been waiting for some clear definitions because they don't want to get afraid and have to, you know, do too much re-work.

Yes, so I think the announcement of this rule is a major step in trying to, you know, bring clarity for folks to

then go and define their systems with the minimum standards will be from the regulatory perspective and then they can really, you know, drive forward to implementation to their systems. Maybe I chunked a couple of those, I'll pause there and pass it to my colleagues.

MS. MCENTIRE: Okay, Bryan, I'll take it from here. I'd like to give some specific examples. You know, this morning Frank Yiannas mentioned the 2006 E. coli outbreak associated with spinach. Sarah mentioned the long-term consequences on consumer's purchasing patterns as a result of that outbreak and the resulting advisory and so things have changed dramatically within the produce industry since that time, both on the preventive side but also on the traceback side. So it was because of that outbreak that the produce industry came together to develop PTI the produce traceability initiative. It's built on the GS128 bar code. So the same basic system, basic infrastructure that's used for seafood, for meat, and poultry, for a wide variety of products, recognizing the value of standards and the need for interoperability.

Just within the past few months, we've done more work working with retailers in the US and Canada to further

standardize the format, to try to increase adoption. It does maintain the one up, one down type of approach, that this rule still sort of does. It provides lot level traceability as the rule does so it's not piece level traceability, but it does require following the physical product. It addresses some of the KDEs that are proposed, so the product description, lot number, production date. My read of the rule is that a lot more data would need to be captured and shared, some of which we feel is maybe a little bit redundant and adds a little bit of bulk to the data package, more opportunities for error to leave the people feeling overwhelmed.

So I'm not sure that the rule further enhances this voluntary system. What the rule would do is require people to share data. So voluntary initiatives like PTI, as solid as they may be, have not been implemented across the board in over a decade.

A rule creates a more level playing field, and I say a more leveled playing field because FDA's authority is still a little bit limited. As I interpret it, we're still stuck with a rule that requires certain entities, like, registered facilities, the first receivers that were discussed

earlier today, to have data from their supply chain but it's not clear that those data suppliers would have to capture or share all those data. So success will still partly be up to industry applying business pressure. Nevertheless, in the decade since FSMA passed, industry has been waiting, as Bryan said, for direction from FDA, and some have been reluctant to make major investments. The set outcome may not align with what FDA is requiring.

So I believe that although the rule won't be finalized for another two years, the FDA has sent a very strong signal in this proposed rule on the expectation. The foundation has been laid voluntarily, and I think that it will really accelerate progress because we do have these foundational programs out there. They have been voluntary. FDA's rule I think helps demonstrate to the industry what needs to be done, and I'm quite hopeful that we both continue to see adoption even in advance of the rule being final and implemented.

MS. THESMAR: From another industry point of view, you know, most are at the end of the supply chain, so we have to receive and capture information from just every commodity. You know, there are thousands and thousands,

sometimes tens of thousands of products in a grocery store. Wholesalers would carry even a wider variety than that. And a lot of our members also have manufacturing facilities, and that is kind of a unique situation in itself. You're receiving and shipping, and it's both ways. So there's a lot of complexity.

Like I said earlier, we've been at the table in traceability for these reasons because we wanted to be able to represent our members and probably based on the entire industry and not a vertically and agreed supply chain. We strongly believe that simple and consistent data elements will help in the accuracy of data sharing across the industry, and I really emphasize simple and consistent because that's going to be key is having that consistency across the industry. And we know that government regulations are tough for the industry to implement. There's a lot of scale that has to happen, a lot of programs and procedures that are implemented, and this one is going to involve probably some significant capital expense, and we want to make sure that the industry can comply, that it's doable, and we think that that's going to make the outcome better and stronger. If the compliance rate is high, then the whole system will work together.

Technology was mentioned earlier and we welcome the opportunity to use technology. We think that either the industry is using technology in all kinds of different ways that are kind of outside the scope of a regulatory program, and hopefully, it'll help us if we can find the right technology for the right purpose to enhance the business processes. We do want to make sure that we're not going to be stuck with the technology that becomes outdated or even language that limits us in the future to move forward as we have technology advances, and we just look at the past 10 or 20 years. It's just mind-blowing how this field has just grown and expanded, and I can't imagine what's coming in 10 or 20 years. But we know the world's going to be different, and we want to be able to adapt to that when the time is right and the industry is ready to move in that direction.

So in terms of the kind of thoughts about the rule, we welcome the opportunity. We're glad that FDA moved forward with rulemaking, and now the hard work starts. We really have to dig in and provide comments to the agency and really make this rule something that is going to make a difference, and I think that's where the industry is.

MS. SORSCHER: Something that comes to mind looking at Hilary and Jennifer's comments is that the burdens and the benefit to this rule really tend to fall unevenly. You know, Hilary highlighted how the burdens can be very great for retailers. You have a number of different products coming in. That might be a very different scenario than a firm, but the benefits fall differently, too. I think romaine growers had a very different experience from the 2018 outbreaks than the retailers did.

And I think one of the reasons why regulation is so important in this space is that there is a collective action problem that you can't -- you have a number of different actors along the supply chain, and if only a few are participating, the system doesn't work. You really have to go all the way to the last mile. And then also, you know, at the end of the day, there's a lot of benefits that you're getting from your neighbor having the system in place, right? Because when you think about these overbroad warnings and the overbroad recalls, the people who are suffering the most are the ones who weren't implicated in that supply chain at all that was involved in the outbreak. So their benefit depends on someone else having a good

traceability system in place, and when you have a situation like that, that's really crying out for some guidance and coordination at the federal level. And I think that's the leadership FDA is providing here, and we really welcome it.

MS. BUCKNER: Thank you, everybody. That's great comments. I think that I was actually back in the day in that 2009 public meeting that Jennifer was talking about where we did talk about data standardization and it's great to see it finally I think taking a step forward with its rule that it hasn't had the opportunity to do in the past because as you all have said, everybody has to play, and you have to play according to the common language. And that is the data standard, and I think from there, as you all have noted, we're so excited about the thought that from here, industry can jump off also on its own just to figure out how the best way to be sharing this information with these data standards is, and we welcome the dialogue on that as we move towards finalizing this rule. So we have two more public meetings after this, more dialogue to be had, and so it's very exciting.

