UNITED STATES

FOOD AND DRUG ADMINISTRATION

PUBLIC MEETING ON

Requirements for Additional Traceability Records for Certain Foods: Proposed Rule

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P R O C E E D I N G S

SPEAKER #1: Testing, testing, testing. 1-2-3, 1-2-3. This is the transcript for the US Food and Drug Administration public meeting. Requirements for Additional Traceability Records for Certain Foods: Proposed Rule. Check, check, 1-2-3.

SPEAKER #2: Show time again, huh?

MR. KAZYNSKI: Yep.

So, if we are... let's get this rolling.

So, looks like my clock is on the time, so here we go.

Good morning, and welcome to FDA's Public Meeting Requirements for Additional Traceability Records for Certain Foods: Proposed Rule. I'm Mike Kaczynski, I will be managing today's event along with my co-host Kari Barret. Today's event has a great amount of speakers and Q&A, and all that fun stuff in here.

So, if you have any questions at any time for our presenters then you have the Q&A part in the lower left-land corner.

If you run into any technical issues, just feel free to log out of Adobe Connect, and log back in. Also, please note that we are recording today's events so if you do miss anything, not to worry -- it will be posted to our website just like the last one was. And, with that I would love to introduce you to our moderator Kari Barrett. Kari, would you like to turn your camera on?

MS. BARRETT: I sure will. Hey, good morning and thank you so much Michael. Michael mentioned we want to welcome everyone to today's public meeting that is focused on the

proposed rule on the requirements for additional traceability records for certain foods.

And, the purpose of today's meeting is to discuss the proposed rule which was issued under the FDA Food and Safety Modernization Act, which we also call FSMA. And, this is the second of three public meetings that we're holding on this topic.

So, we really hope that you'll find today's meeting useful in evaluating the proposed rule and in facilitating the commenting process.

So, as Michael mentioned my name is Kari Barrett and I do lead the public engagement team for FDA's center for food safety and applied nutrition. And, I will help moderate today and Michael will also be with us throughout the day and make sure we stay on track.

During the day we'll walk through an overview and key components of the proposed rule. We're going to have some Q&As, as has been mentioned. We'll hear from some external panels, including our state partners and some of our stake holders. And, we'll also at the end receive public comments.

So, just a few quick notes before we begin. I do want to remind everyone that the agenda and the speaker biographies are posted on the FDA website, so please be sure you

have that to help guide you through the day.

The meeting today will be transcribed, it will also be recorded. The recording usually posts within about a week, and the slides and transcript we are posting after our final meeting in December.

So, with that quick housekeeping it's now time to begin our program and to provide our introductory mark today. I'd like to introduce Mr. Frank Yiannas, he's our FDA deputy commissioner for food policy and response. Frank.

MR. YIANNAS: Well, good morning. Let me get a quick sound check: can you hear me?

MS. BARRETT: Yes, we can.

MR. YIANNAS: Fantastic. Well, good morning. Thank you Kari, thank you Michael, and thank you to each and every one joining us today by way of video. This is going to be a very important that we're going to have today, and we're delighted that you've decided to join us.

Let me begin by recognizing that these are very challenging times; we know that for everyone. And, we at the FDA sincerely appreciate that you're taking time out of your busy schedule to look forward -- to look towards the future and consider how we together can strengthen food safety protections for generations to come.

When today we talk about this concept or idea of food traceability what we're really talking about is the ability

to track a food at every step in its journey throughout the food supply chain continuum. And, by every step what we mean is when a food leaves its source to its origin, when it reaches the consumer.

The draft rule we'll be talking about today is critical. One can also say it's foundational to the kind of end-to-end traceability that we want throughout the entire food system.

I think some of you know that in the Food Safety Modernization Act, also referred to as FSMA, congress always anticipated the need for enhanced tracking and tracing of foods -- of certain foods, that is.

We've used the framework provided by congress to propose this food traceability rule in a draft list of foods for which additional record keeping requirements would apply. And, please note this is an important distinction: notice I didn't say a high-risk foods list.

The reality is that any food can be hazardous if it's not handled correctly, or if the proper steps haven't been taken to ensure its safety. And, we believe that by calling it a high-risk foods list it can be misleading to consumers.

So, instead we're simply referring to it as the Food Traceability List. While limited to only certain foods, we're laying the foundation we believe for a standardized

approach to traceability, record keeping, paving the way for industry to adopt, harmonize, leverage, and very, very importantly -- to scale more digital food traceability.

The proposed rule while under the auspices of FSMA is also a bridge to the New Era of Smarter Food Safety, which commissioner Steven Hahn and I announced in July. Tech-enabled traceability is one of the foundational pillars of our year initiative in which we will leverage new and emerging technologies, new tools, and new approaches to create a more digital, traceable, and safer food system.

This draft rule in the first step in this journey to work to harmonize the key data elements in the critical tracking events -- KDEs, and CTEs -- which you'll be hearing a lot about today, needed for enhanced traceability.

You're going to be hearing from my colleagues, the men and women at FDA, that I'm very proud of the quality of the work that they've done. And, what's in the proposed rule? You're going to hear the details of the CTEs, key data elements, and critical tracking events.

But, I thought for the limited time that we have available early this morning I'd like to start on the “why”: why this proposal is so needed, and in my view why it's so important. I've always thought that the "why" of any proposal or any initiative is critical, because we realize that the “why” serves as the antecedent to the actions that we plan to take

together.

And, so while you'll be hearing a lot of talk today about data and standards I want you to remember one thing -- the big picture. And, that is that this is ultimately all about protecting consumers from contaminated food. It's also about creating a more transparent food system. In other words, it's about getting rid of the anonymity. A lack of transparency is anonymity -- it's about getting rid of the anonymity that often is present as we try to investigate foodborne illness outbreaks. Remember that point.

Everything we're doing is to bend the curve of foodborne illness in this country. I think that's worth repeating: everything -- and, I mean everything that we're doing -- is to bend the curve of foodborne illness in this country and to give consumers the confidence they deserve to have in the safety of the foods that they're serving themselves and their families.

So, let's start with a little bit more elaboration or discussion on why this rule is so important. You see, I believe that better food traceability is actually, and I'm not over-stating this, a game-changer for food safety. I believe better traceability is a game-changer for food safety. In fact, I believe better traceability is all about prevention.

That's an important concept to think about,

because I think at times we hear people say that traceability really isn't about prevention, it's about reaction if there is a problem. And, while I think those comments are well-intended I can't tell you how far I think they miss the mark.

Let me explain: we've made great strides in implementing FSMA. Most of the compliant (inaudible) have arrived. There's been extensive training, as you know. Inspections are being conducted, guidance documents have been written and provided as resources, and enforcement actions have been taken but we're staying true to our mandate of educate while we regulate.

Think about today's food system -- it's pretty impressive when you think about the wide variety of foods that are available to you. You can walk into any grocery store and generally find anywhere from 50 to 70,000 different food SKUs, available to you for a fraction of your hard-earned dollar.

In fact, the food supply has remained amazingly resilient even despite the COVID-19 pandemic. However, I've often stated that I believe that today's food system, while pretty impressive, has one major Achilles' heel. And, I share that because of an informed view and experience of 30 years in the profession.

That Achilles' heel, in my view, is a lack of traceability and transparency. The records involved in moving food through the supply chain are largely paper-based, we all

know that. They're largely one step up and one step back. This creates a system in which it is necessary to track those foods -- one step forward, and one step back. And, to identify where food has gone. Where was it previously? Where did it arrive?

This concept, along with the insufficient and lack of a standardized data approach in identifying that product along a supply chain, creates an inability to rapidly track and trace foods. We've all seen evidence of that.

During an outbreak, this can cost lives, millions of dollars in avoidable product lost, and damage to consumer trust. I cannot state this strongly enough: when there's an outbreak of foodborne illness, it's critical to rapidly identify where the contamination occurred.

Having this information allows us to alert the public and the food industry about what food to avoid, remove that contaminated food from the market, and eventually evaluate what may have caused that contamination so that actions can be taken to prevent this from happening again in the first place. All of this requires extensive investigation, working as necessary with state, local, and international public health officials and federal partners at the CDC and USDA. It's a collaborative exercise.

These investigations cannot be effective without timely access to accurate information all along the food supply chain. And, this is why traceability is so essential to food

safety.

When we look at the current state of traceability across the food supply, we find that even though some companies -- yes they have, and some retail chains have adopted more modern and effective traceability systems. Rarely -- and, I can tell you from first-hand experience -- rarely are these systems compatible with each other, and still many other food companies haven't adopted traceability systems at all. Simply put, we lack a harmonized system of tracing foods from farm to fork that is universally understood and utilized by all.

So, let me continue on the "why". As many of you know, food safety has been my life's work for over 30 years -- first in the private sector, and now humbled and privileged at the FDA. And, there's no question in my mind that there's a strong public health and business case for better traceability; a strong public health and business case.

I was once involved, I think some of you know, in a blockchain pilot that traced mangoes back to their source.

So, let me use that as an illustrative example of what I'm talking about. Mangoes have a very complicated supply chain.

In this country they're grown -- in this hemisphere, they're grown in central and south America. They begin with seedlings that take generally 5 to 8 years for those

seedlings to mature. Once those trees are producing mangoes and they're ripened, they're harvested, transported, processed and shipped before consumers pick them up at the store.

It's a pretty complicated lengthy journey. I wanted to see how good could a retailer trace these mangoes -- sliced mangoes in a packaged clear clamshell, back to source. And, so I purchased a package of sliced mangoes and I brought them to my team at the time while I was working in the private sector.

I put it in the center of my conference room table and said, "The trace-back study starts right now." How long do you think it took them to trace those mangoes back to source? It took them 6 days, 18 hours, and 26 minutes. Now, some think that's a long time but that actually is pretty good when you think about the average trace-back can take; sometimes weeks, or even months.

Fast-forward to a pilot that we did using blockchain technology -- and, I like to emphasize it's never about the technology; it's about the public health challenge that we're trying to solve.

We happen to use distributive ledger technology to capture traceability data attributes very easily at every point of the supply chain. We worked with small growers, a processor, distribution centers, and stores that capture that information.

At the end of that pilot, I scanned the package of those sliced mangoes and we were able to trace those mangoes back to source in 2.2 seconds -- from seven days, to 2.2 seconds.

Now, that's what I refer to as "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 the point of consumption is a game-changer for food safety.

The draft food traceability rule was developed independently of any specific technology, I want you to bear that in mind. And, that will remain the case well into the future.

We imagine that in the future methods for capturing, storing, and sharing traceability data will continue to evolve. We will continue to stay technology-agnostic, and we are not requiring technology for compliance purposes.

However, the basic principle -- the data standard and elements that are needed -- will remain consistent. We recognize there will be many solutions available, and we're going to stay very focused to try to help that those technologies can work together by paying attention to issues like interoperability, governance, comment-structured data, and terminology such as the KDEs and CTEs that you're going to be hearing more about today.

We also need to help ensure that food companies of all sizes -- small and medium enterprises -- can utilize the new tracing technologies with cost proportional to the benefits; little to no cost, or if there is cost it is proportional to the benefits derived. And, we need to ensure that the lessons learned about food safety through insights gathered by better traceability are shared with all in the continuum and even broader.

That's what we mean when we talk about democratizing data and information, so we can all win together. We must create digital, traceable food ecosystems that create shared value -- this concept of shared value is very important. When the continuum starts sharing data and traceability there is shared value created. Farmers win -- there's value in farmers because when these outbreaks happen and there's these overly-broad consumer advisories, farmers that aren't implicated will unnecessarily be damaged and harmed.

Processors, such as the mango example, win because they have better visibility into supply chain and make sure that they're providing a fresher product to their customers. And, retailers win obviously because they're giving the information that consumers desire.

We know that industry is already taking the lead in this quest for better traceability. Why? Well, as I mentioned, primarily because customers are demanding it. And,

it's a good business practice. Let me close with the most important "why" -- you don't have to look too far to find outbreaks that have defined what a lack of better food traceability has cost us and society.

Whether it was the outbreak of E. coli infections tied to bagged spinach in 2006, many of us will recall public health officials told us there were E. coli O157:H7 illnesses linked to bagged spinach, didn't know the brand.

The entire country was advised to avoid bagged spinach, and it took FDA back in 2006 -- granted, this is now what? 14 years ago; quite a long time ago -- two weeks to trace that product back to source. And, when it was all said and done it was a contaminated produce produced by one supplier, one base production, and one lot number.

But, because of the lack of traceability the entire industry suffered. Another example, think about salmonella examples tied to the Peanut Corporation of America in 2009 in the numerous -- and I mean numerous -- peanut-paste-as-an-ingredient-driven recalls that followed. And, some of those recalls came in way too long after the initial recall event. Or, in more recent times, you can think about the multi-state outbreaks of E. coli O157:H7 romaine lettuce in 2018.

Better traceability will have the benefit of not only helping to solve these outbreaks sooner, and potentially

prevent additional illnesses -- prevent additional illnesses, that's a form of secondary prevention by shortening the epidemic curves -- it will also help us get back to source quicker to conduct the much needed root-cause analysis to prevent such outbreaks from happening again in the future.

That's primary prevention. You see, better traceability will result without question in better foodborne illness prevention. And, it will also help prevent food producers from being unfairly impacted by contamination events that have nothing to do with them at all.

Think about the fall of 2018 when E. coli O157:H7 caused illnesses linked to romaine lettuce, and romaine -- because of the consumer advisories -- was pulled from all stores in the country right before Thanksgiving holiday because we had yet to identify the source.

The damage that that does to consumer trust is hard to measure, that damage can last a very long time. Food safety to me, without question, is first about protecting public health but it's also about consumer trust. And, we can and must do better. The reoccurring outbreaks of foodborne illness linked to romaine, for example, illustrate the importance of maximizing our ability to trace foods rapidly. In fact, in the FDA and Leafy Green Action Plan, traceability is significantly highlighted. And, we're already getting a sense of what the impact of better traceability could be in response to outbreaks

of E. coli O157:H7.

In 2019, there was another outbreak associated with romaine lettuce. But, based on some good work done by a state health department retailer that started developing modern traceability techniques and voluntary adoption of labeling we are able to trace that back to a geographical region -- Salinas, California, as opposed to the entire nation -- and, you can see the progress that we're making. One day we hope and we will be able to trace back if there is a contamination of that to the source, maybe the specific branch.

So, there's a lot that we're learning. We can also learn from other industries when you look at how other industries are able to track, through digital means, the real-time movement of planes, ride-sharing, and packaged goods for example. We can see how we can adopt these same approaches to track and trace food.

The benefits have been clear to me for a long time, but the need for better food traceability and transparency have been also highlighted, believe it or not, during the COVID pandemic. What we learned is that by enhancing traceability we might also be able to create the type of transparency that is needed to anticipate and help prevent the type of supply chain disruptions that you might see in a public health emergency, such as the pandemic that we're living through. It can help FDA

and the industry anticipate and help prevent the kind of market imbalances and food waste we saw when producers lost customers. In the normal course of events, it would also be a valuable tool to help to prevent food fraud.

For example, we believe that transparency is a deterrent to fraud and the cost that involves the industry.

It's important to know that consumers are greatly interested in this too. Consumers today we know are farther removed from food production than ever before. But, they do want to know -- and not only want great value, they do want to know how that food was produced and where did it come from.

After 30 years of experiencing consumer reactions to food safety, I firmly believe that taking the measures with food traceability that we're talking about today will improve transparency, and the food system overall. And, transparencies are powerful -- and, people say that food traceability isn't about prevention.

Remember this concept of transparency: the opposite of transparency, is what I think that anybody that works in this profession knows we have today: quite a bit of anonymity. Transparency is a powerful, powerful force. It's the equivalent of shining sunshine down on every point in the food distribution system. And, when you have transparency what happens? People tend to modify and self-govern behaviors because they know everything they do is transparent.

So, transparency is a game-changer for prevention. I'm about to wrap things up, but you know as you think about the long list I just gave you of pros and cons of improving traceability, with me it's easy. It's an easy, easy analysis; the pros far outweigh the cons, as I see it.

In closing, I would like you to do this before we buckle our seatbelts and get on with today's exciting day. I'd like for you to imagine the world in which you scan a product right before buying it at a grocery store, and you can know immediately where it was produced and if that product was involved in a recall.

I want you to imagine if the FDA could trace a food vehicle suspected to be cause of an outbreak from the shelf to source in minutes, maybe even seconds, instead of days or weeks. This draft rule is an important bridge between FSMA and a New Era of Smarter Food Safety. One that will bring us to this type of full end-to-end traceability in the food system; it's a starting very important step.

We are working towards that goal every day, but we cannot do this -- we will not do this alone; we need your input, Speaking of which, we've been asked by many of you to provide additional time for stakeholder input and considering requests to extend the public comment period for this proposed rule. And, the attached information collection provisions beyond the current closing dates of January 21st, 2021, and

November 23rd, 2020 respectively.

I'll have more, and the FDA will have more, to report on that very soon.

So, stay tuned. I've learned from working at the FDA, when I was in the private sector on the other side of the fence so to speak, that there's a lot industry can do and should do to advance food safety and food traceability.

I've learned now that I'm on this side of the fence -- the public sector -- that there's a lot the public sector, such as FDA and USDA and states, can do and will do advance food traceability. What is crystal clear to me, more than ever before now having been on both sides of the fence is that there is so much more we can do together.

Ultimately, whether you're in the public or private sector it doesn't matter what role you sit in as you tune in to today's webinar. We're all working for the same boss -- the American consumer.

So, let's get to work together to keep their food safe. They are counting on us. Thank you very much.

MS. BARRETT: Okay, thank you deputy commissioner Yiannas for your really compelling vision and remarks, and setting the stage so well for today's programs. I'm so glad that you could join us.

At this time, we'll now go to our next speaker who is Katie Vierk. She is our assistant and division director,

office of analytics and outreach. And, Katie will provide an overview of the proposed rule.

So, Katie, welcome.

MS. VIERK: Thank you Kari. Can you hear me okay?

MS. BARRETT: Yes, I can.

MS. VIERK: Thank you. Well, good morning everyone. I also want to thank everyone for being here today. We certainly appreciate the time you've taken to join us.

We know many of you look forward to this proposed rule, and work cited to publish it. And, we look forward to today's meeting and your comments.

I'd like to make sure to thank the FDA staff who is attributed the drafting and the proposed rule for their hard work and commitment to considering the various intricate issues, including the various challenges that come with proposing a rule that encompasses a variety of commodities, entity types, and domestic as well as foreign firms.

Everyone at the FDA works very hard to consider the diversity among the entire supply chain. One of the goals that was a proposed rule is flexibility. We want to maintain traceability throughout supply chains, make sure chains of traceability are unbroken, but also want to be flexible to enable the requirements to work for different business models.

As you listen to the presentations today, you

will likely have a lot of questions. There's 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 a variety of commodities, types of businesses, business models, and for food safety and traceability. In this area is where you have questions or seek challenges in the proposal.

It is important that you provide comments to us in writing and especially provide details about specific scenarios and real-life examples for us to consider. These are the details that help us understand your complexity, and will help us as we move to ensuring a safe and traceable food supply.

So, a little bit of background -- just a brief overview of how we've gotten here: on September of 2011, FDA asked the Institute of Food Technologists to execute two product tracing pilots: FTA -- er, IFT, excuse me, carried out the pilot project at the direction of FDA. In 2013, FDA released the IFT's report on the pilot findings. And, then in November of 2016 the FDA issued a report to congress that describes the findings of the pilot projects, and that often included the agency's recommendation for improving the tracking and tracing of food as required by Section 204 of FSMA.

Also, in February of 2014 FDA issued a federal register notice to solicit comments on our draft approach for developing a list of high-risk foods that we are now calling the Food Traceability List.

And, in September of this year 2020, it's published in a proposed rule-making to establish record-keeping requirements, including the publication of the list of that designation of foods for additional record-keeping requirements. And, here we are today at our second of three public meetings.

So, FSMA Section 204 has a number of considerations and limitations which required a lot of thought in order to craft a proposed rule to rapidly and effectively identify recipients of a food, such as the requirement shall apply only to designated foods, not require a full pedigree, not prescribe specific technologies for maintaining records, and be science-based.

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 said, to draft the proposed rule we knew there was a better way for traceability. Better traceability can be and needs to be achieved individually as well as collectively.

As Frank mentioned, there is a bigger picture here to consider. Transparency is in demand; consumers want information. Food technologies and information technologies to

help the way businesses run are being introduced quicker. And, business are pulled in many directions on which technologies to use, especially for traceability. And, we know that the one step up, and one step back, is not enough.

What we need are data standards, common information, common terminology to be clearly outlined and followed 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 effectively food moves through the supply chain. And, we need technologies to be interoperable.

There are new ideas and tools popping up in traceability technologies, firms of all types and sizes need to be able to determine the technologies that will work best for them with the knowledge that their system will be able to communicate with other systems. The information included in the proposed rule provides that foundation to allow for interoperability. And, it's about interconnectivity.

Hanging it from a responsibility handles, 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 as we see so many diverse supply chains and how they converge. A persistent issue

is linking the movement of a product. The identifiers to link in-coming product to out-going product through the entire supply chain are just not consistently there, and it has a big effect. Lack of interconnectivity affects timeliness, specificity, and response to the incident. And, it affects communication.

We have a difficult time determining a perfect communication because we are waiting for actionable information; this is to everyone's detriment.

So, what would the food traceability rule do? While limited to only certain foods, the proposed rule is 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 rapidly identify and trace foods that may be causing illness. We need to quickly and efficiently list trace the movement of listed foods through the supply chain, and identify and remove contaminated foods from the marketplace.

The food traceability proposed rule was published on September 23rd, 2020. And, we are currently accepting public comments for 120 days through January 21st, 2021. As mentioned in the beginning, we encourage you to provide public comments. Once the public comment period has closed, we will review the comments and work to develop a final rule.

We are under a consent decree to submit a final rule to the office of the federal registrar by November 7th,

2022. The proposed rule has a number of intended benefits. By being able to more quickly identify the source of the contaminated food and remove the food from the market, we would help reduce the impact of foodborne illness outbreaks and prevent additional illnesses and deaths from occurring.

If we had more accurate information to help identify the source of the contaminated -- of contaminated food, we would be able to focus our recall efforts to the implicated products rather than having to issue public health alerts that implicate product categories from growing regions.

More efficient traceability is facilitated when each point in the supply chain is maintaining the same information. Harmonizing and standardizing that information would allow FDA to establish linkages along the supply chain more quickly than we can do now.

We believe our approach is consistent with current industry approaches in terms of identifying the critical points in the supply chain where essential traceability data should be maintained. With enhanced information about the supply chain, we would have more information to inform root-cause analysis to identify and apply lessons learned from outbreaks. This will hopefully help prevent similar problems from occurring in the future.

So, here's a brief overview of some of the key concepts for the proposed rule. These will discussed in greater

detail throughout the day. The proposed rule covers any persons who manufacture processed, packed, or whole foods on the Food Traceability List.

One benefit of the proposed rule is that it touches the entire supply chain from farms and manufacturing processors to distribution centers to retail food establishments like grocery stores and restaurants.

The proposed rule only applies to certain designated foods, which are listed on our Food Traceability List and will be presented in greater detail later this morning. The requirements also apply to both foreign and domestic firms. And, there are some exemptions and partial exemptions, and two options being proposed with regards to retail food establishments.

One approach to traceability and a proposed rule -- excuse me, our approach to traceability and a proposed rule is one that is consistent with current best practices in the industry.

So, we have identified the key points along the supply chain where it is most important to collect traceability information. These are called "critical tracking events", or CTEs, and include the points where the 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. These are called "key data elements", or KDEs, and will provide us with the data necessary to make linkages across points 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 event that is being performed. Importantly, the records required at each critical tracking event -- again, those are growing, creating, transforming, shipping, and receiving.

So, the records required at each of those critical tracking events would need to contain and link the traceability lot code of the food to the other relevant key data elements. By identifying the required key data elements, this will also help to standardize the data the industry maintains for traceability.

An important concept in the proposed rule is placed on the traceability lot code. At every critical tracking event, key data elements must be linked to each traceability lot code of the food that is shipped. This will help make linkages within a firm and across the supply chain. The traceability lot code, and the traceability lot code generator key data elements will help FDA to quickly go back to the entity within the supply chain that originated, created, or transformed the product.

The traceability lot code stays the same as the

product moves through the supply chain until a transformation occurs. In general, the entity who originates or creates the food is the one who establishes and assigns the traceability lot code. This enables FDA to skip points in the supply chain that minimally handle the product and quickly identify that point that can provide FDA with the information leading to the source of the product. There will be more discussion on the traceability lot code, and traceability lot code generator, later on this morning.

So, to help illustrate this point and to visually see how the proposed rule can help in efficiently identifying the source of the product here is an example 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 on paper and/or electronic format, resolving differences in terminology and lack of connectivity, asking the firm clarifying questions at each point -- and this takes a lot of time, and requires a lot of resources.

Under the proposed requirements, FDA would be asking for key data elements related to an entity's critical tracking event for a certain time period, gathering standardized information on paper and/or electronic format, obtaining traceability lot code and traceability lot code generators in order to skip back to the source factor, going to those point

that handles product -- those that create or transform -- order to get to the source efficiently.

Reducing clarifying questions by having access to traceability program records that explain a firm's traceability record keeping processes. This is a vision of the proposed rule, and helps (inaudible) how industry and regulators can work together to have more efficient and accurate traceability.

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

Many of you have heard about the New Era of Smarter Food Safety initiative. Much of our traceability work under this initiative will build on the foundational work of this rule, because ultimately we believe that end-to-end traceability is essential to protect public health and ensure greater transparency through this food system.

Today, you will hear from subject matter experts that were instrumental in developing the proposed rule, along with some of our federal state and industry partner. And, then we look forward to hearing from comments from you all. Again, thank you for joining us today and handing it back to you Kari.

MS. BARRETT: Great, thank you so much Katie for your remarks. And, now we'll go to our next speaker.

We have Karen Blickenstaff, she's our CFSAN response staff director, coordinated response and evaluation network. And, we also have Laura Gieraltowski. She is the CDC lead Foodborne Outbreak Response Team, Outbreak Response and Prevention Branch, Division of Foodborne, Water-born, and Environmental Diseases.

The two of them will discuss the impact of traceability during foodborne illness outbreaks.

So, Karen we'll start with you and then we'll go to Laura. Karen.

MS. BLICKENSTAFF: Great, thank you Kari. Can you hear me okay?

MS. BARRETT: I can, thank you for checking.

MS. BLICKENSTAFF: Yeah, all right. Great, good morning everyone and thanks for joining us here today.

So, my colleague Dr. Gieraltowski and I will be talking a bit more this morning on how traceability impacts foodborne outbreak investigations.

I'm going to start by providing a little bit of background on my office CORE, and then some of the roles and responsibilities of federal agencies during foodborne outbreak investigation.

So, FDA's Coordinated Outbreak Response and

Evaluation network, or CORE, was established in 2011 in order to manage the surveillance, response, and prevention activities related to incidents or outbreaks of illness linked to FDA-regular products to include food, cosmetics, and dietary supplements. CORE consists of several multidisciplinary teams, included among those are three response teams.

The response teams are charged with coordinating complex response activities across the FDA, state partners, and the CDC, bringing all partners together with the ultimate goal of controlling and stopping the outbreak. Outbreaks it corresponds to include one where an in-depth investigation is needed, including the coordination of inspections and investigations, the coordination of sampling efforts, and of course trace-back investigations.

Specific to trace-backs, CORE leads the trace-back analysis from the national perspective in order to help identify a source and the distribution pattern of the implicated foods.

So, there are multiple federal agencies at play when it comes to foodborne illness outbreaks. The Center for Disease Control and Prevention, the FDA, and then USDA's Food Safety and Inspection Services.

Our partners at CDC lead the disease surveillance outbreak protection and investigation.

Additionally, they are involved in education and

training of public health staff. And, you'll hear more from my colleague Dr. Gieraltowski in a few moments regarding the CDC's role in the outbreak response.

As for FDA and USDA, both agencies are charged with establishing food safety policies for the foods that fall under each agency's regulatory authority. We are in charge of inspecting those facilities to insure that they are in compliance with those regulations, we coordinate product recalls when necessary.

For example, when it is determined that a product may present a health hazard to consumers, we coordinate trace-back investigations to determine the distribution of the source of a product that may pose a hazard. And, finally we conduct investigations at farms and production facilities if there is an indication that they could be tied to an outbreak, or is meant to be the source of an outbreak.

At this point, we will transition into more detail surrounding the epidemiology and trace-back work that both CDC and FDA carry out during foodborne outbreak investigations, and some specific examples on how traceability impacts the overall investigations.

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 the delays in the surveillance, ill people are often interviewed about what they ate 2 to 4 weeks after their illness began.

It can be difficult for ill people to remember exactly what they ate, and where they purchased 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 foods or uncommon foods on our standard questionnaires. Ill people may not remember eating stealthy ingredients that are added to foods, such as onion, peppers, herbs, and spices. And, there is often a lack of brand or product information for produce, chicken, and beef. This information is important for our regulatory partners to be able to trace products to the source.

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

Now, I will talk about two case studies that are

examples of outbreaks where the epidemiologic data collection was challenging, and trace-back 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 onion. Onion are a stealthy ingredient, and difficult to implicate with patient recall alone.

Initially, we identified nine illness sub-clusters and red onions were served in all nine. We utilized invoices from restaurants and other points of service to identify a common onion grower. Traceback evidence lead to the company voluntarily recalling red, yellow, and white onion.

Some of the investigation challenges we encountered were: onions are commonly eaten and stealthy, it was difficult to trace back and recall the many foods affected and provide clear public communications, and we learned that it was critical to rapidly interview ill people to identify these sub-clusters.

My next example is a multi-state outbreak of 425 salmonella infections that the 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 trace-back investigation was conducted by the state and local health departments with FDA.

The tracing efforts focused on fresh and frozen tuna supplied to four of the five restaurant clusters. For each of these restaurants, the trace-back 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 in all the restaurant clusters. The common product was a frozen, raw scraped yellowfin tuna from a single processing facility.

Again, the epidemiologic data alone could not identify the source of the illnesses. Traceback was needed to confirm that the 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 import alert, product recalls, and public communications to consumers and retailers. Over to you, Karen.

MS. BLICKENSTAFF: Thanks, Laura. Okay, so when a trace-back investigation is initiated it means we have an ongoing foodborne illness outbreak. Time is of the essence, and we want to move swiftly to prevent additional illnesses.

Tracebacks come with a variety of challenges that we must navigate while trying to move as quick as we can. An up-front challenge is poor consumer recollection of consumption history, and the lack of specific product information.

Understanding the consumer's exposure is the critical first step that needs to happen in order for a trace-back to be initiated. At times, multiple varieties of a certain product, or multiple ingredient items, are identified to determine which specific exposure or ingredient should be prioritized for a trace-back.

At times, we may trace multiple products to help tease out what could be causing illness in order to identify commonalities across the cases.

Additionally, points of sale can and often do have multiple sources of the same product. Poor record keeping is an additional challenge.

Often times, poor record keeping at firms and throughout the distribution chain is an ongoing challenge we face. And, in some instances we receive handwritten records, or records that are difficult or even impossible to read at times.

One of the biggest overall challenges we face when doing trace-back is lack of a rapid and rigorous mechanism to link shipments all the way from farm to fork.

Currently, there is a varying amount of tracing data across the supply chain available, which means we must

piece together information from numerous types of documents in order to extract the useful points, or the useful data, to follow the product all the way through the supply chain.

This can be an extremely time-consuming step. Each of these challenges greatly impacts the efficiency and the effectiveness of the trace-back investigation.

I'm going to highlight the trace-back findings from the E. coli O157:H7 outbreak that was linked to romaine lettuce from the fall of 2019.

This particular trace-back investigation was initiated on November 18th in conjunction with our state partners. In total, the trace-back investigation included 15 points of sale where ill persons shopped and purchased various romaine products.

Now, for the majority of these points of sale we did not have any lot code data available for any of the products that were purchased. Because of this, we needed to request the tracing data to identify all growers who supplied any romaine lettuce used in products reported by consumers and available for sale during the timeframe of September 15th to November 18th.

So, we were looking at romaine suppliers for almost a two-month period. For these 13 out of 15 points of sale without the lot code data available, it took approximately one month to collect, analyze, and identify all the growers that could have supplied lettuce to the points of sale during the

timeframe.

Now, on the other hand there were two points of sale where we did have lot code data for the product purchased. And, in those instances a much narrower scope of data could be requested and the growers were identified within 24 hours or less. And, I want to specifically note here that lot codes are typically not available at the point of sale during outbreak investigation, and I'll go into a little bit more detail on how we obtained them in this instance on the next slide. While this trace-back was ongoing, the case counts were increasing.

So, a broad public advisory targeting a specific 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 trace-back investigation.

So, here this slide just emphasizes the difference in timing regarding comparing the lot code is available versus when it is not available.

So, on this table the first line represents the points of sale where we did not have lot code data. Our trace-back initiation began with state partners on November 18th, and it wasn't until December 13th, or 25 days later that we had a handle on all of the growers that could've supplied product to those points of sale. Because we didn't have the lot code data initially, we had to go back through each step of the supply

chain to gather that information.

So, however, there were two points of sale where we did have lot code information. There was one in Maryland, and that trace-back initiated on November 18th and we had the growers identify that very same day on the 18th. And, then there was a second point of sale in Wisconsin where we did have lot code data available. That trace-back initiated on December 4th, and the following day December 5th we had the grower-level information identified.

So, how did we get the lot codes in these particular situations? As our investigation was starting in mid-November, the Maryland Department of Health informed the FDA of an E. coli O157:H7 contamination in an unopened packaged salad that was collected from a consumer's home.

So, with the availability of that lot code data on the product packaging, the Maryland Department of Health was able to provide the FDA with the corresponding grower information later that same day. Similarly, for the second instance on December 4th, the Wisconsin Department of Health Service reported that E. coli O157:H7 contamination matching the outbreak had been detected again in an unopened bag of leafy green romaine that was collected from an ill person's home in their state. And, they were able to obtain that corresponding growing information the following day on December 5th.

So, for two separate products, which were

separate brands I'll add, FDA was able to obtain that grower-level information within 24 hours or less compared to the 25 days when we did not have any lot code data available. What are the benefits of better traceability?

As shown in this case study, access to specific key data elements creates efficiencies in the tracing process. This situation was unique in that we had product packaging containing the lot code, but it clearly demonstrates how quickly that grower-level data can be obtained when we do have that information in hand.

Now, based on our combined years of experience doing trace-backs we feel that if lot code data and other key data elements are available throughout their supply chain it would likely enable FDA to identify common product sources in 5 to 7 days. This would account for the time necessary to request the record, obtain the records and data, analyze that tracing data across the supply chain in the absence of having that packaging in hand with lot code data on it.

Having this data regularly available could result in swifter product action, and better-scoped product action. We will be able to have a more refined record (inaudible), avoiding the need to have large quantities of records spanning months. These larger (inaudible) are both time consuming for firms to pull and time consuming for FDA to analyze.

So, to summarize: by requiring lot code and other

key data elements to be kept within records throughout 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 illness, and investigate the reason for contamination in a timely manner.

That concludes my presentation, I'll turn it back to you Kari at this point.