In the interest of time, I think I will move to a question about affordability but also about return on investment

that the outside is simply, the outbreak efficiency, et cetera, which is, you know, absolutely the most important thing on this. But we also know from talking with people that industry has found some returns on investment around inventory controls and things like that with tracing. And so I would ask you all to speak to maybe some of those other benefits of tracing because, you know, somebody I think has already noted, there are costs associated with this rulemaking, but there are also benefits associated with it.

MS. MCENTIRE: I can start.

MS. THESMAR: Go ahead, Jennifer.

MS. MCENTIRE: I think the benefits are very situation-specific. So there can be a return on investment for improving a company or a facility's own traceability if they had a high rate of mis picks and with better traceability systems they don't, or there was a lot of shrink, and now there's not. But it really depends on where the company is today, the investment that they're going to make, and what that dealt is where they'll stay in the future. So there are some members of the industry who already have optimized their system, maybe not with traceability in mind, but by adding on additional

traceability measures. They may not see benefits. Whereas other companies may see and have seen substantial benefits. So it's very I think individual. There are benefits to supply chains when we have better sharing data up and down the supply chain so understanding how product is moving, what type of product is selling, where are there bottlenecks in this system. So I think there's with sharing of information, maybe some information above and beyond what's required in this rule that would be beneficial for business purposes. There, there may be additional returns on investments. But we do have to be mindful of the cost. This is not going to be inexpensive, and as Sarah mentioned, I'm not sure that the cost will be evenly distributed throughout the supply chain, throughout the different food groups. So it's part of the reason that I think the regulation provides that level of playing field because previously, as a voluntary measure, there was not always an incentive to be an early adopter if you were going to get caught up in an advisory as well. So I'll let the others kind of opine on the question of cost, return on investment, but it's going to be quite a challenge.

MR. HITCHCOCK: Sarah, you want to go or you want

me to go? Okay. I'll jump in.

So the financial component of this is a very common topic in question that we get. People see some of the capital investment. We saw it in the presentation earlier. There's some significant projections there, and some of that's going to happen over time. It's highly variable as Jennifer mentioned of where people sit in the supply chains, what investments they've made historically or not. So we have done some work around folks that have not made those investments and what it'll take for them to get to a full compliance in a digitized traceability system. And that can be a burden for folks, particularly on the smaller scale of things or upstream.

At the same time, when we look at the rule, we're pretty excited about some of the flexibility that's been maintained there. So people can execute against this in a starting place without having to make incredible -- . And again, they're going to find that it's going to be better for them to make some investments. I think that's where I'm at there.

MS. SORSCHER: I'll say that, you know, we are concerned about making the rule accessible for all different

type players, and one of the things that we're hoping to see from this effort taking place at a national level with multiple players participating is that the cost will go down. There will be solutions that are developed that are going to be -- there's definitely a huge market obviously for having these solutions and that it'll become easier for small players to comply as more and more are adopting this rule.

MS. THESMAR: The cost is something that's come up with our members, too, and the economic impact is staggering as we saw earlier this morning. I agree with what's been said. We also know that foodborne illness is expensive. If a customer is sick, that's a very expensive cost. Recalls are expensive, so balancing it with kind of the alternative I think is something that we need to do, and I know it's evaluated in the economic analysis. The scalability is something that we need to consider in making, you know, kind of I'll say open source for lack of a better term, but the systems available for those smaller members of the industry, but I think that's where the consistency and the simplicity in the data elements is going to really help.

And sharing fewer data elements among multiple

supply chain partners, you know, is doable. They do it for other things. For example, payment systems. You know, the industry, really traceability records kind of model payments between companies between supply chain partners, and that industry has been very integrated with capturing consistent data. So we can look to other industries as was alluded to earlier and look at scale model.

I think data time is important. Just knowing what to expect and when to implement it, and that flexibility is absolutely key as Bryan said. Having the flexibility to make the system work for a company but still be able to talk to other suppliers and other companies, I think is going to be critical.

So there's still a lot of work to do in this area. We'd love to put the business case on top of traceability. Some of those case studies are out there, but yeah, it's been a heavy lift so far on the industry just to do traceability for the purpose of food safety. I think if we can tie in those inventory controls or payment systems or even labor-management would be really compelling from the business point of view, and that's also talking to other people in the industry. The food safety folks are all onboard. We understand

that. We're brought in. But talking to the supply chain folks, talking to the IT folks, talking to even procurement and those organizations within the company, it's going to be really important to layer in those other components that are going to help us.

MR. HITCHCOCK: And we've seen examples where folks really struggled with the first capital project justification, and then when they go for the second one, the conversation is a lot easier because they were able to get the hard data within their system, within their supply chain to substantiate all the other cost benefits that come along with this. Some of those are hard. Some of those are soft benefits that they're then better able to articulate.

MS. BUCKNER: Thank you, all. That was a great discussion. As Frank mentioned this morning, we're very interested in scalability and aware that we need to make this accessible for everybody and really hope that again having these data elements that are standardized can allow us to really be having this conversation, and I know that's a big push for the new era initiative, you know, look for dialogue, that opportunity to explore this, you know, as well as we have this

conversation about the rule going forward.

So we've only got a couple of minutes left in this session. Any final thoughts from folks? We've heard great comments about how traceability will improve food safety, which is the reason we're all here and the reason we're all doing this, they need to be speaking a common language. I've heard a lot of statements about simple data elements, so we'll expect to be hearing about that in the comments, and, you know, I think it's an exciting time. This is a great conversation to be having and so just welcome any final thoughts from folks?

MS. MCENTIRE: Rebecca, thanks again for having us here, for having this public meeting. I know you were required to have the public meeting, but still, it's been particularly good. You didn't have to have a good one, and I think this is good. We do appreciate that.