MS. BARRETT: Great. Thank you both Karen and Laura for your remarks this morning, and for all of the content that you walked us through. We now have up next Brian Pendleton, he is our senior policy advisor, policy engagement coordination staff, and FDA's office of policy legislation and international affairs. And, Brian will discuss the scope of the proposed rule and exemptions.

So, good morning Brian, and take it away.

MR. PENDLETON: Thank you Kari, can you hear me?

MS. BARRETT: I can, thank you.

MR. PENDLETON: I apologize if there's some leaf blowing, or mowing down below on the streets.

So, hopefully that's not going to interfere too much. Good morning everyone, and thank you for the opportunity to talk to you today about the scope of the proposed rule on food traceability -- that is, the farms and firms that would be subject to the rule as well as exemptions from the rule that we

have proposed.

So, who would be covered under the rule? The rule, as Katie said, applies to persons who manufacture, process, pack, or hold foods that are on the Food Traceability List, or the FTL. And, that includes foods that are specifically listed on the list, they actually appear on the list as well foods that contain listed foods as ingredients. And, this includes entities throughout the supply chain from the farms and manufacturers and processors, to the distributors and wholesalers and all the way to retail food establishments including but not limited to grocery stores, convenience stores, vending machine locations, restaurants, online food retailers, and meal kit delivery companies.

And, this applies to both domestic and foreign entities that manufacture, process, pack, or hold FTL foods. This slide presents an overview of the exemptions that we have proposed and I'll be talking about. Some of them are set forth in the statute, Section 204 of the FSMA.

That includes farms that sell foods directly to consumers, and food that's produced, packaged, and labeled a certain way on the farm. And, we have also proposed exemptions on our own initiative for very small farms, produce, and shell egg that receive a certain processing. Produce that FDA has listed as being rarely consumed raw.

Transporters of food, non-profit food

establishments, and those who manufacture, process, pack, and hold food for personal consumption. We've proposed some partial exemptions, some of which are consistent with the statutes.

For example, commingled raw agricultural commodities, very importantly as I'll mention it doesn't include fruits and vegetables. Fishing vessels, and farm-to-school programs, and there was one partial exemption in the statute that applied to grocery stores who received food directly from a farm and we propose to broaden this to all retail food establishments.

It's also important to note an additional partial exemption for foods on the Food Traceability List that receive a kill step. If, under the proposal of a person applied the kill step -- that is, processing it to significantly minimizes the pathogens such as cooking or pasteurization, to of the foods on the Food Traceability List, they wouldn't be required to maintain the records required by the rule or the shipping of that food as long as they document the application of that kill step.

In addition, subsequent recipients of a food on the kill step to which... a food on the Food Traceability List to which a kill step has been applied would not need to maintain the records that would otherwise be required under the rule.

The first exemption I'll talk about is for a certain small originator of food, and the proposal defines the

originator as a person who grows, raises, or catches a food or harvests a non-produce commodity. That would include things like egg collection and taking seafood in an aquaculture operation. Farms or farm activities of farm mixed-type facilities would be exempt from the rule with respect to the produce that they grow when the farm isn't a covered farm under the produce safety regulation in accordance with the provision in Section 112.4A.

Basically, that means that farms with no more than $25,000.00 in average annual monetary value of produce sold. Also exempt would be shell-egg producers with fewer than 3,000 laying hens at a particular farm, as well as originators of other types of food and an average annual monetary value of food sold of no more than $25,000.00 This would include small aquaculture farms, and potentially small farms that grow non-produce farms if the food were to be added at some point in the future to the Food Traceability List.

Another exemption, it's for farms when the food is sold directly to consumers. The exemption would apply to a farm with respect to food produced on the farm, including food that's also packaged there that is sold directly to a consumer by the owner, operator, or agent in charge of the farm.

This would include applicable food sales at farmer's markets, roadside stands, internet food sales, and sales through community-supported agriculture programs. As an

exemption proposed for certain food that is produced and packaged on a farm -- so, the rule wouldn’t apply to food that's produced and packaged on a farm provided that certain conditions with respect to the packaging and labeling are met.

Specifically, the food's packaging would have to remain in place until the food reaches the consumer, and that packaging would have to maintain the integrity of the product and prevent subsequent contamination or alteration.

In addition to the food's labeling that gets to the consumer, without specifying the name, the complete address, and the business phone number of the farm, although we waive the requirements that include that business phone number to accommodate the religious belief of the farm owner.

An example of a food that could be eligible for this exemption 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. But, not eligible for this exemption would be things such as produce that is produced that is packed or packaged in containers such as clamshells with holes, cardboard boxes, vented crates, plastic bags with holes, and netted bags.

So, those would be foods that would not be eligible for the exemption. 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 and the produce safety provision in Section 1.12-2B are met.

Basically, that means that the -- that refers to the application of the commercial processing, disclosure that the food is not processed to adequately reduce the presence of microorganisms of public health significance, and a written assurance from the customer that it, or a subsequent entity in the supply chain for that produce, would be performing the commercial processing.

It's important to note that this exemption would apply to all who manufacture process, pack, or hold that produce; not just the farm that grew it. And, it would apply both before and after the processing takes place.

The rule also wouldn't apply to shell eggs, but 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 egg. And, that regulation defines this treatment as "The technology or process that achieves at least a 5-log destruction of salmonella and (inaudible) for the shell eggs. Or, the shell eggs would need to be produced with the Egg Products Inspection Act."

We're also proposing to exempt produce that's rarely consumed raw; the produce safety regulation lists a number of foods that are deemed to be rarely consumed raw. I'm

going to go and list all of them now, but some of the examples would include beets, sweet corn, potatoes, and several kinds of beans.

So, produce rarely consumed raw would be exempt. We are proposing a partial exemption for commingled raw agricultural commodities. The rule generally wouldn't apply to a commingled raw agricultural commodity which the statute and the proposed rule defines as a commodity that's combined or mixed after harvesting, but before processing.

So, very importantly, this would not include fruits or vegetables that are raw agricultural commodities that are subject to the produce safety regulations. In fact, shell eggs are the only potentially commingled raw agricultural commodity that are currently on the Food Traceability List.

So, that would be a general exemptions but if a person manufactures, processes, packs, or holds then such a commingled agricultural commodity has to register with the FDA as a food facility with respect to that commodity. And, they would have to keep records identifying the immediate previous source, and immediate subsequent recipient of that produce for that raw agricultural commodity in accordance with the existing food traceability regulations in Subpart J.

So, some of these facilities are subject to the Subpart J traceability requirements. Those who aren't would now need to keep under the proposed rule these one-up, one-back

records that would be required under Subpart J. Another exemption we are proposing is for retail food establishments which the proposed rule defines as establishments with 10 or fewer full-time equivalent employees. And, we're actually -- we propose a co-proposal for this exemption. Option #1 would be a full exemption from the rule for these small retail food establishments. Option #2 would be exemption from the requirements to make available to FDA in certain circumstances an electronic sortable spreadsheet that contains traceability information that we are requesting for certain foods and certain date-ranges.

We would request this spreadsheet, as what we discuss later today, in circumstances such as when we're (inaudible) a foodborne illness outbreak investigation to help prevent or mitigate foodborne illness outbreak when we're assisting in a recall implementation, or otherwise addressing a threat to public health.

For example, when there's a reasonable belief that a food poses a risk of serious adverse health consequences or death. Now, these two options have different pros and cons.

For example, the full exemption -- because of a lesser volume of food of these smaller establishments, the compliance costs might outweigh the benefits and we might be able to obtain information from larger firms that sold the same food using the same distributor. But, a full exemption for the

small retail food establishments could delay our ability to -- if they needed information that -- the information that we need when we're investigating outbreaks. And, also could hinder our ability to narrow the scope of implicated products during an investigation.

With respect to the exemption for -- from the requirement to make available a sortable spreadsheet, the smaller firms might be less likely to have the resources needed to easily produce such a spreadsheet.

So, exempting them from the requirement could ease their burden. At the same time, that would keep them within the scope of the proposed rule and retain the traceability benefits that that would yield.

So, we request comment on each of these options or any other alternative approach that you think might be appropriate for these small retail food establishments under the proposed rule. We're also proposing an exemption for retail food establishments regardless of size. This would be a partial exemption.

Under this, the rules generally wouldn't apply to retail food establishments regarding food produced on a farm, including food produced and packaged there and then sold directly to the retail food establishments by the farm's owner, operator, or agent in charge.

But, the retail food establishment would have to

keep a record for 180 days just so the name and address of the farm that was the source of the food. Similarly, we're proposing a partial exemption for farm-to-school programs.

The rule generally wouldn't apply to an institution operating a child nutrition program authorized on the Richard B. Russel National School Lunch Act, or Section 4 of the Child Nutrition Act of 1956, or any other entity conducting a farm-to-school or farm-to-institution program regarding the food that's produced on the farm and sold directly to the school or the institution.

But, the school food authority, or the relevant food procurement entity would have to keep a record of, again, the name and address of the farm that was the source of the food.

We're also proposing a partial exemption for the use of fishing vessels. The rule generally wouldn't apply to the owner, operator, or agent in charge of a fishing vessel with respect to food that's produced through the use of the vessel. But, if the owner, operator, or agent in charge has to register with FDA as a food facility with respect to the food that is produced through the use of the vessel.

So, for example if the vessel catches the food and also conducts the processing on the vessel then that person would have to keep the one-up, one-back records that are required under the existing Subpart J traceability requirements.

Other exemptions that we are proposing are for transporters.

We think that in most cases for the type of information that we are requesting be maintained under the proposed rule, we can get this information from others in the supply chain for foods.

So, we're proposing to exempt transporters. Also exempt would be non-profit food establishments, persons who manufacture, process, pack, or hold food for personal consumption, and 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 foods.

For example, this would include persons such as a hotel concierge reception desk staff and an apartment building staff in an apartment that receive and store foods on the foods traceability list for consumers but they're party to the purchase of the food and they're not in the food distribution business.

So, that's a brief overview of the scope of the proposed rule, as well as the exemptions that we have proposed. I look forward to your comments on these issues later this morning, thank you.

MS. BARRETT: Great, thank you so much Brian for your remarks. We are now going to conclude our first group of subject matter expert presentations. And, we have next in our

lineup Yuhuan Chen. She was a CFSAN Interdisciplinary Scientist, Division of Risk and Decision Analysis. And, Christopher Waldrop, he's our CFSAN Senior House Scientist, Office of Analytics and Outreach. They will speak in more detail on the Food Traceability List.

We're going to start with Yuhuan, and then we'll go to Chris. Yuhuan.

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

MS. BARRETT: I can, thank you.

MS. CHEN: Thank you very much. Greetings everyone. To inform the designation of the Food Traceability List, which involves a risk-ranking model for food tracing, I will give an overview of the model and highlight the development process model criteria, and how we classify foods and score commodity-hazard pairs. I'll begin with the FSMA requirements, talk about the methodology, and give result examples. In FSMA Section 204-D2A, (inaudible) lays out the requirements on which the designation of high-risk foods must be based.

It must be based on (inaudible), the known food safety risks including the history of outbreak, 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 broad range of subject matter experts. We put together a project advisory group, and developed a draft approach which was published in 2014 for comments.

We then revised the approach, collected data, and developed a model. As is the case for our risk assessments, we conducted peer-reviews of the model and the underpinning data. Throughout this process, the project advisory group helps decide how best 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 at the Food Traceability List, was to create a data-driven model, use it to score food hazard pairs based on the risk factors specific in FSMA and everyday scores appropriately to create a ranked list of foods, such as for commodities and commodity categories.

So, designating the list is a policy deliberation. My colleague Chris Waldrop will talk about the risk management decisions shortly. The risk-ranking model has seven criteria. To address the statutory factors, we created

these criteria using best practice in decision and analysis.

This figure 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 cost of illness.

This is a multi-criteria decision analysis model for ranking food hazard pairs based on public health criteria.

So, how do we classify foods? We consider both the food characteristics and the manufacturing process, and classify FDA-regulated human foods into 47 commodity categories.

For example, low-acid canned foods, and fresh produce. These commodity categories are adopted from similar categories in the reportable food registry -- RFR program -- and, the facility registration program. Within each commodity category we identify commodities, and overall a comprehensive list of commodity-hazard cares based on data and expert knowledge. The model then scores each pair independently. To do that, we need scoring definitions.

Let me take a minute to go over a couple of examples. Here is the scoring definition for Criterion #1. It's a matrix with the frequency of outbreaks on the X-axis, and the occurrence of illnesses on the Y-axis.

So, each food hazard pair, based on data, a score of 1, 3, or 9 is assigned.

For example, 10 outbreaks in 1,000 cases would give a score of 9. On the other hand, if we have one outbreak in 100 cases the score would be 1.

The number of outbreaks and cases are weighted by the year for relevance. Data weighting is explained in detail in the methodology report, which is Reference #16 in the proposed rule.

Here is a scoring definition for Criterion #3, the likelihood of the contamination of the hazard in the food. The definition is based on sampling data, or other data such as RFR and recall data.

For example, if the contamination rate is more than one percent the score will be 9. Sampling data are also weighted for relevance.

We developed scoring definition 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 elicitations to fill the

data gap.

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 distills all these data, scores the seven criteria for each commodity-hazard pair, and eventually generates a ranked list of commodities.

Considering microbial and acute chemical hazards, we identify approximately 770 commodity-hazard pairs that involve 210 commodities and 60 hazards. The model uses over 10,000 data points. Let me draw your attention to the left 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 scoring definitions.

The branch shows how the model calculates a risk score for a commodity-hazard pair, such as a Commodity A, Hazard 1; it is 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 is associated with multiple pairs.

From there, the model abrogates the scores for the pair to calculate a risk score for the commodity; 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 a subset of the overall 770 pairs in the model.

The color blocks indicate the contribution from the criteria scores. The figure on the right shows a branched list of a subset of commodities. The longer the bar, the higher the risk score. To facilitate understanding of the model, we have created a user-friendly tool; a web-page that can be accessed at the URL on the slide. The tool is interactive; it allows you to review 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 requirements that is systematic, science-based, and data-driven. And, it has been peer reviewed to ensure credibility. With that, I will hand it over to Chris.

MR. WALDROP: Hi everyone, can you hear me?

MS. BARRETT: Yes, we can. Thank you Chris.

MR. WALDROP: Okay, great.

So, thank you very much. Good morning everyone.

There are a few other aspects of the Food Traceability List we wanted to highlight. In using the data from the model and developing the Food Traceability List, FDA is focused on 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 potentially contaminated with E. coli O157:H7, or reef fin fish potentially contaminated with ciguatoxin. 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 the packaging of the food in most cases. FDA can then rapidly identify the source of the allergen-containing food and take appropriate regulatory actions.

Therefore, enhanced record keeping for traceability would not greatly enhance FDA's ability to identify

and response to undeclared allergens in food. Third, as we review data used in the model to generate the Food Traceability List we decided to not include results for certain food hazard pairs that were attributed to contamination and/or growth of pathogens at retail or point of service.

Examples of this include C. perfringens in fresh soup, or norovirus in cakes. Such contamination is generally due to unsafe food practices at retail and point of service, such as lack of timed temperature control, ill food workers, or improper cleaning and sanitizing of food surfaces. Once the retailer or point of service location is identified as the source of contamination, there's no need to further trace the source of the food.

As such, enhanced record keeping requirements would not significantly improve traceability in those situations. FDA considered different levels of granularity in categorizing food for the Food Traceability List, such as commodity and commodity category.

An example of a food at the commodity level would be tomatoes, while food at the commodity category level would be the broader produce or agricultural commodity. We determine that commodity was the appropriate level of granularity for the Food Traceability List.

Food items within the same commodity designation generally have similar characteristics, associated hazards, and

production and supply chain 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 pair is 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 had described. More information about how this was done is available in a memo, accompanying the proposed rule, and included in the docket.

Using the results of the risk-ranking 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 variety of tomatoes including roma, beefsteak, cherry, etc., or all varieties of peppers such as sweet peppers, poblano peppers, jalapeno peppers, etc. For some foods, there are a few exceptions.

For example, the category of fin fish would not include (inaudible) fish such as catfish as those are regulated by USDA. Additional detail is available in a memo accompanying the proposed rule, which 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 a peanut butter filling that do not undergo a kill step would also be covered by the proposed rule. Each proposed requirement in the rule pertains to all such foods, unless an exemption applies.

Comments may be submitted on the Food Traceability List, in addition to comments on the proposed rule. We will publish a final version of the Food Traceability List when we publish the final rule. One other note, we have received a number of inquiries already seeking more information about specific foods, or type of foods, that are on the Food Traceability List.

We are currently considering ways to help clarify that, and will be releasing additional materials in the future. 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 to happen very often.

If we do determine we should update the list, we will do so via a notice from the Federal Register providing the public with an opportunity to comment. We will then review those comments and post a notice in the Federal Register identifying any changes we decide to make.

Any additions to the list would become effective one year after the date we publish any final changes to the Food Traceability List, unless otherwise stated in the notice. Thank you very much, and with that I'll turn it back over to Kari for the next part of our agenda.

MS. BARRETT: Great, thank you so much for your remarks Chris and Yuhuan. We are now at a point where we are going to take some questions. There are quite a few question in our chat.

A couple of reminders: if you have additional questions, as noted please submit them to the chat. What I'll do is I will read the questions out loud to our earlier presenter who are all now coming online, you should be able to see them in a moment. And, we may have some additional -- up to 18 members available too, if they're needed for the question.

So, let's just wait a second make sure we have everybody. Okay, so I think we're ready to start with the questions. It looks like our first one is for Karen, and the question is: "If lot code data is available on packaging, why would it also be needed on records?"

MS. BLICKENSTAFF: Yeah, thanks Kari. That's a good question.

So, in speaking directly to the case study I presented that particular situation was pretty unique and not typical of what we traditional see. It's pretty rare,

particularly in produce outbreaks involving products with short shelf-life that we have products with packaging collected from an ill person's home which ends up testing positive for the outbreak strain.

In the majority of the situations, the product and packaging in question, or the outbreak may be linked to items that don't have any sort of outward packaging you know, which is common especially in terms of produce.

So, in the majority of outbreak instances we'd need to refer to the records from the supply chain to get the lot code data and other key data elements in order to quickly identify the ultimate source or growers of the product in question.

MS. BARRETT: Great, thank you so much. It looks like our next question may be best for Becky Goldberg, if Becky's on. The question is: "Could you please provide additional clarification regarding the partial exemption for fishing vessels and how that would apply to foreign persons?"

MS. GOLDBERG: Yes, hi. This is Becky, can you hear me?

MS. BARRETT: Yes, I can.

MS. GOLDBERG: Great, thanks. Yeah, great question.

So, first of all, all of the requirements and exemptions here apply equally to foreign entities as well as

domestic entities.

So, there's not a difference there. And, with respect to the specific partial exemption for food produced through the use of a fishing vessel, that exemption is set up the same way as a couple of the other ones that you'll find in the rule, like the commingled agricultural commodities. In both cases they say that, except as specified later in the draft language that you would be exempt.

So, in the case of fishing vessels it's ‘except as specified’ in paragraph J2 with respect to a food that is produced with the use of a fishing vessel, the Subpart does not apply to the owner, operator, or agent in charge of the fishing vessel.

So, in general the main takeaway is that the fishing vessel is exempt, except you just need to look at that J2. And, that J2 only talks about if you are required to register with FDA under section 415 -- so, that's food facility registration some of you might be familiar with.

So, sometimes there are fishing vessels who have to register as food facilities; I think it's the larger ones that do processing, and think like that. If you're in that type of situation, then you don't get a total exemption here.

You're still exempt from everything that's explained in the proposed rule, but the one things you do need to do is keep one-up, one-back records. And, the specific

provisions are stated here -- it's 1.337 and 1.345 that comes from the Subpart J requirements that some of you might be required -- might be familiar with.

But, that's only if you're a fishing vessel that has to register with FDA, and those types of fishing vessels should already know who they are because they are registering with FDA. For all other fishing vessel, it's a total exemption from these proposed requirements.

So, I hope that helps. And, some of the other exemptions are structured the same way that came directly from language that congress provided.

MS. BARRETT: Great, thank you. Thank you for elaborating on that. Okay, our next question is for Chris, and this is a little bit long so bear with me. Collards... let's see, let me go... "Collards are on the list of produce that is rarely consumed raw, which is Section 112.2-A1, and listed as a leafy green on the Food Traceability List. But, a different Section 1.1305E appear to indicate anything on the list of produce rarely consumed raw is exempt. Why not just remove collards from the traceability list?"

MR. WALDROP: Yeah, thanks Kari. Good question.

So, collards are a type of leafy green which is why they were included in the description of leafy greens on the Food Traceability List. However, the questioner is right that they are -- collards are listed as "rarely consumed raw" as part

of the produce safety regulations.

So, therefore collards are exempt from the proposed food traceability rule based on that exemption.

So, apologies for any confusion on that. We sort of inadvertently included collards on that description of leafy greens on the list, but collards are exempt from the traceability rule.

MS. BARRETT: Great, thanks for that clarification. Okay, the next question Brian: "What is defined as farm under this rule? Is it the same as defined in CFR 112?"

MR. PENDLETON: Thanks Kari. I think that... well, the proposed definition of farmer refers to -- excuse me, the definition of "farm" in the existing Subpart J traceability requirements -- sorry-which is that 1.328, and I believe -- and there's others here can confirm that that aligns with the existence, er, the definition of "farm" in the produce safety regulation at 1.123C. And, I believe it also in the preventive controls regulation as well. But, if Chris or Katie can confirm that, I think that is the case. I believe that we tried to do that.

MS. BARRETT: Does somebody else want to weigh in on that?

MS. BUCKNER: Hi, this is Rebecca Buckner. Yeah, I can weigh in on that. Yes, it is aligned. It is aligned across the produce safety rule, and the preventive controls

rule. The only place where the definition of "farm" is slightly different from the one Brian mentioned under the registration rule making is, the definition farm for eggs which is defined in Part 118, and is a little different. But, otherwise the definition for farm is aligned across all those rule making.

MS. BARRETT: Great, thank you.

MS. GOLDBERG: And, just to clarify further. Hey, sorry this is Becky. Just to clarify further, the way we define -- the way we propose to define a rule... sorry, the way we propose to define farm in this proposed rule is specifically by pointing to those two other definitions.

So, we propose to define it the same as it is in all the other rules. We point directly to that definition, except for eggs -- we propose to define it the same as it is in the egg rule, and point directly to that definition.

So, in both cases it’s completely aligned in the proposal.

MS. BARRETT: Great. That's good, okay. Now, the question -- Becky, glad you're there, it's for you: "If an exempt farm sells, for example, leafy greens to a first receiver who needs to have a location identifier and location description of that farm, doesn't that negate the exemption for the farm? (Location ID and description of harvest, cooling, packing)." Let me know if you need me to repeat any of that.

MS. GOLDBERG: I have it. No, thank you. Yeah,

this is a great question.

So, no, we don't think that it negates the exemption for the farm. So, this type of situation arises if the farm is exempt because of its size, right?

So, the extremely small farms -- the same ones that are exempt under the produce safety regulation are also exempt -- would also be exempt in this proposal. So, they are exempt. Right?

So, they have no requirements to establish and maintain any records. However, it is a good point that other people in the supply chain whoever purchases the food next, which might be the first receiver or it might be another farm -- sometimes it happens that way -- but, whoever it is, if the next person in the supply chain is not exempt then they are going to need to know some things. Including, as the question points out, they'll need to know things like the location identifier, and the location description of the farm that they bought it from.

You know, we anticipate that they would be able to know those things. Right? The name and the place of the farm they got it from, however we do welcome comments on if there would be situations where it would be hard for them to figure out the things they need to know in light of the fact that the original farm was exempt.

So, we definitely welcome comments on that.

Yeah, hope that helps.

MS. BARRETT: Great, thank you. And, there are a number of additional questions so we'll go to our next one. Katie, I think this one is for you: "What responsibilities do retailers have to track to each consumer?"

MS. VIERK: Hi, thanks Kari. Right now, under the proposed rule there are no requirements for retailers to track to individual consumers; that is not part of the proposed rule.

MS. BARRETT: Great, thank you for the clarification. All right, Brian here's one for you: "Under location description there is the phrase 'Physical location name'. What is that?"

MR. PENDLETON: Thanks Kari, that's a good question. And, we propose to define the physical location name as the words that are used to identify the specific physical site of a business entity where a particular critical tracking event -- transformation, shipping, etc. -- occurs. And, if the produce states that a physical location name, it might be the name -- it might be same as the an entity's business name if the entity has only one physical location.

So, there's a proposed definition of the term 'Physical location name' which would apply in the context of the regulations where that KDE is requested.

MS. BARRETT: Great, thank you Brian. Chris,

this is one of scopes, let me get to it. The question is on the Food Traceability List, meat salads are exempted from ready to eat deli salads. And, the question is: "What are some examples of meat salads? Tuna salad? Ham salad? Deviled ham?"

So, what do we mean when we say meat salads?

MR. WALDROP: Sure.

So, the intention around the term meat salads was to refer to salads that are regulated by USDA such as chicken salad, or ham salad for example.

MS. BARRETT: Okay, thank you. All right it looks like we have a lot of questions here. Becky, "if a traceability lot code should be a on package, are you considering adding this to the proposed rule?"

MS. GOLDBERG: All right, thank you. Yeah, there's been a little confusion on this. The proposed rule does not require the traceability lot code to appear specifically on the package. We've tried to set it up to be flexible in terms of how the traceability lot code would move through the supply chain; it does not have to be specifically on the package.

MS. BARRETT: Great, thank you. Another good clarification. Yuhuan, this one is for you: "Would the number of hazards associated with a commodity impact its chance of being on a Food Traceability List?"

MS. CHEN: Thank you for the question. The number of hazards? Not necessarily. Because, how we identify

the hazards and how we score commodity-hazard pairs are two different steps. The inclusion of a pair in the model for scoring does not necessarily mean data across seven criteria would indicate that the pair would receive a relatively high-risk score.

So, usually each commodity is associated with multiple hazards therefore multiple commodity-hazard pairs. The model scores each pair independently, and then abrogates the scores for the pairs to calculate a risk score for the commodity. The abrogation method is not sensitive to the number of commodity-hazard pairs. The risk score for the commodity based on the methodology which is explained in the methodology report -- the risk score for the commodity is mainly driven by the highest score commodity as a pair.

So, overall the number of hazards identified for one commodity does not necessarily affect whether the commodity would have a risk score that is above the line, so to speak.

So, we took this approach, this two-step approach, so that it can allow us to identify a comprehensive list of commodity-hazard pairs for scoring without worrying ahead of time that whether a pair would get a high score or a low score. And, so that is an important aspect in this systematic approach that we took. Thank you for the question.

MS. BARRETT: Yes, thank you. Thank you for expanding on that.

So, the next question, Becky I think for you, is: "Please expand on what a full pedigree is referencing."

MS. GOLDBERG: Right, thank you for that. And, to clarify, the proposed rule would not require a full pedigree. In fact, usually I think if we're referring to a full pedigree we're referring to it specifically to make the point that we are not requiring a full pedigree. In fact, in the Food Safety Act congress specifically instructed us not to require a full pedigree.

So, I think what that phrase usually means is a complete list of everywhere -- this is just in my mind, it's not a phrase that we've defined -- but, I think generally what it would mean is a complete list of everywhere that a food has been. Right?

So, we're not requiring that a retail food establishment, for every food they have, that they themselves know every single place in the supply chain that that food has ever been. Right? We're doing things differently.

So, I think that's usually how the phrase is used but again that's not something that we're proposing to require.

MS. BARRETT: All right, great. Thank you. Let's see, I think we have time for one more. Karen, if you have lot code data for some of the salads, why was the broad advisory still needed?

MS. BLICKENSTAFF: Yeah, good question.

So, again, this is referring back to the specific example that I noted in my presentation.

So, the initial positive sample results that gave us the lot code data were available on November 18th, and this was the same time we were initiating our trace-back investigation at multiple points of sale. And, from the records we were reviewing we noted evidence of co-mingling of romaine in the finished product.

So, one lot of finished product contained romaine source from multiple growers.

So, while we have the grower level data it does not clearly pinpoint one grower.

Additionally, there were discrepancies noted in grower and harvesting information provided at a processing level.

So, ultimately the lack of standardized KDEs really hindered our ability to quickly narrow the scope of the trace-back to particular growers and ranches.

So, to prevent additional illnesses, we have to go out with a broad public advisory on November 22nd. And, in that second positive product sample which provided additional insight into the source of contamination was not identified until November 4th.

So, that was a couple weeks after the initial advisory had gone out.

MS. BARRETT: Great, thank you Karen and thank you to all of our morning presenters. Great session, very good Q&A. As noted, there are some remaining Q's that we're not going to have time for. Certainly, all of the Q's inform the content of our public meeting. It will inform whether or not we need to put out some more communications to offer further clarifications. But, if you did submit something specific that you would like to get a response from the FDA on, please resubmit your question to our CFSAN technical assistance network. It's also called the TAN, you will find that on our CFSAN website. And, then that way it's ensured to get a response and we can also continue to track the questions that we're getting.

So, at this point it is time for us to take our first break. We're going to take 15 minutes and we'll reconvene right around 11:30.

So, thank you everyone and we'll now break.

SPEAKER: Thank you Kari. Our next section.

MS. BARRETT: We sure will, and I see Angela is ready so we're going to jump in.

So, welcome back everybody. I hope you had a good break. We'll continue now with our second group of subject matter expert presentations. And, first up we have Angela Fields, CFSAN senior consumer safety officer and CORE who will discuss the requirements of the proposed rule.

So, Angela.

MS. FIELDS: Thanks Kari.

So, today I'll be discussing the proposed record requirements under this rule, and we'll be discussing what records will be necessary for the traceability program, what the key data elements or the KDEs that would be required for each critical tracking event or CTE, how we are proposing to qualify for an extension or waiver, and what records would need to be maintained. The traceability information is maintained in varying ways and forms across the food industry.

As a result, there can be a significant impact on the time needed to analyze tracing data collected from each firm during a trace-back 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 that 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 investigation.

Additionally, person's that would be subject to these requirements may enter into agreements with individual-to-firm to create and keep the records that would be required for

this rule on their behalf. This is to accommodate the varying business relationships and constructs, and it should be noted that these and all other records that would be required under Subpart S.

While most of the proposed records would need to be retained from two years from creation, all traceability program records would be required to be maintained for two years following their discontinuance.

Having a record of these changes would be helpful during retrospective outbreak investigations, or historical cases were associated with an ongoing outbreak investigation. All firms that would be covered by the rule would be required to maintain traceability program records. Listed here are the components that would be required for a firm's traceability program. A description of relevance, reference records.

While it is encouraged that they require 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 projection logs.

A firm's traceability program records would mean to include a description of the reference records on which the firm maintains the required KDEs. This description would

explain where on the reference record the traceability information appeared and, if applicable, a description of how reference records for different tracing events for food are linked.

Linkage up to incoming and outgoing products, such as product descriptions and to the next firm. We have also proposed a list of foods on the food tracing list that are shipped. The proposed rule would require anyone who shipped food on the food tracing list to keep a list of which safe foods they shipped 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 food tracing list foods list can help FDA and a firm more quickly identify associated foods, potentially speeding up timing on product actions.

This list can also assist a firm when identifying foods that a firm manufacture, processes, packs, or holds that will be subject to this rule. The list of foods which indicates which foods on the food tracing list a firm generally ships, even if there are gaps in the shipment.

Additionally, a description of how traceability lot codes are assigned. The traceability lot code allows a food to be unique identified within the supply chain.

As a part of a firm's traceability program record, firms will be required to describe how they establish

and assign traceability lot codes. Because of the crucial role that traceability and lot codes play in the proposed rule, it is important the regulators know how firms created and assigned these codes so that they can better understand the scope of the records they are reviewing.

Also, other information that may be needed to understand data provided within the required record. The proposed rule would require firms traceability program records to include any other information that would be needed to understand the data within their traceability records, such as internal or external coding systems or classification schemes, (inaudible), and abbreviations.

This would help regulators understand the terminology, methods, and systems a firm uses in its traceability operations. Traceability lot codes are proposed to be a descriptor that is used to identify a traceability lot.

This is similar to what industry currently refers to as a lot, or lot code. Traceability lot codes are an essential part of this rule, as all KDEs would be required to be linked to them in the records provided to FDA.

We wanted to ensure that a single descriptor could be used to easily identify specific product lots, referred to as the traceability lots in this proposed rule. It should be noted that traceability lot codes stay the same through the entire supply chain, unless there's an activity that are

performed which will be discussed next.

The proposed rule also allows for flexibility, as it relates to establishing a traceability lot code. There are no proposed requirements on how a firm can create their traceability lot codes.

The traceability lot codes can be a firm-only lot code, or in addition to other lot codes used with that firm's internal traceability system. For foods on the Food Traceability List there's also no proposed requirement to place or create KDEs along food products.

Firms that manufacture, process, pack, or hold foods on the food tracing list would be required to create and maintain records of the key data elements that are relevant to the CTEs, or critical tracking events, performed by that firm.

Firms that ship food along the food tracing list would also be required to send certain KDEs including the traceability lot code to the receiving firm.

The traceability lot code, and other KDEs, would not need to be written on the package of the product but they could be sent other ways. Such as via email, or as a part of a document that accompanies the shipment such as a bill of lading.

As mentioned, traceability lot codes are essential to this proposed rule and should only be manipulated in specific situations to avoid creating confusion that can hinder trace-back and trace-forward efforts. Therefore, the

traceability lot code would only be able to be established or assigned in a firm originates, transforms, or creates a food on the food tracing list and would be linked to the records containing the required KDEs.

In situations where a first receiver receives the listed foods, where the originator has not assigned the traceability lot code the first receiver would be required to establish and maintain a record of the traceability lot codes for the 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 collection 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 a point of service, then 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 the 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 within a single firm.

To improve traceability as envisioned by the proposed rule would allow FDA to more quickly identify the source of a contaminated product, reduce the scope of product recalls, and conduct more timely root-cause investigations to learn about how contamination occurred in order to prevent future outbreaks.

At the heart of the proposal is the 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. For each CTE, entities would be required to establish and maintain records for key data elements.

The CTEs include the points where food would be grown, or food would be transformed either by changing a food on the food tracing list, its package and/or its label regarding the traceability lot code or traceability product identifier such as by combining ingredients or processing a food, either by cutting, cooking, comingling, repacking, or repackaging for example.

Also, where food on the food tracing list would be first created, making or producing a food on the Food Traceability List.

For example, through manufacturing or processing. And, using only ingredients that are not on the Food Traceability List. The definition further states that creating

does not include originating or transforming of foods. And, where the food would either be shipped or received from one point in the supply chain to another.

The proposed record keeping requirement would apply to all foods on the food tracing list, which includes products that contain listed foods as ingredients.

Firms can elect how they would like to maintain their KDEs, however they again would be required to be linked to the traceability lot code. One of our CTEs represents what key data elements are required for growers.

Many farms are in rural locations that lack street addresses.

In addition, these 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 for their farm and the shipment record information in name of the transporter.

The grower would also need to provide certain KDEs to the next point in the supply chain, linking these data elements 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 this presentation.

It should also be noted that the growing coordinates would not be required to be passed along unless the grower chooses to do so. The only requirement would be to

maintain a record of them, and provide the information to FDA when necessary.