I guess one final comment when it comes to that flexibility and scalability, I think the flexibility is important not only for today to recognize the diversity of players out there, the diversity of supply chains out there, but also looking toward the future and recognizing that we don't want to be limited by the systems that we have today and the

technologies that we have today. So I think looking at the data elements and how they're to be shared, how the information is to be communicated through the supply chain. We should be open to the possibility that we may be able to do things dramatically different in the future when it comes to communication and sharing information. So I wouldn't want the historical challenges to dictate to prescribe a path forward when we need to have some new opportunities to open up for us. We have advanced ship notices. People have talked about RFID for a long time. I don't know that it's practical today, but I think we need to keep an open mind when it comes to how we're going to be managing information in the future and giving people the flexibility and the options to have the bicycle version or the Cadillac version. You can still get there, but giving that flexibility I think will be very important, and focusing in on what are really those key data elements and what are the critical tracking events I think will make it an easier list and easier adoption.

MS. BUCKNER: Sarah?

MS. SORSCHER: I echo what Jennifer thinks, and we're very excited to see this role coming out. It's been a

long time coming, and again, I know you're under court order to get it out, but I'm sure we're all -- it's just very exciting to see it finally come to fruition. And I think moving into this, I think FDA probably did more than we would've imagined possible given the framework we had, you know, it's a good frame that you've put out. I think we're going to be thinking about ways to -- you know, ways the system might evolve over time, ways to ensure that it's building in that flexibility to adapt. You know, consumer practices might change. We might start eating things that are raw that we're not eating now. You know, these types of questions are what we're going to be thinking about as we look at this rule, but in general, I think it's a really solid starting point. And we're very grateful to FDA for putting it together in these very challenging times.

MS. BUCKNER: Thank you.

Anybody else? Hilary?

MS. THESMAR: Yes, I can jump in. So I echo what my colleagues have said. I think we need to remain super focused on the goal of speeding up foodborne illness outbreak investigations, and I think we should measure that post-implementation of this rule. When it is a final rule and

implemented, I think we need to make sure that we actually made a difference and can trace product faster, find the source. That's going to be key, and I think just the overall goal of reducing the impact of foodborne illness is huge, and keep that in mind. Sometimes we get, you know, stuck on tangents or go down different roads, but I think as long as we keep that goal front and center, then the industry will be much better off in the long run.

MR. HITCHCOCK: That means I'm last. Totally echo all the comments from my fellow panelists. I think the initial thought for folks is even though the timeline on this has a few years for formalization, my encouragement for folks is to get started because this is not something you turn a switch. You don't go buy the system off the shelf. There's a lot of homework to be done evaluating your supply chain parameters and those types of things in setting up the systems. The sooner you get started on that, the smoother this is going to go as we get forward to implementing the finalized rule. So that would be my final bill. Thank you for the opportunity, and thank you for joining us today.

MS. BUCKNER: No, thank you all so much. I'm

glad to know that you think it's a good public meeting. Yes, we were required to have it. We would've had one or three anyway more than likely. Anyway, I'm glad you're enjoying it, and I just want to say thank you so much to all of you for hearing your experiences and perspectives with traceability and how its implemented is, you know, just incredibly useful as we move forward in this dialogue and our overall efforts around traceability under a new era also, not just with this proposed rulemaking. Again, we really appreciate your participation today.

And, Kari, with that, I think I will turn it back over to you.

MS. BARRETT: All right. Well, Rebecca and panelists, thank you so much. That was really wonderful, and we're giving you a warm round of applause. It was just really, really interesting to hear the dialogue and the various perspectives. So thank you.

We are now at a point where we're going to take a break. We're going to break now, and we're going to come back at 2:50 p.m. and start our public commenting process. So thank you all, and we'll be back again in 15 minutes.

(Off the record.)

MS. BARRETT: All right. Do you want me to start with the webcam or you want me to just jump in?

MR. KAWCZYNSKI: No, you can just jump right in if you'd like.

MS. BARRETT: All right then. Well, welcome back, everybody, and as mentioned, we are going to start our public commenting session. This is really an opportunity to hear from our stakeholders, their reaction to what we've proposed, and further perspectives. So I really want to welcome everybody who has signed up to give us comments this afternoon and for the time that they've taken to prepare their remarks.

It looks now like we have 10 to 15 people who are able to give comments. We have some others who may not be able to join, so I'm going to run through the names that we initially had and call out a name. If there's no response, then we'll move onto the next person. So I would just ask everybody who is on and ready to just be sure that you remain situated in case we move a little faster than anticipated.

So for the process, I'm going to call each individual as I mentioned by name, and our commenters will have

three minutes to give their remarks. At three minutes, we would ask if you could please wrap up or before. And if you go over the three minutes, again, just if you could close and submit then your full comment to the docket. All of you should submit full comments to the docket, but I just, you know, certainly as part of our process, we do have to keep people to the three-minute time limit.

So with that, I think we're ready to begin with our first commenter. So, Michael, if you want to put up the slide?

MR. KAWCZYNSKI: Yes, not a problem. All right. We're just going to double-check. Some of these, like I said, have cancelled. So this person was unable to attend so I think our first one -- let me just double-check. Hold on a minute. No. Hold on a second. This isn't in the same order that I have down here. There we go.

Bryan, I'm going to unmute you now. You will have the first opportunity. Bryan, you want to go ahead and unmute your microphone? I think you're there.

MR. HITCHCOCK: Yes, I'm here.

MR. KAWCZYNSKI: All right. Bryan Hitchcock,

would you like to kick us off. Let's see. Bryan Hitchcock from the Institute of Food Technologists. Go ahead.

MR. HITCHCOCK: Great. Thank you. I didn't think I was going to be first after just being on the panel, but I'll go ahead.

Good afternoon. I'm Bryan Hitchcock speaking on behalf of the Institute of Food Technologists. IFT founded in 1939 is a non-profit scientific individual member institute whose mission is to advance the science of food and its applications across the global food system to ensure sustainable, safe, and nutritious food for all.

IFT appreciates the opportunity to provide input on the requirements for additional traceability records for certain foods known informally as the food traceability rule. In 2011, IFT performed traceability pilots at the request of the FDA as described in FSMA Section 204. Producing a report with recommendations for the devising of this rule. Within the report, the key data element and critical tracking event constructs along with global unique lot-based identification are identified as foundational to effective traceability systems.

These concepts help underpin interoperable

standards for achieving food safety and scaling of adoption. Global pre-competitive public-private partnerships are productive collaborations driving voluntary standards, coordinating pilots, standardizing KDEs and CTEs, creating best practices, and facilitating communication and engagement. IFT's leadership with the global dialogue for seafood traceability with over 70 seafood industry organizations exemplifies its success in furthering traceability.

In driving enhanced traceability upstream towards production, small scale producers and processors have financial personnel and technological constraints. IFT strongly encourages FDA to create capacity-building initiatives for enabling data collection capabilities for these stakeholders in the U.S. and globally. Pushing them to evaluation and implementation will be pivotal to implementing the rule. Additionally, FDA should continue its leadership role in addressing questions around data management, privacy, and transparency as traceability becomes more digitized, and then traceability becomes common to all food products in the near future and will be necessary for addressing yet unanticipated recall scenarios.

IFT anticipates the rule as the basis for regulatory harmonization across the global food system. Education and training on utilizing digital technologies will be immensely important as they may require new skills. We highly encourage that education and training be given careful consideration. IFT, with its global food traceability center has a long history of active engagement in food safety and traceability and partnership with the FDA, non-profits, and the private sector, including undertaking task orders, conducting primary research, leading pre-competitive industry platforms, creating implementation tools, and delivering educational programming.

IFT looks forward to participating in this exciting new journey and stands ready to partner with the FDA and private enterprise in implementing the food traceability rule. Consumers are counting on all of us to give them great tasting, nutritious, and most importantly, safe food. Thank you.

MS. BARRETT: All right. Thank you, Bryan.

Michael, are you --

MR. KAWCZYNSKI: All right. Yes, next one up is

up on the screen, and I will unmute Luis. Hold on one second.

MS. BARRETT: Luis Saucedo, Trust Guardians.

MR. SAUCEDO: Hi, thank you very much. I appreciate your support on this wonderful presentation from today. They were really -- . I just want to think about how with the possibility that we have in the small company. There was some illustration about it, what would be required and whatnot, but it's about technologies and information technologies we have available and the cost for the industry. Blue Surf to Mexico to America, how they will be a challenge to suppliers or providers for these services are really high cost and the licenses available to them are really expensive and sometimes require minimum of a -- and amount for the fees -- required. So I'd really like to know if it is considered any properties small companies -- in the requirements -- before because I believe that it will be a challenge for them. Many of these small companies export to U.S. So this is the market for them. This is a -- and they have the challenge if they don't have the proper possibility requirements you have the proposal. They will be also market with the effects in -- thank you.

MS. BARRETT: All right. Thank you and thank you

so much for calling in today.

All right. I think we'll go to our next commenter, which is Donna Garren, American Frozen Food Institute. Donna?

MS. GARREN: Hello, my name is Donna Garren, Executive Vice President of Science and Policy for the American Frozen Food Institute, or AFFI.

MS. BARRETT: Donna, you sound like you're far away. Okay. Here we go.

MS. GARREN: AFFI is the voice of the frozen food industry, representing all segments of the frozen and beverage industry throughout the U.S. and globally. Thank you for the opportunity to share AFFI's perspective and insights about FDA's food traceability proposed rule today. My comments will be brief as AFFI members are in the midst of better understanding the details of the proposed rule and developing our final comments. I want to center my comments today around one, the need for a process for stakeholders to provide feedback and input on the food traceability list. Two, the likelihood that industry will need more than one year to address new foods added to the food traceability list. And third, the importance of

getting the key data elements or KDEs right as this rule will affect more than just those foods on the food traceability list.

First, AFFI urges FDA to share its thinking regarding the manner and the frequency with which it will update or modify the list of food subject to adding tracing elements and requirements. While AFFI is supportive of using a model and assisting with the evaluation of foods for the addition or removal from the food traceability list model no matter how good they are will almost always have limitations. For this reason, the decision to add or remove foods from the food traceability list should involve transparent public consultation.

Secondly, industry will need more than one year to address new foods added to the food traceability list. If we use 2020 as an example, it would have been virtually impossible for food companies to consider and add additional regulatory compliance elements for a new food added to the traceability list.

Thirdly, AFFI understands FDA's desire to standardize the information entities that must be maintained at critical tracking events. Some of the KDEs proposed include new terminology or represent information that may not be maintained

today. We are taking a close look at the KDEs and will be providing feedback on those pieces of information that will add the most value to traceability efforts.

Finally, AFFI and other food and beverage trade associations would like FDA to seriously consider the need for extending the public comment periods for the food traceability proposed rule and particularly the paperwork reduction act which is due later this month. The Food and Beverage Industry cannot assess the record-keeping burden without fully doing a deep and full dive into the proposed rule and its impact.

Again, thank you for allowing me to provide oral comments during this public meeting. On behalf of the frozen food industry, we look forward to working with FDA and finalizing this proposed rule and continuing to ensure the U.S. consumers have the safest food possible. Thank you.

MS. BARRETT: Thank you, Donna. Thanks so much for your comments.

We'll now go to our next commenter, which is Rachel Gabato with Ripe Technology.

MS. GABATO: Yes, I'm here.

MS. BARRETT: Yes, you can start, please.

MS. GABATO: My name is Rachel Gabato. I'm the COO of ripe.io, and on behalf of our team, I would like to thank the FDA commissioner Frank Yiannas and his team for allowing public remarks.

ripe.io provide a blockchain-powered platform to assess information on the origin, the journey, the quality and the sustainability of food. We enable supply chain participants to digitize events and their related attributes allowing for transparency, visibility, and trust. The pandemic has highlighted the opaqueness and rigidity of our food supply chains. It has stretched the global supply chain in unprecedented ways, and we should both understand and learn from what's happened. The reduction of personnel, the increased distancing measures. The government-imposed restrictions have brought substantial challenges to on-site safety audit processes, the ability to source authentic and safe ingredients, and the vetting of new vendors ensuring required criteria are met.