Since sprouts pose unique safety concerns, as reflected in the special provisions for sprouts in the produce safety regulations, additional KDEs would be required for growers of sprouts. These KDEs would create linkages between spouts and the seeds used to produce them.

Requiring sprouts for (inaudible) records on seed lot assigned by seed harvesters, conditioners, processors, and repackers, along with the dates of seed harvesting, condition, processing, and repacking could help to better scope a sprout recall event and identify the seed lot used to grow the sprouts involved in a contamination event. Another CTE that we've identified is shipping. Shipping would be the other KDE -- 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 shippers of listed foods to keep are similar to the records that receivers of foods would have to keep. And, by requiring that most of these records be passed along from the shipper to the recipient, the rule would avoid dislocation of efforts and ensure that the requirements for the receiving CTE could be met. As was the requirements for the receivers of foods, if an important food was subsequently transformed a shipper of the food produced through transformation would not be required to keep or send

forward a record of the entry number, or any imported foods that is a component of the food.

In addition to the shipping, there are also been KDEs that have been identified that must be sent forward. To ensure that those who receive foods would be able to obtain the information they would be required to keep under the proposed rule, we propose to require persons to ship listed foods to provide their customers with certain information related to the foods they ship, and, as this information may not always be provided under current commercial practices. Our next CTE is receiving.

The receiving CTE would be one of the CTEs that all firms and supply chains would be responsible for maintaining with the exception of the originator or creator of the food. For retail food establishments -- especially small RFEs -- that would be covered by the proposed rule, we recognize that many may find record keeping requirements to be challenging.

We are therefore proposing to require their suppliers to send them most of the records that the RFEs would be required to keep 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 that would be documented, the resulting food would not be regarded as being imported and the receiver of the food produced through transformation would not be required

to keep a record of the entry number or any imported food that is a component of the transformed food.

In addition to maintaining receiving KDEs, certain firms would be required to maintain first-receiver KDEs. A receiver of a food would be the first person other than farm who purchases and takes physical possession of a listed food. Examples of these first receivers could include manufacturers, processors, buyers of seafood from fishing vessels, and distribution centers.

Only listed foods that are originated, grown, or harvested for a non-produce commodity, raised or caught, would have a first-receiver. The concept of the first receiver was created because foods on the Food Traceability List to include several different commodities with (inaudible), growing, and production practices and associated business relationships.

Because of this, the first receiver would be the first person who was best positioned 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 ensure that comprehensive records relating to the origination and handling of the foods were maintained by a single person who both owns and possesses the food.

First receiver records include information about farms. Maintenance of these records of a first receiver of listed foods would likely help prevent delays in determining who grew and physically handled the 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 food tracing list to which the originator of the food had not assigned the traceability lot code, you would need to establish a traceability lot code for the food and maintain a record for the traceability lot code linked to the KDE.

However, in situations where a FTL food isn't made exclusively from non-FTL ingredients, a CTE identified at creation, there would not be a first receiver. This unique tracing 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 of fishing vessels made for the identified seafood. Here we have an example for first receivers that were linked to cantaloupe.

In this example, a farm grows cantaloupe which is on the FTL. The farm sends the cantaloupe to an on-farm cooler who sends it to a distributor. Since the distributor other than farm who purchases and takes physical possession of the

cantaloupe, the distributor would be considered the first receiver. The distributor would then send the cantaloupe to a retailer, as identified in this example.

Our next example relates to mango. In this example, farm #1 grows mangoes which, again, are on the FTL. Farm #2 purchases and takes physical possession of the mangoes from farm #1. Farm #2 then sends the mangoes to an on-farm packer who sends them to an on-farm cooler.

The mango is then sent to an importer or wholesaler. The importer/wholesaler is the first person other than a farm who purchases and takes physical possession of the mangoes. The importer and wholesaler would then be considered the first receiver. The importer/wholesaler would then send these mangoes to a retailer.

Our next example represents shell eggs. In this example, a farm harvests shell eggs which are on the FTL. The farm sends the shell eggs to an inline washer-packer who sends them to a distributor. Since the distributor is the first person other than a farm who purchases and takes physical possession of the shell eggs, the distributor would then be considered the first receiver. Consequently, the distributor would then send the shell eggs to a retailer.

Our next CTE is transformation. Transformation of a food on the food tracing list would involve taking a listed food and changing the food, and its packaging and/or labeling,

such as by processing it, combining it with other ingredients, comingling it, or repackaging it. Two important points to consider about transformation. Transformation only applies to FTL foods.

Additionally, this requirement would not apply to retail food establishments with respect to the listed foods they sell directly to consumers. Our next CTE is creation.

Creation of a food on the Food Traceability List would involve making or producing a list of foods, such as for manufacturing or processing using only ingredients that are not on the food tracing list.

Similar to transformation, RFEs, or retail food establishments, would not be required to maintain creation records for foods that are shipped directly to consumers.

There are some multi-ingredient foods on the current draft version of the FTL. As a result, it was necessary to make requirements for ingredients that are not on the food tracing list. Unlike with transformation, there would be no Subpart S records available for the immediate previous sources of any of the ingredients. Therefore, a firm would not be able to satisfy proposed KDEs for transformation.

Because of this, the concept of creation was made to serve as the starting point for Subpart S record requirements. As you can see in this example for the CTE for soft cheese supply chain, the diagram shows soft cheese which is

on the food tracing list. This diagram is of a creation event because the ingredients of this particular soft cheese -- milk and salt -- are not on the food tracing list.

So, requirements under the proposed rule would begin at the point of creation, or the firm that manufactures the soft cheese. Then, since soft cheese is on the FTL, record keeping requirements would apply for the rest of the supply chain all the way to the retail food establishment.

Here we have an example of a supply chain for fresh cut romaine. Romaine is on the list, so it would be covered under the proposed rule. This slide shows the relevant CTE for each point in the supply chain, and the KDEs that would be required at the subsequent point.

You have the grower which would be required to keep grower KDEs. Next, you have an on-farm cooler who would need to keep receiving KDEs based on what they receive from the grower, and the cooler would also need to keep and send shipping KDEs to the next point in the supply chain.

Next, we have an on-farm packer. The packer would need to keep receiving KDEs based on what they received from the cooler. The packer would also need to keep and send sending -- shipping KDEs to the next point in the supply chain. Two additions, 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, the statement that the shipper is a farm, location identifier and location description of the originator of the food if not the shipper, the business name, point of contact, and phone number of the harvester of the food if not the shipper. The date and time of harvesting, the location identifier and location description of the place where the food was cooled and packet if not the shipper, the date and time of the cooling and packing, if cooling or packing has already occurred.

Next, we have the produce processor. The produce processor would be considered the first receiver in this specific example, because they again would be the first person other than the farm who purchased and took physical possession of the listed foods.

The produce processor would need to maintain their receiving KDEs as well as a specific first-receiver KDE based on what they received from the on-farm packer. Since the produce processor is transforming the romaine heads into fresh-cut romaine, they would have to maintain transformation KDEs as well.

Also, the produce processor would need to keep and send shipping KDEs to the next point in the chain. We next have a distributor who would need to keep receiving KDEs based on what was received from the produce processor.

The distributor would also need to keep and send

KDEs to the next point in the supply chain. Finally, you have the retailer who would need to keep receiving KDEs based on what we've received from the distributor.

In this example we have a seafood supply chain for fin fish specifically. Fin fish 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 fin fish would be the first receiver, and would have to maintain specific KDEs related to seafood obtained from the fishing vessel.

Then, record keeping requirements would apply throughout the rest of the supply chain all the way to the retail food establishment. The proposed rule establishes procedures for requesting modified requirements, or for an exemption for a food or type of entity.

FDA will consider whether to modify requirements or grant exemptions on our own initiatives, or based on the citizen position by an interested party. Based on the information in this petition, FDA will determine whether application of the identified requirement is not necessary to protect the public health.

Requests should meet the requirements for citizen positions in 21 CFR 10.30, and would need to include specifically the food or type of entity to which the modified requirements or exemption would apply. If the petition request

modified requirements, specified the proposed modifications to the Subpart S requirements, and present information demonstrating why application of the requirements requested to be modified, or from which exemption is requested, is not necessary to protect the public's health.

Proposed rule also establishes procedures for requesting a waiver of requirements for an individual entity or type of entity. FDA will consider to modify requirements or grant exemptions based on our own initiative, or based on a handwritten request from an individual entity or a citizen's petition for the 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 type of entity, and the waiver will not significantly impair our ability to rapidly and effectively identify recipients of a food to prevent an outbreak, or address credible threats of serious adverse health consequences or death to humans.

And, the waiver would otherwise not be contrary to the public's interest. Examples of unique 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 points of contact for the individual entity to which the

waiver would apply, or individual entity waivers, or the type of entity to which the waiver would apply.

The requirements of Subpart S to which the waiver would apply, information demonstrating why application of the requirements are expected to be waived would result in an economic hardship. Information demonstrating why the waiver would not significantly impair FDA's ability to rapidly and effectively identify recipients of a food to help prevent or mitigate a foodborne illness outbreak. And, information demonstrating why the waiver would not otherwise be contrary to the public's interest.

The proposed rule would also require that records be maintained as either original paper records, electronic records, or (inaudible) 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 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 threats to public health.

So, I would like to review some of the proposed rule key concepts. Traceability lot codes should carry through the supply chain and can only be established and assigned when

origination, transformation, or creation occurs.

Additionally, all proposed KDEs would be required to be linked to that traceability lot code. Where possible, firms can reuse KDEs provided by the immediate previous source to meet proposed requirements.

For example, a traceability product identifier could be recycled. Traceability program records would be required to explain terminology in a firm's internal traceability system that may differ from any of the terminology that's been identified in the proposed rule.

A firm can work with supply chain partners regarding who will be keeping records and how, as long as the covered entity can provide FDA the records within 24 hours of the record request. FDA would not visit third party locations to collect the requested information, but would expect to receive it from the covered entities. The third party could be a separate business, or could also be someone who is a part of that firm's supply chain.

Additionally, we wanted to highlight that any firm can be a receiver. However, the first receiver KDEs are more specific. The full definition of a first receiver is the first person other than a farm who purchases and takes physical possession of a food on the Food Traceability List that has been grown, raised, caught, or in the case of a non-produce commodity, harvested. This again identifies the fact that foods

that are created do not have a first receiver.

Additionally, we like to highlight that transformation does include repacking. The goal of the proposed rule is to insure that KDEs, especially the traceability lot codes, can be maintained across the supply chain for more efficient and effective tracing while providing firms flexibility within their existing tracing system.

We are seeking comments that provide examples of business models that may not be compatible with the proposed rule with an explanation of why. We realize that the examples that we see and provided are simplistic and do not reflect the full range of business models used by various industries. We would also seek comments for you to identify and explain if there is any confusion within the proposed rule. Thank you, turning it back to you Kari.

MS. BARRETT: Great, thank you so much Angela. That was a lot of ground to cover, I think. The summary was really helpful for the audience. Okay, we're going to go on now to our next presenter. Welcome, Aliya Sassi. She is our senior economist office of policy legislation and international affairs, and the FDA office of commissioner. And, she will provide us with an overview of the regulatory impact analysis of the proposed rule.

So, Aliya I will turn to you.

MS. SASSI: Thank you Kari. Good afternoon

everyone, glad to be here to talk about (inaudible). This is an outline of my today's talk, I'll start by going over the estimate numbers and this is covered by this rule, then discuss the estimated benefits, costs, impact on small business, and international affairs.

There are two CORE options when it comes cover retail food establishments, or RFEs. Under Option #1 of the CORE proposal, the retail food establishments with 10 or fewer (inaudible) will be fully exempted.

Under Option #2 these retail establishments would be exempted only from the requirements provided here under certain circumstances with an electronic sortable spreadsheet containing requested information. During this talk, I'll set down the estimated impact to both options side-by-side. Entities that could be affected by the CORE not only include retail food establishments.

Overall, this rule covers entities that manufacture, process, pack, or hold food that FDA has placed on the Food Traceability List, and that are not subject to any exemptions discussed in this example. You can see both the estimated number of covered firms and the number of establishments (inaudible) by parts. One firm can direct several establishments.

Under option #2, the rule as currently proposed will cover approximately 422,000 firms operating 566,000

establishments.

Under Option #1, the total number of covered entities would be lower -- 188,000 firms operating 332,000 establishments. This is a family of quantified costs from the benefits of the rule. The costs and the benefits are annualized for the same years as 7% of this country and presented for (inaudible) dollars.

This proposed rule is an economic (inaudible) action as defined by Executive Order 12866. We estimate that annualized costs of the rule and the CORE proposal Option #1 would be $411 million per year. Annualized cost/benefit would be $567 million per year, based on an estimated 84% (inaudible) from government.

Other CORE proposal Option #2, the annualized cost of the rule would be $535 million per year, and annualized cost/benefit would be $626 million per year.

In addition, the estimated cost to foreign entities are about $295 million per year, a portion of which could be passed through from entity to consumers (inaudible) inclusive. Using three -- using examples from three product recalls with additional (inaudible) benefits for both Options #1 and #2, an overly broad recall could range from $1.7 billion to $5.6 billion per year.

We'll have complete information on other benefits, and describe them qualitatively. This slide shows the

breakdown cost by options and industry standards. Compared to Option #1, costs for Option #2 are greater by $124 million and benefits are greater by $60 million. This is because on the Option #1 the retail food establishment would need to comply with the CORE.

However, by exempting RFEs with 10 or fewer (inaudible), then that's our Option #1. The time limit is given an accuracy of traceability efforts, and the impact. Under Option #1, FDA abilities the number of recall and the ability of RFEs to have data to be able to identify and remove contaminated products from the shelf, would be lessened.

It could be that non-quantified benefits will also be lessened under Option #1, compared to Option #2. (inaudible), but all RFEs regardless of their size allow for more consistent, organized, and specific information that covers the entire supply chain of listed foods.

This proposal made with (inaudible) public health benefits and foodborne illnesses, it estimates related to outbreaks a list of foods, are averted. The primary health benefits of the value from the deduction of the foodborne illnesses or death, (inaudible) required by this rule are likely to be reducing the time that the contaminated list of products is on the market.

This public cost-benefit could be generated in the following two conditions (inaudible).

First, a foodborne outbreaks occurs and, second, the traceability records required by this proposal will help (inaudible) you to quickly and accurately locate a commercially distributed relative product, and ensure that it is removed from the market. This may also lead to more efficiencies with FDA and industry resources needed for an outbreak investigation.

But, attention that results in a (inaudible) recall, and also by avoiding overly broad recalls and advisories for a list of foods. Additional non-health benefits may include increased food supply efficiencies, such as improvements in supply chain management and inventory control, more expedient initiation and completion of recall, avoidance of costs due to our methods of preventive actions by the consumer.

Other efficiencies from a standardized approach which is the ability including, and includes a transparency and trust and potential disturbance (inaudible). We'll have complete information that will enable us to quantify these benefits, or to quantify the discounts between the two CORE proposed options.

In the (inaudible), we discuss them qualitatively. We submit public health benefits based on a model provided in the 2012 (inaudible) by the Institute of Food Technology. We include the size of the eight-piece study from the (inaudible), plus 10 additional case studies using data from the CDC along with an investigation and intervention data from

FDA. As explained in the (inaudible) analysis, we focused our (inaudible) on four pathogens: Cyclosporine, E. coli, Listeria monocytogenes, and nontyphoidal salmonellae. Outbreaks caused by these four pathogens represent over 90% of all illnesses officially attributed to foods.

According to FDA, access to local and other key data elements throughout the supply chain would likely enable FDA to identify common product sources in about 5 to 7 days, or an average of six days as opposed to the 37 days that it takes now, based on the studies approved (inaudible).

We use these determinations to estimate the resultant 84% improvement based on reduced time to trace the implicated product. In sum, we estimate that the burden of foodborne illnesses attributed to listed foods by multiplying the estimated total annual number of illnesses that would be prevented by the weighted average burden for illness. That is a total from the FDA-posted foodborne illness model.

This slide shows our upper and lower estimates as public health benefits. Both Option #1 and #2 estimates vary by a wide range. We estimate that annualized benefits of the rule under CORE proposed Option #1 would range from approximately $33 million to $1.4 billion per year with a primary estimate of $567 million per year.

Under Option #2 of the CORE 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, implementation of multi-site food recalls may result in social benefits from overly broad recalls. Although recalls are rightfully implicated from the (inaudible), overly broad recalls that involved loosely related, or unrelated products could be unnecessarily costly.

There are no benefits from removing un-implicated products from the market. Therefore, avoiding removing un-implicated products is a benefit. Using three case studies, and supermarket scanner data, we estimate that these social benefits at the risk of the value of going (inaudible) during each recall event. We chose (inaudible), estimate sole risk for the short of length of a Class I recall and that's our best-case scenario, and (inaudible) is the longest one of a Class I scenario, our worst case scenario.

The last two columns on this slide represent the estimated low and high (inaudible) on sale. This proposed rule is finalized with imposed compliance costs on covered entities by increasing the numbers of records that are advised for this (inaudible).

Covered entities would incur incurring costs to establish and maintain traceability records. Some firms may

also incur additional investments and trading costs, and systems that would enable them to establish, maintain, sort, and make available upon our request their traceability records.

Moreover, firms would incur one-time costs to read and understand the rule. This slide shows our upper and lower estimates of cost, with the (inaudible) that annualized costs of the rule under CORE proposed Option #1 would range in cost from $34 million to $2.4 billion per year, with a primary estimate of $411 million per year.

Under Option #2 of the CORE proposal, the annualized cost of the rule would range in cost from about $43 million to $3.2 billion per year, with a primary estimate of $535 million per year.