The -- of major foodborne illness outbreaks requires the industry to expedite its efforts in the development of faster and reliable detection and response tools. We are

here today to discuss the new food traceability proposed rule. We can safely say that these efforts are well underway and that the industry has risen up to the task, yet, much remains to be done. When we remarked last year, we stressed how digitization is a necessary requirement.

The new rule with the condition to report on key data elements of critical tracking events within 24 hours makes that requirement even more stringent. Digitization alone won't suffice, however. Collaboration and trust, process of elimination, and efficiency reductions are all critical factors to the successful implementation of this rule. At Ripe, we have enough evidence showing that a system of records based on distributive ledger technology integrated with other systems, sensors, IOT devices, and GS1 bar codes can foster the collaboration, automation, and trust so critical to achieve enhanced traceability. Our platform is already configured to collect the KDEs from the five CTEs in an independent and immutable fashion. Linking the CTEs can be automated with rules to ensure the sequence, consistency, and integrity of the data are preserved in real time.

However, we concur with the FDA that improving

traceability alone can only offer a partial solution. We have been focusing our efforts in two areas. First, related to improved inclusiveness, especially at the farmer/producer level. We offer onboarding service to small growers at no cost, ensuring they can be part of the digital and connected transformation.

Second, it the widening of the data collection scope and building data analytics. By linking traceability data to quality and sustainability attributes such as seeds and genetics, soil composition, conditions. We enable predictive models on food quality and safety.

In conclusion, by fostering digitization at the farmer/producer level and widening the data collection scope and practices, we can provide comprehensive data analytics across the food supply chain. We applaud the FDA's work in amplifying and focusing attention on the rule that innovative technologies can play in improving the food supply chain. We appreciate and respect the opportunity to speak today. Thank you.

MS. BARRETT: Thank you. Thank you for your comments today.

Michael, we'll have our next commentor.

All right. We have Jeanne Duckett, Avery
Dennison.

MS. DUCKETT: Good afternoon. My name is Jeanne Duckett, and I work for Avery Dennison. Avery Dennison is one of the original thought leaders in the automatic data capture and identification or AIDC. Our contributions to the industry include developing barcode symbology, leading innovation in RFID technology, the development of new and emerging data carriers, and enabling that physical-digital connection, ensuring that the critical part of good, clean data is captured. We are actively involved in industry pilots. We are recognized advocates for standards development and AIDC technologies.

Currently, we serve leadership capacities within multiple standard organizations including in global, GS1, and ISO. We appreciate this opportunity to submit comments in response to the Food and Drug Administrations' proposed rule at this public meeting. Avery Dennison applauds the FDA for their leading work in a proposed rule on food traceability and also their developments of the four pillars of the new era of smarter food safety.

The recognition of the intersection of the

culture of food safety, tech-enabled traceability, enhanced outbreak response, and emerging business models. The FDA's goal of bending the curve of foodborne illness is laudable, and the FDA is leading the discussion globally for the implementation of food traceability. However, when looking beyond this critical result enabled to do a product traceback, the rule can be a wind for the entire ecosystem, from producers to the consumer as a result of improving process efficiency and inventory visibility. Avery Dennison, along with standards groups and other NGOs, have been able to consistently model the possible ROI of the transparency supply chain making this rule viable.

The FDA is leading the global conversation and the harmonization of food traceability and should be recognized for that work. The four cites the FDA is showing in technology independent for data platforms and data carriers will ensure that this rule remains relevant in the coming decade as technology evolves. We support this technology independence, however, technology independence doesn't apply a need for a lack of standardization.

We recognize the need for the adoption process across a wide ecosystem; however, even within the range of

resources and skill, limiting the feasibility for mandating electronic traceability. We strongly recommend that the FDA consider working with standard organizations to define the semantics of the key data elements. There is likely to be a number of new solutions developed to assist suppliers leading this rule. With the current ambiguity and key data definition, the door is open that solutions can noninteroperable.

Ultimately, this has the potential to add cost and slow adoption as either translators or developer solutions updated. Cost has been relayed to is an issue. Consumers and slide chain members will be best served with globally ubiquitous supply chain interoperability. Standards lower the cost and barriers to adoption. The FDA should continue their work with standard organizations in defining and harmonizing on the key data elements. Thank you.

MS. BARRETT: Thank you, Jeanne, for your comment. Okay. We'll go on to our next commenter, and that's Bill Ritcey, Blocksyste. Bill.

MR. RITCEY: Good afternoon. I am a 40-year vet in the food industry. I'm the Senior Advisor at Blocksyste, an ATI -- I appreciate the opportunity to state a few comments and

ask a few questions. First, we applaud the efforts of the FDA and their focus on safety -- . In the food industry a large percentage of -- under a private label or customer brand. In many cases, there are multiple suppliers.

MS. BARRETT: Bill, this is Kari. We're going to give you some more time so don't worry about that, but it is hard to hear you. I'm wondering if maybe you can speak closer to the phone or to be still when you're speaking. For some reason, you're coming in and out a little bit. Thank you.

MR. RITCEY: Is this better?

MS. BARRETT: That's much better, and we'll give you back the time that I just took. Thank you.

MR. RITCEY: Okay. Thank you. In the food industry, a large percentage of the products sold is under a private label or customer brand. In many cases, there are multiple suppliers who pack the same product under that brand. Currently, the objective is to ghost the manufacturer at the distributor and consumer levels. Particular attention needs to be given to the identification of the manufacture of these brands for those down the supply chain to make proper identification.

I believe excluded in manufacturers who apply a kill process to their items will create a record keeping hardship. In the same item and brand, there could be one manufacturer that applies this process and one that does not. I do not believe the format of the notification or how it would be included in the documentation was specified. To purposely exclude those items from the information gathering might be more of a challenge than a benefit.

While the rules concern individual companies gathering and reporting the information, there is the technology to support a link supply chain where data may be able to be passed from one company to the other, possibly reducing the challenge to individual organizations that are down the supply chain to collect all the data as required. While I understand the reluctance of the FDA to identify specific ways for the industry to fulfill their requirements, the application of this technology could not only increase supply chain efficiency, but save considerable time. Could a move to that type of platform be phased into the rules? Transporters are noted as excluded from the rules.