Here are the estimated costs for the entire industry at provision, and the difference between the two options. The highest cost would be capital investment costs, especially under Option #2, and shipping records costs. This slide shows our estimated lower and upper bound costs for small business by industry type.

These costs are similar for the two CORE proposal options. Using small business administration definitions of a small business, and the U.S. Census data, we estimate that about 90% of firms have a (inaudible) rule of small entities. Because some small firms may have annualized cost that exceeds one percent of their annual revenue, we find that this proposal

will have a significant economic impact on a substantial number of small entities. But, not on all small entities.

SPEAKER: Hi, Doctor. You dropped out of Adobe momentarily.

So, you're on audio right now, so we can either move your slides forward or if you would like to just log back in we can pause just for a quick second.

MS. SASSI: I think this is my… I only have two slides left.

So, let's just continue.

SPEAKER: Okay.

MS. SASSI: We estimate that this rule would affect about 212,000 foreign entities, and that the annualized cost for foreign entities would be about $259 million per year. A portion of the costs could be passed through to U.S. entities and consumers via price increases.

So, they may experience high costs. We face uncertainty concerning the portion that may be passed through. However, requirements of these rules apply to all domestic entities in the same manner regardless of whether they are suppliers, either domestic or foreign.

So, estimate this path of the proposed rule on foreign entities. We extrapolate from the main cost estimate by comparing the number of foreign facilities in FDA food facility registration model to the primary estimated number of domestic

establishments minus retail food establishments. We assume that the number of foreign retail establishments affected by this rule is negligible. Next slide please. Are you able to...

MS. BARRETT: Yes, it's been advanced.

MS. SASSI: Excellent. There are several areas where we are seeking comments and information to help us include our estimates and narrow the ranges.

For example, the number of covered entities, the degree to which the entities already satisfied the requirements, percentage of remaining traceability investments needed by each industry, and the corresponding additional expenditures.

The expected benefits due to complexity of previous (inaudible) health benefits of averting shorter foodborne disease outbreaks, the current number of foodborne illnesses caused by diseased foods, and overall our estimate of cost and benefits and the extent to which the cost may already be internalized by covered entities.

Thank you very much, this concludes my presentation and I'm turning it back to you, Kari.

MS. BARRETT: Great, thank you so much. I appreciate your remarks, and we'll go to our last speaker of the segment, which is Andrew Kennedy. He is the New Era Technology Team Leader in the FDA office of food policy and response. Andy is going to walk us through the real-world application of the proposed traceability rule.

So, Andy I'm turning it over to you.

MR. KENNEDY: Great, thanks a lot.

So, hopefully you can hear me okay?

MS. BARRETT: We can, thank you.

MR. KENNEDY: Perfect.

So, yeah I had the unenviable job of converting all this into an actual real-life example.

So, that's what I'm going to walk you through today.

So, we are going to start off with a basic example of salad kit prepared with tomatoes and iceberg lettuce. The focus will be on the tomato grower, salad kit maker, distributor, and retail stores.

So, this presentation shows abbreviated data due to time constraints. As you can imagine, walking through every single record in this slide chain would take some time.

So, to see the details of slide chain records in spreadsheet format, a link will be provided when the presentation is posted online. And, I believe that will be after the last show of meetings.

So, you can see this diagram this is intended to illustrate how several different types of firms in a supply chain might meet the requirements of the proposed food traceability rule, and how that information could 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 other none FTL ingredients I won't be showing here. For the purposes of this scenario, it is assumed that the tomatoes are the commodity of interest in the trace-back.

So, the iceberg lettuce farming information will not be shown.

So, this chart provides a quick snapshot of the data we'll be walking through. Specifically, I will show the farm's program records and shipping KDEs including the originator, harvester, cooling, and 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 will abbreviate program records and receiving KDEs for the processor, distributor, and retailer.

I will represent the information in a technology-agnostic manner and, I think as you'll see through the rule, we don't specify how to do this; what we're looking for is the outcome and the data. But, I developed the examples based on what I imagine the sortable spreadsheet might look like for each actor in the supply chain.

So, for discussion purposes let's imagine that the farm is providing paper records to the produce processor.

So, they receive the product, they receive the paper records, and then they digitize that information upon

receipt, and store it in their receiving system.

So, that's where they keep the records. The processor then captures the ingredients and finish production in their manufacturing software.

So, that's, again, they're keeping the transformation information in their manufacturing software which is used to produce an electronic advance shipment notice when they ship the product to the distributor. That will incorporate the shipping KDEs, and the product itself -- you know, I imagine it will be labeled with the traceability product ID description and lot code, which would enable the downstream recipients to know what product ID and lot code that is. Not required, but in practice that's typically what happens.

The distributor receives and verifies the information into their warehouse management system, and shares their shipping KDEs to the retail food establishment via a proof of delivery system.

So, that would be a system where you drop the product off at the RFE. That information is then transferred to the retail food establishment.

So, the product itself -- you know, through that distribution process it would keep the original label from the processor.

So, the retail food establishment would know -- would have the exact same label on the product that was at the

distributor.

So, please note that this is only an example and is by no means intended to be the only way that data can be kept and shared. The 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 retained ownership of the crop from planting to shipment to customers, and they've agreed to keep and send the records on behalf of the organization that they worked with.

So, there's the central repository for all that data under Tom's Tomato Farm #1, Harry's Harvesting, Patty's Packers, Johnson Storage.

So, they're kind of working together and sharing their information to Tom's Produce so they can be the single point of contact for all that information.

So, these slides do not focus on the iceberg lettuce in the salad kits which is sourced from a different company.

So, this slide depicts program records. In this case, it's a reference record -- a bill of lading. Program records are critically important for our understanding of traceability KDEs. The first type of required record is in the reference record description. This example shows the bill of lading.

So, listed in the first column under reference

record you can see bill of lading abbreviated as BOL.

So, that kind of gives us an idea that's how you're going to convey the information from the farm to the receiver is through this BOL. The second column is listing the rule KDE.

So, that's how we understand the KDE. It's a listing of the KDEs as they appear in the rule. And, then the third column shows the corresponding name on the actual document or electronic record. In this case, it's the BOL.

So, a good example is the transporter name KDE which is equivalent to the term “carrier”. And, that is show on the bill of lading.

So, this firm calls it carrier but we would be looking for the transporter name as the KDE.

So, columns 4 and 5 show linkages to other records in linking KDEs.

So, please note this example does not the entire bill of lading or all reference records that this firm produces; I just kind of took a little snapshot of one to show you an example. The next type of required program record is the list of FDL foods the organization ships. Please don't confuse this with the shipping CTEs.

So, this is a master listing of traceability product identifiers and associated KDEs including category, brand, commodity, variety, pack size, and style. If the

products shipped are multi-ingredient, the product name KDE would be used instead of the commodity and variety of KDEs. The point is 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 shipment, receipt, and transformation. Second, this enables investigators to quickly determine what types of products a firm produces without combing through all the production and shipping records. And, a lot of times these are -- you know, this is information that is put on people's websites so you know what they sell. Okay, next up we've got the lot code assignment method.

So, this is important for investigators to understand how lot codes are determined and assigned by the traceability lot code generator. And, I saw some questions in the chat box around this. Traceability lot code generator, because this gives us a send of the scope of the lot code -- so, in this case I create a very specific one and the reason for that is I wanted to... if I get the phone call, and someone say, "We're tracing back this product with this lot code. Can you help us figure it out?" The more specific it is, the easier it is to differentiate between different lots.

So, in this case there's a very specific methodology. Other methods are less specific, but combined with the traceability product ID you can get to a unique combination.

The important thing to consider is how, combined with other KDEs, this can identify a certain quantity in types of foods and narrow the scope of the (inaudible). Okay, location master.

So, although not required, under the category of Other Information firms may want to create a master listing of locations. This shortens the numbers of KDEs required in critical tracking events, but linking the full list of location description KDEs to the location identifier.

So, typically firms maintain electronic location and product master listing in their business software.

So, this is typically where this information would reside. Next up, we're going to go into the growing KDEs.

So, this is an example of the growing KDEs.

So, what I put together here was an example traceability lot code with the growing area. For each FDL 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 shown above. And, we've had questions about using other identifiers and so forth. The point is, the coordinates take you back to a piece of ground, so it is important to have the actual coordinates.

So, your actual records may include more information.

So, you might have ranch, field, block, and sub-block, and the GLN and a bunch of other information. But, we

that growing area coordinate so that we can point back to a piece of dirt.

So, anyway, this kind of gives you an idea. No, you don't have to share this information forward. This is information that the grower keeps so that when asked about that individual traceability lot code you can identify the location. All right, so now there's several slides showing the shipping KDEs.

So, this is the start point of the information that the farmer would need to keep and send to the processor.

So, there's two active dates. One, you've got to keep it. Two, you've got to send it.

So, imagine all of the orange boxes that I'm going to show are part of the same tab of the spreadsheet. To begin with, the farmer would provide information including the traceability product identifier, quantity, and unit of measure, and link that to the traceability lot code. To make the critical tracking event easier to read, I've included and abbreviated traceability product description in here so the cherry tomatoes 10 lb. case -- that's an abbreviation. And, as I showed before, you would have a complete listing of all the KDEs linked to that traceability product identifier. This is just a shortcut because I have no idea what 614141007349 is.

So, anyway, it's just a device so I can see what that product individually is. Okay, so next on the shipping

KDEs we have the traceability lot code generators.

So, these three columns on the spreadsheet -- so, we show the location identifier, the description, the point of contact, the traceability lot code generator.

So, that's when we get back to find out about that product information and the traceability lot code. Okay, so on the "Ship to" information we have the location identifier and the location description.

So, this is where the product is being shipped to. In this case, it's fresh processor plant #16, and we've abbreviated that location. Though, this is where it came from.

So, we've got the KDEs -- you know, the "Ship from" KDEs.

So, in a similar way I've abbreviated that but also included the shipment date and time in the "Ship from".

So, this information only needs to be kept.

So, the actual bill of lading number and transformer name are shown here.

So, finally we've got our shipping KDEs. Now, we're going to move into our farm information KDEs.

So, the first statement is “I’m a farm”.

So, that is how we tell the receiver that you are the first receiver. Next up is the originator.

So, the farmer communicates the originator's location, identifier, and description creates traceability lot

codes sent to the processor. In this case, I reference a location master that's in program records.

So, for the harvester I send the business name, contact information, harvest date, and time. For cooling, I just send the traceability product -- er, location identifier description and the cooling date and time. And, in this case cooling and packing is done by the same place -- Patty's Packing Shed.

So, it's the same thing and the same information just a different date and time. Okay, so as the next step in the processor they are the first receiver.

So, the fresh processor receives the ingredients, and processes those into the salad kit.

So, of the organizations they're working with, Tom's Produce is the one that ships the produce on. Lizzy's Lettuce, who is not shown, provides the lettuce. And, then the food distributor is who they ship it to.

So, in this case we're focusing in on the records that are required for this fresh processor. Okay, so the program records -- for the sake of time, I've abbreviated the processor's traceability program records. They're very 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 that the processor ships to. On this first receiver KDEs... one sec. Okay, so the first receiver KDEs are very similar to what was shipped from the farm.

So, we have originator, harvesting, cooling, packing, etc. And, all that is linked to the traceability lot code.

So, that's really a mirror of what was sent. Then, the receiving KDEs are also a mirror of the shipping KDEs.

So, you've got the product information, the source of the recipient, the date and time, and the traceability lot code generator, and other reference information.

So, that is how the information goes from the farm into the receiver.

So, it's not expected that everyone all along the chain sees every bit of information. This is the hand-off; the information that is sent from the shipper to the receiver. Okay, so this is where the rubber hits the road for creating a new product.

So, this step captures the product being produced through the transformation, including the new traceability lot code quantity and unit of measure.

So, first step is to take the products that are used in the transformation.

So, in this case the cherry tomatoes and the iceberg lettuce, and the traceability lot code and the quantity;

how many are being used. And, that is used to create the output which would be... you know, in this case we've got the garden salad kit and a 12 oz. -- you know, I've shown a UPC code in here just as an example that's commonly done but not required. You've got the work order number, so the reference record and the work order number, you've got the new traceability lot code, and then you've got the location where it was transformed. In this case it's fresh processor plant #16. You've got the date that was transformed, and the quantity and unit of measure of how many new products you've made. You've got all of the information you need to know about that product from the transformation. And, we've linked it so if you go back here -- we've linked it to these ingredients.

So, that's how we do the trace-back is we go from that finished good, shown here, back to these ingredients.

So, that's the key to getting back to the farm. All right, so now we've made our product.

So, the next few slides we're going to walk through how do we ship it on to the distributor. So... and, this is going to look pretty familiar to what we did from the farm side.

So, we've got the product information so the lot code, the unit of measure, the quantity, the ID and the description of the finished good that we're shipping, and our new traceability lot code generator.

So, the process is the new traceability lot code generator.

So, we update that information. We've got that new point of contact, we've got our ID for the location and our description.

So, now it all points back to fresh processor plant #16.

So, when the phone call is made to bob around they're going to ask about the lot code and product that we just produced.

So, this is the immediate subsequent recipient; in other words, the "Ship to" is the distributor DC100. And, that came from our fresh processor plant, and here's our date and time of shipment. This information, again, kept only in our shipping system so that BOL, the transporter name -- all that is kept only.

So, now we're into the distributor.

So, we're halfway there in the supply chain but believe me because it goes a little quicker because a lot fewer records are collected from here on out.

So, the distributor receives the salad kits and ships them to the retail food establishment, which in turn sells the kits to the consumer. Okay, so the record… again, to shorten those up, these would be pretty simple. Unless the distributor does things like repacking or transformation, these

would be very, very simple. Because, they're mostly just receiving and shipping. And, then on the receiving KDE it will look just like the outbound. Shipping KDEs, with the exception of the date and time, would be the receive date and time and they look just like the outbound normal receiving KDEs that you saw at the processor. The next point is, the product information of what the distributor is going to send outbound.

So, we're going to do our outbound shipping. In this case, it's a shorter, smaller number of cases that are going to be going out the door. And, these are going to be sent with the traceability lot code generator information of the fresh processor plant.

So, this information is going to the retailer, this is how the retailer knows who did the processing. And, the immediate subsequent recipient is the retail store.

So, store #1052 is getting the information, they're getting the product, they're the subsequent recipient. And, the shipper is DC100, and the shipping date and time is shown here. Again, the distributor keeps the bill of lading number and transporter name in their records. And, finally the retailer -- the retail food establishment -- the only connection they have to the fresh processor is that traceability lot code and lot code generator. But, they are receiving the actual product from the distributor and they sell it to the customer.

So, similar program records. They would have

their own unique program records. And, then on the receiving side they would receive the product information so the traceability lot code quantity and the unit measure, and the traceability product ID and description that was assigned by the processor and the traceability lot code generator information that was assigned by the processor.

So, that would enable you to go straight back to the processor from that information. You have the source, you have the distributor information, what distribution center it came from, and then the recipient would be the recipient location.

So, what store was received to at that date and time. Okay, so on the overview if you look at it end-to-end, there's a lot of information at the beginning and it kind of narrows down as you move to the end. And, I've color coded the different KDEs just so you have an idea of what each type of KDE, each different participant has to do.

But, once we have all of that information put together, that enables us to do a trace-back investigation pretty easily. Because, once you have that traceability lot code, the generator, the product ID, and description you can leap-frog from the retailer to the processor. And, then ask them about the ingredients and you get all of the first receiver KDEs, so you have all of the grower information, harvest information, packing information.

So, you can get all the information you kind of need about the growing operation from the produce processor with the exception of the growing KDEs where you have to go back to the farm and ask for the growing KDEs. But, you would have most of it right there at the produce processor with a little bit more information required to get the growing location.

So, that certainly does expedite trace-back. And, from a trace-forward perspective, all of those KDEs and CTEs that we use for trace-back can also be used for trace-forward and then can be... and, other programs can use that as well.

So, the way to think about this is you're kind of creating the railroad tracks for traceability information in this process. Okay, so I believe we're into the question and answer time.

So, handing it back.

MS. BARRETT: Great, thank you Andy. That was an excellent walkthrough, thanks so much for doing that. A lot of good information. We'll bring up our other earlier presenters from this segment of this agenda for Q&A.

So, we'll run this the same way we did last time. Please, again submit any questions you have to the chat. I will read the questions out loud. This is Kari Barret, and we'll ask again our presenters, we have three, here to respond. And, if there are any additional FDA staff members who have joined they

may respond as well.

So, let us go ahead and begin. There are a number of questions already in the queue. And, Angela Fields, this one looks to be for you. The question is: "What are the requirements for the traceability lot code, and how does this relate to the current use of lot codes?"

MS. FIELDS: Thank you Kari for that question.

So, again, within the proposed rule we do not have specific requirements how a traceability lot code can be created; we just specify that only during origination, creation, and transformation could a traceability lot code be assigned and -- established and assigned. And, then again there's no requirement for that traceability lot code to be printed on products, just that all KDEs must be linked to the traceability lot code.

MS. BARRETT: Wonderful, thank you very much. Okay, our next question is one I think it's for Becky who is joining us. "Becky, can we expect FDA to mandate this new food traceability rule to include all food types in the future, not just the list FDA has currently released?"

MS. GOLDBERG: Yes, thank you.

So, first all, it's important to understand that the Food Traceability List itself can change. We've proposed a system for how we would update the list if needed, which basically involves a notice in the federal register telling the

public that we have a specific update that we are thinking of making. Like, if we're thinking of adding a new food to the list or taking one off then we'd put a notice in the federal register, we'd take comment on that, and once we had made a final decision we put another notice in the federal register. And, then unless we stated otherwise we would give an extra year for anything new on the list to have to come into compliance.

So, the list itself can change; people shouldn't think that it will always be the list that they say here. However, to this specific question it is not the case that we would ever say... well, unless congress passed a new law, under the current law we are not allowed to say that this rule applies to (inaudible).

We are required to designate certain foods, which is what we're going to do with the Food Traceability List, and those are the only foods to which the record keeping requirements can apply.

So, it would take a new law from congress if congress wanted to decide that this should be expanded to all foods. But, that's not something that FDA would do on our own.

MS. BARRETT: Great, thank you very much. Let's see, we'll go to the next question. And, Angela Fields it looks like this is for you. "Again, when is it acceptable for an originator to leave it to the first receiver to assign the traceability lot code? When must the originator assign the

traceability lot code, i.e. where the first receiver would not be permitted to?"

MS. FIELDS: Thank you Kari for that question.

So, in most cases the originator would assign the traceability lot code. There could be instances where the originator is exempt from the rule, and would therefore not be required to establish and assign a traceability lot code, which would then result in the first receiver establishing and then assigning it. And, if you were the first receiver of the foods on the food tracing list to which the originator had not assigned the traceability lot codes, you again would need to establish the traceability lot code as well as maintain a record of that traceability lot code linked to the KDE. To address the second part of her question, a first receiver would not be permitted to assign a traceability lot code if the entity did not perform transformation and creation in instances where the originator has provided a traceability lot code.

MS. BARRETT: Great, thank you very much. Andy Kennedy, this one is for you. "How would companies use PTI labels in your scenario?"

MR. KENNEDY: Yeah, that's a great question.

So, PTI labels capture -- and, for those who aren't familiar PTI is the Produce Traceability Initiative. And, that initiative is an industry-backed initiative and they define standards for barcode labeling of cases of produce. And,

the core bits of information they put in that barcode -- one is a product ID called a G10, and the other is the lot code.

So, the lot code is equivalent to our traceability lot code, in effect. And, then the G10, or product ID, would be the equivalent to our traceability product ID.

So, in your reference records when you describe how your traceability program works, if you use PTI you might indicate that the way you are sharing your traceability product identifier and lot code to the recipient is via that PTI label.

So, that could be one way of sharing information about your product to the subsequent recipient. Over.

MS. BARRETT: Great, thank you. Aliya Sassi, this one is for you. The question is: "I believe you listed training as a one-time cost. Wouldn't that be a reoccurring cost as new employees are hired, and also retraining of current employees?"

MS. SASSI: Yes, in the PRIA we assume that training related to this rule will be a one-time cost. Well, these costs are only for additional training to comply with the requirements of these rules.

So, we basically assume that while training new employees some outdated training materials, and content in new hire training, will be replaced with training related to these rules. We also ask for comments on our assumptions and our estimates.

MS. BARRETT: Great, thank you.

So, that's one to comment on. Thank you. All right, Angela Fields question for you: "FDA has proposed that the traceability and lot code not be changed when shipping or receiving. Can the traceability product identifier, and traceability product description be changed by each entity that ships and/or receives?"

MS. FIELDS: Thanks, Kari.

So, the proposed rule, again, only has requirements when a firm can be able to manipulate the traceability lot code.

So, again, transformation, origination, or creation. All other KDEs can be changed by an entity, and would be required to be linked to the corresponding traceability lot code.

MS. BARRETT: Great, thank you so much. All right, we're going to go to our next question. And, again this may be one for a legal counsel. "For tracing shell eggs back to their origin, I am curious how this will work. Is it record keeping only, or perhaps printing some sort of coating on the egg packing?"

MS. GOLDBERG: Yes, thanks. This is Becky, I can take that one.

So, great question. You know, and really it's the same for eggs as for anything else on the list. We tried to

keep the proposed rule flexible, so it's not a requirement that any information be printed on the packaging.

So, in terms of the phrase about if it is record keeping only -- so, you know the proposed requirements are mostly record keeping. It's things that you would keep, you know, within your company; the records that you would maintain. But, there's also requirements for shippers to send along certain information to the recipient of the food. And, again, this is the same for eggs as for anything else.

But, in terms of how they send that information along -- and there is a list in the proposal of the specific key data elements that they need to send along and some of the presenters went over this already.

But, in terms of how they would do it they certainly do not need to do it by putting it on the package. They could do it, for example, in an email. They could do it in an advance shipping notice -- an ASN. They could do it in paper documents that accompany the shipments, such as a bill of lading.

In general, we try to keep the proposal flexible with respect to how the records would be set.

MS. BARRETT: Great, thank you very much. And, this next quick question is looks like we may need to go to one of our earlier presenters. I don't know if we have Chris Waldrop available on the line. Chris?

MR. WALDROP: Can you hear me?

MS. BARRETT: Yes, okay Chris. Great, we have a question for you and it's: "Why are all finned fish grouped together on the FTL when the model assessed three different types of fin fish based on the associated hazards?

For example, histamine and ciguatoxin."

MR. WALDROP: Sure, and if you look at the list on the -- that we posted as part of the proposed rule, it does say fin fish, including smoked fin fish. And, that was -- we grouped that as sort of a communications tool to be able to let people know and help them more easily understand what we were talking about, and grouping the fin fish together.

There's a footnote there that does show that this did consider the different histamine producing species, the ciguatoxin species as well. And, so they all are kind of grouped in that same category under fin fish, but the model does consider each of those separately and all of those different commodities, or different types of fin fish, wound up on the list.

MS. BARRETT: Great, thank you. All right, Andy Kennedy this one is for you: "If we receive salad kits and then repack them, are there additional steps that need to take place if we add an additional ingredient from a different supplier?"

MR. KENNEDY: Yes, thank you for the great question.

So, if you add an additional ingredient and essentially repack that product it becomes a new product with a new lot. Yes, you would create a transformation critical tracking event. It includes the product you have to date, and then add in that additional ingredient.

So, it would be a secondary transformation.

So, within a processer there could be many different transformation steps.

So, you could have intermediate products that then become finished goods.

So, that would be common and then you would just have to include the ingredients which would be your semi-finished product and your new ingredient, and then create that transformation at that time. Over.

MS. BARRETT: Great, thank you Andy. Angela Fields, this one is for you: "Can you walk us through an example of KDEs and CTEs for peanuts from farm to processor that makes peanut butter that goes to a food manufacturer that uses the peanut butter in a food made and packaged for retail sale?"

MS. FIELDS: Yes, thanks Kari.

So, to discuss the peanut butter quickly -- again, this is an example of creation.

So, peanut butter is a food on the food tracing list that is made from peanuts and other ingredients that aren't necessarily on the food tracing list. And, so because of this

the requirements would begin at the point where the peanut butter are made given that the ingredients used to create the peanut butter are not currently on the food tracing list.

So, peanut butter sandwich crackers are a product made from the food that's on the food tracing list. And, so because the peanut butter is added to those crackers, again, that would qualify it to have Subpart S records.

So, from the point of creation where the peanut butter is at the manufacturer and then is processed, again that begins the Subpart S records, and so there would be records of creation as we discussed during the presentation that would include things like identifiers of creation dates, and then assigning the new traceability lot code to that.

So, at that point from the peanut butter processor we move forward through the distribution chain, and again the same... record into a new product such as peanut butter crackers. Then, there would be transformation KDEs that would be required where the peanut butter is transformed into crackers, or processed into crackers. And, then from that point maintaining the transformation KDEs, the remainder of the supply chain would again be maintaining those same shipping and receiving KDEs.

MS. BARRETT: Great, thank you. Becky Goldberg, looks like this one is for you: "What is the exact date that this law is fully in place?"

MS. GOLDBERG: Yes, thanks. Good question.

So, first of all before that happens of course we have to issue a final rule. Right?

So, right now the comment period is still open on the proposed rule. When the comment period ends, we then will be reviewing all of the comments we received and writing the final rule. And, then we'll publish the final rule in the federal register. That's likely to take place probably in the fall of 2022, publish the final rule in the federal register. But, it won't take effect that instant that it publishes.

What we've proposed here in the proposed rule is that the final rule would become effective 60 days after the date that it publishes in the federal register. However, firms would have an additional two years after the effective date before they have to come into compliance with the final role.

So, now those are the timelines we proposed; not to make things more confusing, but it's possible that the final rule might have different timelines. Because, in those timelines the way that this will happen is that it will be a couple years before publish a final rule, and then once the final rule publishes it would be 60 days plus another two years before firms would have to come into compliance.

So, don't worry and there will be a lot of communications documents to help along the way.

MS. BARRETT: All right, thank you so much for

walking us through that timeline. All right, this next question is for Angela Fields: "If a retail establishment receives a created food that includes an ingredient that is on the FTC, would they be required to keep traceability records?"

MS. FIELDS: Thanks Kari.

So, to reiterate creation of a food on this Food Traceability List would involve making or producing a list of foods that is using ingredients that are not on the food tracing list.

So, again, if you're creating you are not using any ingredients or any other foods that may be identified currently on the draft Food Traceability List. Retailers are covered by those rules that receive any food that falls on the food tracing list. They would, in turn, then have to maintain receiving records. There is one circumstance that if a created food receives a kill step, then there would not be additional records required for that point.

So, for example, in the previous example where we discuss the peanut butter if the peanut butter crackers—if the peanut butter was produced for the peanut butter crackers where the crackers were then further baked, or maybe peanut butter cookies, with there being that kill step applied the Subpart S records would then end at the point where the kill step is applied and would no longer go forward.

MS. BARRETT: Great, thank you. It looks like...

oh, Andy. This is a big one that we get a lot. The question is, for Andy Kennedy: "Do I need blockchain to do this?"

MR. KENNEDY:

So, I mean you're certainly welcome to use the blockchain to do this but, no, this is a technology-agnostic rule.

So, we do not specify what technology we need to use. And, in fact, the way the rule is designed where data can be sent to your trading partners... as you move along the supply chain, you can leverage existing communication systems you have with your trading partners.

So, we don't anticipate that you have to use blockchain to do this, or real any other technology system specifically. It's really a decision between trading partners, that's the way they share information with each other. And, also for each firm to determine the best way to keep information using their existing business systems that they have today with some enhancements, or if they prefer to add new systems to their landscape that's totally fine too. But, we try to design the rule in such a way that it would complement existing business systems. Over.

MS. BARRETT: Yeah, thank you so much. Again, I know that's one that has come up in the past. And, here we go. Angela Fields I think this is going to be our last question for this session: "Are traceability lot codes 100% unique throughout

the entire system?" Angela, I think you're on mute.

MS. FIELDS: Oh, thank you. Traceability lot code systems are not required to be unique throughout the entire supply chain. The only requirement would be that any KDEs that are reflected on the records would then need to be linked to that identified traceability lot code.

So, if firms choose to reuse ... link to that specific traceability lot code, and it would need to be identified on the records -- er, in the traceability program records.

MS. BARRETT: Fantastic. Thank you so much to our last group of presenters here, and other FDA staff who are available to answer some of the questions that we have.

As earlier, if we weren't able to get to your question in this session please resubmit it through the CFSAN technical assistance network -- or CAN. And, again, that helps us track the questions we're receiving as well as our response. And, also all of your questions will certainly help us consider future communications and clarifications, and our third and final public meeting material.

So, thank you all for the wonderful questions and to our FDA staff for the answers. At this point, we are now going to move on to our state panel that we have. I am going to turn over the moderating... I am waiting as people come up. Great, I see Vinetta. All right, so let me do this...

I am going to turn now to Vinetta Howard-King who is the Human and Animal Food Program Director East, and the FDA Office of Regulatory Affairs. And, Vinetta is going to run a panel of state perspectives on the traceability issues.

So, Vinetta I am turning it over to you.

MS. HOWARD-KING: All right, thank you. Hello everyone. As mentioned, I am Vinetta Howard-King and I am the director of the office of human and animal food east and FDA's Office of Regulatory Affairs. And, as mentioned today I am honored to be moderating a panel with two of my esteemed state colleagues.

So, I thank them both.

So, today with us we have Laurie Kidwell, who is a supervisor on the Rapid Response Team for the Indiana State Department of Health. And, we have Lisa Hainstock who is a food safety specialist in the emergency response and enforcement unit with the Michigan Department of Ag. and Rural Development.

So, welcome to you both. Thank you for participating in this panel to discuss the impact and the importance of traceability in the food supply from a state's perspective.

So, I want to go ahead and get started. I'm going to start, Lori this question -- I'm going to start with you, and then we'll move over to Alisa.

So, Lori states are boots on the ground, how

would a more harmonized capability enhance your ability to improve your role in outbreak investigations and product tracing of listed foods? I can say that again. I hear a phone ringing, sorry. Do you want me to repeat?

SPEAKER: Looks like Laura had to disconnect, she had a little phone -- so, let's let her dial back in real quick. Laura!

MS. HOWARD-KING: Well, Lisa I'll start with you with the same questions. Okay, so I'll repeat the questions: "States are boots on the ground. How would a more harmonized traceability enhance your ability to improve your role in outbreak investigations and product tracing of listed foods?" I think you're muted. Lisa, you're muted sweetheart.

SPEAKER: Yep, on your own phone you're muted.

MS. HAINSTOCK: Ah, there we go. Sorry.

MS. HOWARD-KING: All right.

MS. HAINSTOCK: Thanks Vinetta. First, let me preface my answer with a basic truth and I think that when these outbreaks occur, the citizens in our state have an expectation that we're doing what we can to investigate and take action to reduce the change that our families are going to get sick, or their families are going to get sick. And, that includes identifying and tracing the food or foods that are causing the illness. They expect us to be fast, and they expect us to be right.

So, to meet that expectation the state's role in these outbreak investigations is to rapidly provide the basic trace-back investigation building blocks, or foundation, that the federal agencies are going to use to construct its national trace-back investigation. And, we're doing that all on top of already really busy schedules and regulatory challenges that we're facing every day.

So, this requires requesting the data from industry, and reviewing sometimes hundreds of documents. And, then figuring out what those data elements that we don't have so we can contact the firm, again, and ask them to help us interpret the records and fill in the gaps, if possible. And, oftentimes this is taking multiple calls and emails and this can last sometimes for a period of hours, days, and sometimes weeks. I think as you've heard from some of the speakers today, depending on how fast industry can get back to us.

So, if we as a state can gather more standardized and complete information like lot codes or other key data elements, right up front in each of these firms the less time and effort we're going to need to spend going back and forth from industry trying to fill all of those gaps, link incoming and outgoing shipments, and the more time we're going to be able to spend on the other investigational or regulatory activities that might be necessary as part of an outbreak investigation.

So, it means that if we can get more accurate and

actionable info to our federal and industry partners that they can use to find out where the contamination is happening, maybe they can take action quicker to remove these specific products off the market, and maybe keep it from happening again.

MS. HOWARD-KING: Thank you, Lisa.

So, Lori I want to ask you the same questions. "States are boots on the ground, how would a more harmonized traceability enhance your ability to improve your role in outbreak investigation and product tracing of listed foods?"

MS. KIDWELL: Thank you, Vinetta.

So, for Indiana an improved and harmonized traceability system would enable a quicker identification of the source of the foodborne illness. During food emergency responses, it's very important to be able to trace back suspect food vehicles quickly and effectively so that our available resources may be focused on those implicated manufacturers, distributors, farms, in a timely manner.

So, in many states -- Indiana included -- regulatory agencies are struggling with limited resources.

So, ensuring that these resources are strategically focused will increase the chances of identifying and correcting the problems that lead to the outbreak, and to implementing effective mitigation actions.

So, once the source of a suspect vehicle is identified, investigators may then look for the possible

practices that may have led to the contamination, growth, or survival of pathogens. The identification of how and why the outbreak occurred will facilitate immediate long-term correction.

So, many of the listed foods have been historically difficult to either trace back, or trace back quickly, and have an history of being involved in outbreaks. Produce for instance, that can be rather difficult to trace back and oftentimes the harvest locations rotate by season.

So, being able to trace them back to their sources while the produce is being harvested, distributed, and/or sold is very important.

So, that way it would allow investigators to sample implicated product and observe food safety practices of that implicated product. Effectively traceability processes would also allow food industry and regulatory officials to quickly develop and release more focused public messaging and product recalls. Rapidly removing the product from shelves or allowing the retailers our consumers to identify implicated product may reduce the number of cases in a foodborne illness outbreak. And, of course reduce the economic impact on the food industry.

So, one of our best practices that we found useful is having points of contact and relationships with our food industry partners.

So, this does help in quickly obtaining records and information during responses. But, like Lisa said, oftentimes we're contacting them multiple times to have them explain the records that they've sent us because there is no consistency across food industry, so.

MS. HOWARD-KING: Okay, thank you very much. Lisa, I'll start with you for the second question. Based on your experience, how has a lack of consistent record keeping hindered outbreak investigations?

MS. HAINSTOCK: Yeah, that's a question I think both Lori and myself could talk at length on. But, you know what I can say is trying to trace products, especially those that are on the Food Traceability List, can be extremely challenging. You know, right now different firms seems to keep track of all of their own key data elements, but basically that's very inconsistent across the board, even at the same level in the same supply chain. They keep track of the data that is important to them, but again we have to keep asking them to interpret it for us.

So, it adds a lot of time. I guess I can equate it to saying that having inconsistent record keeping between links in the supply chain, or between different companies, is often like trying to put together a puzzle where there's pieces either missing, or the images in front of the pieces is really indistinct.

So, the full picture of the processes and application isn't clear, and as I said before time really isn't on our side.