Given the objective of completely tracking a

product from farm to table and given that through the bill of lading document, the trucking company actually becomes responsible for the product while it is in their possession. Shouldn't the trucking company be included in the rules? There is certainly the possibility of an issue while the product is in their possession.

In moving the FDA to more of a proactive role as a preventer of food safety issues as well as the governance for the industry in that respect, there could be also attention paid to the environment the product travels in. Given manufacturers the opportunity to define their own traceability lot codes as long as they include a translation document that explains the format will create tremendous confusion down the supply chain as distributors try to keep records from hundreds of suppliers that are formatted differently.

Although implied, I recommend that the food service channel is specifically included in the rules, especially when referring to entities closer to the consumer. The terms RFE and grocers might cause some incorrect interpretations. Will there be a suggested format for reporting the digital sortable records being collected. This will be

essential in the efficient transfer of information between trading partners and to the FDA. Thank you.

MS. BARRETT: Thank you very much.

All right. We'll go now to our next commenter, and that is Stephanie Harris with the Food Marketing Institute. Stephanie.

MS. HARRIS: Good afternoon. My name is Stephanie Harris Chief Regulatory Officer and General Counsel at FMI, the Food Industry Association. FMI is the trade association that advocate on behalf of a wide range of numbers within the food industry value chain. From food wholesalers and suppliers to grocery retailers. FMI strongly supports FDA's goal of improving public health by ensuring entities throughout the supply chain speak a common language to facilitate faster, more efficient traceback activities. We appreciate FDA's willingness to hold three public meetings and to engage in a dialogue with stakeholders on the agency's proposed rule for traceability. Although we plan to submit more detailed written comments, there are several issues we think are important to raise at these early stages in the rule-making process.

First, it is not clear which foods are included

in the food traceability list. For instance, what constitutes a soft cheese? Would cream cheese count? This threshold question is central to firms' understanding of whether and to what extent the proposed rule would affect their businesses.

Second, we urge FDA to provide flexibility with respect to how records required under the rule are maintained. While an electronic sortable spreadsheet may seem like a simple enough request, this format will be an advancement for many companies and outdated for others.

Finally, we wish to impress upon FDA the complexity of the proposal and the challenges that it presents. FMI's members will be involved in potentially all of the critical tracking events, and will therefore be required to keep extensive records throughout the supply chain. Given the rules' many nuances, we are finding that even for a single food, the analysis of whether and how the rule would apply is complex and requires consideration of numerous factors. These include the conditions for the exemption for produce that receives commercial processing are met or whether an entity is a receiver if it is not a customer of the upstream entity to name just a few.

Moreover, the proposed rule would require industry to become familiar with significant new terminology. These complexities, coupled with upcoming holidays and the challenges of the ongoing COVID-19 pandemic will make it very difficult for industry to submit comments by the comment deadline. We hope FDA will consider an extension to the comment period which would provide stakeholders the time necessary to work through the proposed requirements and provide meaningful feedback. We are confident that with enough time for consideration and stakeholder input, we can create a workable vital rule that increases transparency, mitigates foodborne illness outbreaks, and facilitates food recalls.

Thank you for your time and consideration today.

MS. BARRETT: Great. Thank you, Stephanie, and we will learn food industry association. So I apologize for the older language and food industry association. So thank you.

And we'll go to our next commenter today. That is Dominique Mital, Fresh Food Factor. Dominique.

MR. KAWCZYNSKI: Hello? Dominique, please make - there you go. Now we can hear you.

MS. MITAL: Yes, good afternoon. My name is

Dominique Mital, and I'm talking on behalf of -- of America -- .
And I want to thank the FDA for this initiative because
traceability is very important to us in the industry.

It's just that I consider the person that should
be practice the traceability, they're -- to make sure that us as
manufactures, we can have the key data information that we would
like to have to process the traceability. With that said, as a
distributor, most of the time, they just put lot numbers but
it's -- because that is the only lot number that the product
comes with. So how else as manufacturers we can trace a product
that is being -- that is not coming to us with the right number?

That's one of the problems I'm facing right now
in the industry, and I'm wondering how the FDA with the new rule
that they have for the traceability, they can help the
manufacturers so they can have key data elements that they would
like to have to trace any type of -- . That's all I wanted to
say. Thank you.

MS. BARRETT: Thank you so much for your comment.

We'll now go to our next speaker, and that is Ron
Volpe.

MR. VOLPE: I'm here. Yes. Hey, my name's Ron

Volte, and I'm the FDP International Market for Persequor. We're a Danish software company that builds track and trace solutions for a variety of industries, often in regulated environments. I'd also note that I've led global food supply chains across 30 countries with a live manufacture, Kraft Foods Global, and a large grocery retailer, Kohls Supermarkets in Australia.

In each case working with trading partners, I've seen firsthand the opportunity that exists across companies of all sizes to improve on track and trace and recall processes. There is certainly exceptions, but my observation is that fewer companies have it together than those that don't. And in the absence of regulation-driven motivation, investment and capabilities to do this with new technology have been put off. This is quite consistent with what I view as an overall lack of investment and technology that we should've expected to see based on the massive increase in complexity we've seen in food supply chains in recent years.

Persequor applauds the work the FDA is leading. In the wake of COVID-19, we've seen an increase in consumer concern for safety of their food which puts pressure on

companies to the food supply chain to step up their game in the area of traceability. The work of the FDA, as well as groups like GSI to bring standardization and consistent processes to the food chains of companies, ensures that the approach globally would not be fragmented.

Here at Persequor, working with countries like Australia, Thailand, Denmark, and others, I often see reference to the FDA's work as they design their own regulations. Persequor looks forward to supporting companies and the FDA in this journey. Our technology enables the capture of capture synthesis and analytics of critical tracking events from farm to consumer. Much of those events required by the FDA but any event for which a digital event is created. The advantage of automation deficiency from the record keeping perspective. We also enable the sharing of data across trading partners within the supply chain based on the requirements of the individual parties.

I've personally worked in various environments where sharing data with trading partners is not enthusiastically supported. I've also seen examples of companies selling the data to trading partners. My view that neither of these

approaches is effective. It's been cited many times in 80 percent of the data you need to run your supply chain so it's outside of your organization. My experience is that the concerns about responsibly sharing data or the idea that the biggest benefit comes from selling that data to another party are massively overshadowed by the significant operational advantages and improved ROI that comes as they share data.

Traceability enabled transparency is the gift that keeps on giving in that it enables valued creation across the supply chain. We are excited about the work the FDA is doing, and we look forward to work with companies to create tech-based test and learning environments as they navigate this new environment. Thanks so much.

MS. BARRETT: Great. Thank you, Ron. Thanks for your comments today.

We're now going to go to our next commenter, Patrick O'Connor who's with the International Warehouse Logistics Association, and Patrick, do speak loudly so all can hear. Thank you.

MR. O'CONNOR: Okay. Thank you very much, Kari.

I am Pat O'Connor. I represent the International

Warehouse Logistics Association, and I appreciate the opportunity to provide comments at today's virtual meeting.

IWLA represents warehouse-based third-party logistics providers. Many of our members operate food grade warehouses, both dry storage and cold storage, the storage handling and distribution of food products for manufacturers, processors, distributors, and retailers. As a third-party warehouse, we are an intermediary in the food supply chain. We do not own or take title to or sell the products that are in our warehouse. The role of the third-party warehouse is well-established in federal and state law. Our food council is reviewing the proposed rule, and we'll be submitting written comments to the docket.

In the interim now, our food council members have identified several issues and questions that I'll just raise today, and I'm not looking for answers to these questions. I just want to put them on your radar for the time being.

Number one is the kill step. Traceability records, as we understand the proposal, are not required for listed food where the producer has supplied the kill step, provided the producer maintains records of such kill step. We

would suggest so that FDA needs to explicitly require the producer to provide a statement to subsequent receivers in the supply chain that a kill step has indeed been applied. Otherwise, how will the receiver know that he does not need to maintain traceability records on that product?

The second issue, in the proposal, the first receiver is defined as the first person who purchases and takes physical possession of the food shipment. However, the three PO warehouse never takes title or purchases the product. He may receive the product, but he doesn't take title or purchase the product. So we don't see that the warehouse would ever be the first receiver, and we think that this is an issue that you may want to address as this rule-making goes forward.

The next topic is the import situation. Who indeed is the first receiver? In some scenarios, it could be a foreign entity. Does this matter with respect to this rule-making if the first receiver is a foreign entity? If the first receiver is a foreign entity, they would not be able to supply the customs entry number or required data element. So the information received by the 3PL would be incomplete.

Question, what about a shipment where the

importer purchases the product, but the 3PL warehouse takes physical possession? There would, in fact, then be no first receiver in that scenario because the warehouse only has possession but has not purchased the product.

Next question, what does a 3PL do when a shipment arrives and there's no traceability information provided by the foreign owner, either because there is no first U.S. receiver or the first receiver did not do his or her job? So as an intermediary, these are some of the questions that we ask as we review this proposed rule.

The last question is we understand from the proposal that a receiver or holder can designate someone else to establish and maintain traceability records. We still have the requirement to make sure that's done, but we understand we can designate somebody else to do that. For a 3PL it may make sense to have its customer maintain these records. Question though, can this be done if the customer is, say, a Canadian company or other foreign entity? Can we assign that responsibility for maintaining those records to a foreign entity?

Again, we will submit these and some other questions in our written comments. I, too, thank FDA for

putting on this virtual meeting. Thank you, very much.

MS. BARRETT: Okay. Thank you, Pat, and thank you for the issues raised. Please do submit those to the docket, and we'll now go to Scott Donachie. He's with Companies for Zero Waste.

MR. DONACHIE: Thank you. You pronounced my name correctly. I love it. Thank you.

So my name is Scott Donachie. Thank you, everyone. It's an honor to speak today. I'm the CEO of Companies for Zero Waste. I founded the organization, it'll be two years in January, and our mission is to mitigate human suffering eliminate human suffering by changing the way that we currently manufacture goods. And our company brings in advisors globally to help out OEMs and the government with specific projects and waste. I don't even like to use the term waste. We like to use the term resource optimization.

Our mission today is to really accelerate that and their also connecting a lot of leaders that are internationals specifically in Europe to educate the OEMs, the policymakers, the regulators, and the investors in North America so that we can accelerate the movement from a linear to a

circular economy.

That being said, a circular economy is not that easy, and not every material is sustainable, green, or circular. When it comes to the food waste industry, I would just like to make the note, and I'm more of a generalist, but corporations are still operating in silos and so is the government. So our job is to really bridge that gap, and we see a very big opportunity now to educate policymakers, regulators, investors, OEMs, and startups and bring them together to accelerate the process.

We believe that human behavior will actually move us quicker than just technology itself. But how do we change human behavior when it comes to producing goods and also looking at end of life.

I also, too, would like to make a note for the FDA. We would like to showcase certain technologies and optical sorting, AI, and then robotics that can help separate waste before it goes to landfill. So once again, my name is Scott Donachie, the CEO of Companies for Zero Waste. We're a global advisory firm that helps out the full supply chain. You can Google us at companiesforzerowaste.com, and I really appreciate

this opportunity. Thank you, everyone.

MS. BARRETT: Okay. Thank you, Scott.

We now will go to our next commenter, and that is Adam Brock, Dairy Farmers of Wisconsin.

Adam.

MR. BROCK: Yes, I just want to thank FDA for putting on this event today, and also for the initial events you held in person in October of '19 that went over the new era of modern food safety. So thank you again for that. I thank FDA.

Overall, Dairy Farmers of Wisconsin represents the farmers in Wisconsin, dairy farmers, over 7,000 farms, and we also work closely with over 200 dairy companies. As you know, as we've talked about and the FDA has said, one size will not fit all. A large multinational corporation is very different from a small farm, and although there are exemptions, the four key things that come to mind are as follows with the regulation. I'd like to briefly discuss the broad categories, specifically soft cheese.

My question is soft cheese by what definition? Is it compositional standards? Is it defined by the company? Is it tied to 21 C.F.R. 133? So clarification on that would be

very useful. Education to industry which is open voice by other individuals. We have a new lexicon. That industry is going to need to understand and adapt. Those who have not dealt with GS1 traceability will take some time to learn more about the exact terminology.

The question also I have or would like FDA to consider, how well does that terminology align with the Chapter 12 of the guidance document tied to the preventive controls for food safety course if they're a connection.

And then the third issue is, you know, looking at farmers and artisans, does this become a hurdle for them where they need to look at software? What do they need? And obviously, I think you've spelled out some of those now, but I think there's some ambiguity in that area. One size as I said does not fit all. What works for Kraft does not work for a small artisan.

And then more data privacy issues. If you're thinking data privacy and interoperability. Others have voiced this as well, but again, locking into a specific software system could be a potential hurdle to market access and economic development.

With that, I very much appreciate you giving me the time to speak, to provide some feedback, and we are very supportive. We just want to make sure we are not inadvertently locking out the farmers that may perhaps at one point look to become processors, and we want to make sure that they have supply chains open for them. So thank you again, and have a good rest of your day.

MS. BARRETT: Great. Thank you so much, Adam, for joining us today and for your comments.

I believe we have one last potential commenter, but we may be having trouble reaching that commenter.

Michael, can I turn to you?

MR. KAWCZYNSKI: Yes, Ankit Kumar, we tried calling you. If you put your number in the Q&A pod on the lower left-hand corner, we can call you in real quick, but we did try calling with the number you provided. Otherwise, we're just going to move onto our closing remarks. So we'll just give you a moment to see if you want to submit that. Again, if you type your phone number in the Q&A pod in the bottom left-hand corner, we'll give it a shot.

MS. BARRETT: And again, that's Ankit Kumar,

Registrar Court.

MR. KAWCZYNSKI: Yes. All right. It looks like no so let's go to our closing remarks.

MS. BARRETT: All right. Well, first of all, I would like to thank everyone who did present this afternoon. I really appreciate the time that they took to prepare those remarks and share them with us and just encourage everyone to get their comments into the docket. So that will conclude our commenting section.

And now we'd like to bring our final speaker of the day. We have Dr. Susan Mayne with us, who is the FDA CFSAN Director. Dr. Mayne has been actively engaged in this rule-making process, and we look forward to her remarks.

So, Dr. Mayne, I'll turn to you.

MS. MAYNE: Great. Are you able to hear me, Kari?

MS. BARRETT: Yes, it's perfect. Thank you.

MS. MAYNE: Good. Thank you. So good afternoon, everyone. I know all of you have been with us virtually for many hours today, so I will try to keep my remarks brief.

First, I know life looks a little different for most of us these

days, and for some, it's become more complex. It seems like work and school are all happening at home, and so I really want to thank you all for taking the time to join us today to discuss the food traceability proposed rule.

Second, I want to thank all of our panelists for participating. Your perspective and feedback are vitally important during this rule-making. You all have given us a lot to consider, and I hope the discussion today has helped all of you listening to think about the requirements we have laid out in this proposal and how they may affect your specific interest.

I know we did hear from a number of you today that there is some confusion about some of the requirements and some of the concepts in the proposal. We all recognize that we have introduced some new concepts in the proposal, and it will take time to understand those requirements, and we are committed to providing clarity around what it is we are asking and how those requirements would apply across the food industry.

As part of this commitment, yesterday we released a number of additional resources on our website that I believe will be helpful in developing a better understanding of this proposed rule. In addition, I hope the discussion today has

been helpful in clarifying the proposed requirements and will help you to think about how these requirements might apply to your business.

Although I know that this kind of virtual public meeting isn't our ideal situation, we are listening carefully to the feedback, and I am glad that we have had this opportunity today to discuss and support this important rulemaking.

I have been fortunate to lead the Center for Food Safety and Applied Nutrition for six years. During that time, we have done incredible things to improve food safety, not the least of which has been the implementation of the seven foundational FSMA rules. But even so, one critical element has been missing, comprehensive, harmonized, food traceability. The lack of enhanced thorough and standardized food traceability systems has proven time and time again to be a tremendous barrier in our ability to rapidly respond to outbreaks. The traceability systems we have in place today far too often leads us scrambling for information during the critical hours, days, and weeks after we learn about an outbreak from our state and local partners and CDC. During an outbreak, this can cause millions of dollars in avoidable product loss, a loss of

consumer trust, and an increase in consumer illnesses and even deaths.

We heard today that we can improve consumer trust in the safety of our food supply through the increased transparency that enhanced traceability would allow for. It's for all of these reasons that I truly believe this effort to enhance traceability in the food supply is something we can and must all support.

The team that wrote this proposed rule, many of whom you met today, brought with them a diverse set of experiences and extensive knowledge of FDA-regulated foods, foodborne illness outbreaks, food safety, data and risk analytics, traceability, and more, all of which is reflected in the proposed rule. While limited to certain foods, the proposal this stellar team put together presents us with a common language and framework that can be built upon as we continue to pursue enhanced and modern food traceability into the future. We know we cannot achieve our goals for enhanced traceability without all of you.

In developing this approach, we took into consideration the existing standards that some firms and

industry groups have already adopted, and when possible, we strive to make the proposed requirements compatible with those standards. We also looked at data and information learned through our experiences handling outbreak and recall situations and information shared with us by stakeholders over the years. Your feedback today and throughout the comment period will continue to inform the approach we ultimately take in the final rule. I look forward to continuing these discussions with all of you as we've moved this rule forward. Thank you, again.

Let me turn it back to Kari, our moderator.

MS. BARRETT: Great. Thank you so much, Susan. This does conclude our public meeting today. We really want to thank everyone at FDA and all of our external presenters who helped in the planning and preparing for this meeting, and we do look forward to continuing to work with all of our stakeholders. As we move forward with this rulemaking, we look forward to your comments to the docket. We want you to encourage anyone who couldn't join us today to join us later this month when we have our second traceability public meeting. And with that, have a wonderful afternoon and a great weekend, and thank you very much

(Whereupon, the meeting concluded at 3:38 p.m..)

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