So, states are regularly asking different companies virtually the same list of question and requesting the same kind of records in every investigation. But, what we get in return is often super different; as different as, I don't know, chalk and cheese. I've received everything from super complex Excel spreadsheet pivot tables, to almost illegible scanned handwritten receipts. And, I can tell you that I've always got a handwritten receipt from a wholesaler that say "lettuce", and give no other information that help us to identify a brand or a type of lettuce; pretty hard to do something with that. We can't even ask case patients if they ate or purchased Brand X because we don't have to go on. And, it's really important because we often use the information from one trace-back leg, help us with adding to the questionnaire that we use to question other case patients, because it helps us to narrow down that outbreak focus. If the trace-back is hitting the wall, then that hampers our ability to do that and to drill down to get better epidemiology. We run into situations where the lack of a lot code or other information that could link a shipment back to a grower has actually incorrectly implicated a product; it's coming from one place, when it actually came from an entirely different location. And,

I think Lori alluded to as well that, you know, some of these listed foods have got short shelf lives. And, the longer it takes us to trace these back and for a company to do a recall, the greater the number the people that can be eating it is higher. And, that means that the bigger the outbreak might actually be.

So, You know without the lot codes and these other key data elements -- you know, the standard list -- it's really hard for us to go about trying to shorten the time that it's taking for us to do this quickly. You know? It's adding days to something that, in a perfect world, or in a time when there is a consistence of recording keeping requirement should only take hours.

So, if there's a way that we can do that and industry can work with us, I think that that's going to be certainly the most positive thing to do that.

So, I am really looking forward to hoping that as we move forward on this that we can all work on the states, and the federal agencies can work together with industry to help alleviate some of these big data gaps that we have and the time that both we as government people and the industry has to put into answering these questions. If we have this data up front, I think it's going to be a benefit to all of us concerned.

MS. HOWARD-KING: All right, thank you Lisa.

So, Lori I want to ask you the same question:

"Based on your experience, how has a lack of consistent record keeping hindered outbreak investigations?"

MS. KIDWELL: Well, I think a lack of consistent record keeping has caused us to see reoccurring outbreaks happen year after year where we can't quite identify the source. And, we know again because sometimes many of these products on those lists they rotate by harvest season.

So, if we can't identify it this year there is a likelihood that we may see another outbreak the next year. And, so I think having better records that are easier for us to understand and assist in ruling out these multiple sources where we can't just narrow it down would help in not only preventing additional cases from occurring with the current outbreak, but prevent seeing reoccurring outbreaks in the future as well.

We've also seen with many of the products, I think having better record keeping would help but if we've got comingling going on at the retail level then it may be difficult to rule out some of these other products, or cross-contamination as well.

So, that's one thing that's been a challenge for us in the past. Another issue that we've had is contacting firms to ask for records and then waiting sometimes several days to receive those records. I'm not quite sure if it's an issue with getting those records, having them accessible, or if there's legal or confidentiality concerns that they may have in

providing these records.

But, having them provide us these records quickly is very, very important in effectively investigating outbreaks. Again, like Lisa had mentioned, we often have issues when we are looking at these records trying to interpret exactly what these records mean, because they can be very different across the food industry.

The other thing is that, more often than not, there's no identifying code or number that follows the product through the distribution chain.

So, we're oftentimes reliant on those interviews with the food industry, with interviews as well as observations.

So, if we're going there and what they're telling us does not match what we're seeing in the records, or what we're seeing as we are there on site. Those are some things that take a lot of time to work out while we're doing these trace-back investigations.

So, having some type identifiable number that's going to follow this product through that we can match up between bills of lading, or invoices, or whatever their records for documentation is, going all the way back to the source would be very helpful.

So, another issue that we've seen -- well, in one case we actually had inaccurate records that led us to the wrong location. And, the more records we pulled the more it seemed to

indicate that that was the location but what we were seeing did not correlate with that, and what they were telling us did not.

So, it was very confusing. It cost us extra time, extra resources when we were dealing with that issue.

So, there's been many challenges that we've dealt with in regards to traceability.

MS. HOWARD-KING: All right, thank you both. All right, the next question, and Lisa I'll start with you: "What's been your experience working with different size retailers in tracing investigations?"

MS. HAINSTOCK: Well, you know I don't want to do a disservice by saying that smaller retailers are less capable of providing good records. What I can say, is that in many circumstances typically they don't always have somebody who is specifically tasked with that type of duty; they may have somebody who is involved in keeping records but they might also have many other duties.

So, being able to try to talk to them regularly and getting those records can sometimes be a little challenging because they're wearing many hats. And, so one of the benefits of sometimes working with larger retailers is because they do have specific groups of people who are tasked with this type of activity.

Either, you know, food safety response people who know exactly who in their firm can get me the records that I

need to get, and can readily get the answers to the questions that we have, or...

SPEAKER: At this time, Kari are you still there?

MS. BARRETT: I am still here.

SPEAKER: All right, I will turn my camera off and let you take it away.

MS. BARRETT: Okay, fantastic. Yes, welcome back everybody and again I hope you had a good lunch. At this point, I'm really going to turn it over to Rebecca Buckner who is our CFSAN Senior Science Adviser to the center director. And, Rebecca will be moderating a panel of external perspectives on the food traceability proposed rule.

So, Rebecca the stage is yours.

MS. BUCKNER: I'm here, there we go. Can you hear me, Kari?

MS. BARRETT: I sure can, thank you.

MS. BUCKNER: Great. Yes, thank you very much. I'm Rebecca Buckner from FDA and it's my pleasure to moderate this afternoon's panel discussion on perspectives on the traceability proposed rule. If the (inaudible) panelists can turn on their cameras, that would be great.

All right, I think we're getting everybody. Perfect, great. We are fortunate to have with us this afternoon four very accomplished panel members, and we appreciate them taking the time to participate and share their knowledge.

Our panelists for this afternoon are Mitzi Baum -- Ms. Baum is chief executive officer at Stop Foodborne Illness, a position she has held for about a year and a half. Prior to beginning her tenure with Stop Foodborne Illness, Mitzi was with Feeding America for 23 years where, among other positions, she was managing director of food safety. In this role, she guided the development of food safety initiatives, including development and execution of food safety strategic plan and oversight of third-party food safety audit programs.

Next, joining us this afternoon is Jason Culotta. Mr. Culotta is the President of the Mid-West Food Products Associations. Prior to his current position, he served as director of industrial development for progressive rail incorporated.

He was also a senior director of government relations with Wisconsin manufacturers and commerce. And, he served as a policy adviser to Wisconsin governor Scott Walker in 2011. Our third panelist is Randy Graham. Mr. Graham is chairman of the Illinois Specialty Grower's association, which represents fruit, vegetable, herb, and irrigated growers in Illinois. He also currently owns and operates Curtis Orchard and Pumpkin Patch in Champagne, Illinois.

Randy has been involved in food safety issues for many years, following a juice outbreak in the mid-1990s he worked with partners to develop and administer the nation's

first (inaudible)-based cider, apple cider certification program. And, finally we have with us this afternoon Joseph Scimeca. Dr. Scimeca is Senior Vice President of regulatory and scientific affairs at International Dairy Foods Association. He has extensive technical, regulatory, and scientific expertise that includes over 33 years of industry experience. In his position with IDFA he provides strategic regulatory and scientific leadership for the dairy, food, and beverage industry covering areas including product safety, quality, and labeling. And, product identity standards.

Prior to IDFA, he worked in regulatory affairs at Cargill for 16 years. As you can tell, this panel has a wealth of food safety and tracing experience, and again we really appreciate their time this afternoon. With that, let's get started with our discussions.

This afternoon, we're going to start with an overarching question that I will ask each of you to speak to, and then we'll move on to follow up questions that you can just jump in on, or I may call on you for an answer.

So, to start us off here is the overarching question: I will ask each of you to briefly discuss your experiences with traceability, and your perspective on why traceability is important. Maybe we can go in the order I introduced you, which means that we would start with Mitzi.

MS. BAUM: Thank you, Rebecca. And, good

afternoon everyone. I appreciate the opportunity to speak with you all today. Stop Foodborne Illness, or STOP is a national non-profit public health organization. And, our mission is to support and engage people directly impacted by foodborne illness, and mobilize them to prevent illness and death by driving change through advocacy, collaboration, and innovation.

STOP was founded by mothers whose children died due to an outbreak of E. coli O157:H7 over 26 years ago from tainted hamburger meat. The contaminated product was traced back to nine different meat suppliers.

This trace-back was necessary to identify where the system was failing consumers, and this is how the system should work. I do want to reiterate, that the process is about consumers and keeping them safe, and this traceability is always relevant as it is fundamental to any food supply chain. And, it is for this reason that traceability is critical to stop foodborne illness.

It's imperative to stop as we represent consumers who've been impacted by foodborne illness, and we amplify their voices through our work focusing on constituent advocate services which includes our new navigational map for those that are in crisis, post-crisis, or managing long term consequences of surviving a severe foodborne disease.

Our speakers bureau, the alliance to stop foodborne illness which we work directly with industry to

influence their internal food safety culture, food safety policy work, and consumer-focused food safety research.

STOP's constituent advocates are courageous individuals who share their stories of surviving severe foodborne disease, and many of our constituent advocates share their stories of losing a loved one due to something as base as eating. I encourage all of you to read their stories on STOP's honor wall, as they are intended to move industry to put the consumer first, to prevent others from having to suffer as they have. You know, we discuss numbers daily and data that drives our work. And, in previous presentations today there was a lot of talk of very large numbers.

So, when you read these stories they force you to focus on the smallest number, and that number is one -- this is the number that represents each individual, each consumer that's been impacted by adulterated food.

You can find our honor wall and read those stories are www.stopfoodbornillness.org. The definition of traceability is merely the ability to follow a food item and its ingredients through all the steps in the supply chain both backward and forward. Consumers don't know where every ingredient in their fast-food burger comes from, nor do they know where the spices in their delivered cooked, cook-yourself meal originate.

They trust the businesses that are selling them

food, or making meal kits, have and maintain this information. It would never cross their minds that these companies would never provide that information if they became ill. And, moreover, that it could not be provided in a timely manner.

In Dr. Sassi's presentation earlier today, she shared that it's estimated that the primary benefit established by the proposed rule is an 84% reduction in traceability time, based on the four pathogens piloted which were STEC, Cyclospora, Listeria monocytogenes, and nontyphoidal salmonellae. That's an estimated reduction in time from 37 days to 6 days to trace-back. Can you imagine how many lives that could possibly impact?

Traceability is fundamental to what we do in the food supply chain, and it has the ability to protect and save lives. Thank you.

MS. BUCKNER: Thank you very much, Mitzi. Now, we'll turn to Jason.

MR. CULOTTA: Hi, thank you Rebecca. And, I also appreciate the opportunity the FDA has extended to have our association engage in this panel, and in this discussion. As Mitzi shared, traceability is crucial for the consumer, but it's also required of us as food processors to be able to prove that. And, I want to talk about our association is largely in Illinois, Wisconsin, and Minnesota, and comprised of vegetable canners and freezers.

So, the traceability issue has been very important in that. I want to share a little bit about how that's done in this industry, because I think it's instructive for the broader issue of the rule change.

So, beets, carrots, kidney beans, pumpkins -- there's a bunch of these products that originate from the upper-Midwest. In fact, about 90% of our canned green beans, peas, and sweet corn all come from Minnesota and Wisconsin.

So, apparently our electric prices aren't as low as in the northwest. But, we've got a number of brand as well as private label manufacturers. And, these type of shelf-stable foods are in high demand, of course, right now given the conditions we're in.

So, every processor has a traceable code that allows the source of the raw product or the grower to be identified. A number of -- there's a range; some are off the shelf systems that have been implemented and used by some processors, and other have undertaken great expense to have a significant internal system by which they can track this information.

So, some of the key inputs that our industry looks for is, where was the product grown? When was it harvested? When were pesticide applications made? When was the product husked, or... I've got to reconnect here. Husked, washed, cooked -- any number... I lost my video connection. I

guess I'll keep talking.

SPEAKER: That's okay, we can still -- you can go ahead and try, but we can still hear you.

MR. CULOTTA: All right, sounds good. Or, ran through a seamer or placed in interstate commerce.

So, if the inputs are made into these systems then we know that we're going to have the right or the accurate outputs.

So, this goes back to being able to trace which field a given product might originate from.

So, some of the key system aspect having in place is any processor has got to be -- as I mentioned, to be able to trace a product back to the farm from the market. And, that traceability must be done on the packaging or the casing.

I shared an example, when Rebecca and I first talked I shared about a smaller processor we have who, on each can that they produce, their product has an alphabetical code on that, and that identifies to that processor which field that that particular product originated from.

So, FSMA -- Food Safety Modernization Act -- allows each process to tailor their system to the individual company needs. And, one of my points of emphasis is that, for the industry to be able to generate the results that are needed for regulators, having that flexibility for the processor to comply with by designing the system within those parameters that

FSMA provides has been a really positive thing; it has resulted in the information needed.

So, typically their product is tracked by a truck-load, which I find that interesting.

So, then I wanted a little bit about recalling a product. The regulation state that a processor must be able to recall in an adulterated product within 100% of their ability, and our members are frequently subjected to a number of audits, whether it's by FDA, by state regulators, and frequently by customers who are looking to begin doing business with one of these companies. And, a number of trace exercises are required. And, so these systems are tested pretty regularly with mock recalls, and pretty much there's just the question of a few hours in which 100% recovery is needed.

And, so some of our folks -- I've heard that can be as many as 100 trace exercises in a year, so that we're ready when the real issue, if it would arise, that we're ready to respond to that.

So, I think just with this traceability standard that we're talking about, obviously the more robust system we have, the better there is. And, this gets to be difficult for small practices who may lack the resources, whether it's staff or the IT budget, or whatever it may be to furnish a system.

So, I think I'll leave it there and let the panelist comment.

MS. BUCKNER: All right, great. Thank you so much Jason, now we're going to turn to Randy Graham. Thank you.

MR. GRAHAM: Thank you for having me. I'd say that as President of Illinois Specialty Growers Association I primarily represent the smaller growers that Jason was speaking about, and for my constituents I think everybody agrees that traceability is very important, and we do want to participate in that at all levels.

It is a challenge sometimes for my members to know exactly what's required of them and how to best implement the requirement. Some of us have the advantages of working with companies that we are venders for, so we have their information, their requirements, and we know how to comply with them.

So, personally I produce cider some of the Schnuks stores in Illinois, and they have a very robust traceability system and a lot of requirements as far as they want to know my food safety plan, they want to know how my farm is laid out, sourcing of all the products -- that sort thing.

We do have a kill step in our production system, and also a lot coding method so we have traceability from that standpoint. But, then when I look at other aspects of my business where I will deal with perhaps Amish growers -- I've made my store into kind of a farm market where I represent Amish growers and I bring in some of their products and retail them.

So, I need to make sure that I am able to

separate those products by grower for the one-step-back process. And, then I'm the retailer so my consumer is actually the step forward, so they know where they purchased that product.

So, as I look at this system I think from my perspective as a small producer and one who represents small producers, we mainly need a system that is easily understood and easily implemented.

So, whether that requires templates of some sort that we can actually access and use, I think as we've been implementing the produce safety regulations of the Food Safety Modernization Act, a lot of the growers mainly struggle with the feeling that they have to kind of reinvent the wheel all the time, and reinvent their own system.

So, if we have some kind of a template or a centralized system -- even a database that we can access and participate in, I think that would go a long way towards helping the smaller producers comply and know that they are actually complying successfully.

MS. BUCKER: All right, thank you. And, we'll turn the stage to Joe.

MR. SCIMECA: Thank you Rebecca, and I also want to thank the agency and you and the other organizers for the opportunity for IDFA to be part of this panel.

So, IDFA -- or the International Dairy Foods Association -- is based in Washington, D.C., and represent the

nation's dairy manufacturing and marketing industry. IDFA's diverse membership ranges from multinational organizations to single-plant companies, from dairy companies and cooperatives to food retailers and suppliers. Together they represent 90% of the milk, cheese, ice cream, yogurt and cultured products, and dairy ingredients produced and marketed in the U.S. and sold throughout the world.

So, IDFA has been involved in traceability for a very long time. IDFA has a standing food safety committee that has met on this issue over the years with the goal of helping our members implement traceability systems. This also includes facilitating partnering with other dairy industry stakeholders.

For example, the Dairy Innovation Center for U.S. Dairy was created several years ago, and it was recently revised as a voluntary organization that worked with leaders from across the dairy value chain to align on pre-competitive priorities. One of the areas is food safety, which includes traceability, guidance, and the creation of an associated checklist.

In addition to providing info on the components of a traceability system, the guidance provides multiple examples of dairy product supply chains, from origination to the retail store shelf. Identifying the various points of creation, transformation, or transfer. These examples help provide dairy producers and processors with clear model in which to build their own traceability systems.

In addition, the guidance provides several examples of mock recalls that will help provide dairy product producers with more robust recall systems built on effective traceability systems. The checklist which I mentioned, which in practice can be used as an audit, contains 21 points that are needed to be in place in order to have an effective traceability system. Now, personally I've been involved in traceability going back a number of years. In 2009, IFT was awarded a five-year competitively awarded contract from the FDA to complete a number of tasks.

In 2011, IFT completed one of these task orders which included the need to conduct product tracing pilots. IFT conducted two product pilot tracing exercises involving tomatoes and a complex food -- frozen Kung Pao chicken, which also included FSIS because it was a chicken ingredient. Four pilot scenarios were created with the assistance of a number of experts.

A series of public meetings were held, webcasts, and discussion on the feasibility and cost considerations involved. Ultimately, the findings and conclusions of this body of work led to reports submitted to the FDA that was also published.

So, I was part of the expert panel that helped advise on the pilot scenarios.

In addition, around this time IFT created the

Global Food Traceability Center, and through my role at Cargill where I was at at that time, I was instrumental with having Cargill be one of the founding sponsors of this center, so thank you.

MS. BUCKNER: All right, thank you very much to all of our panelists. That was great; a nice mix of food safety and also industry perspectives there which I think is very helpful and will be really useful for our dialogue that we're about to have.

So, my first question to all of you is: how can traceability improve food safety? We heard a little bit about that from Mitzi, but I would ask all of you to speak to how you think this rule, and traceability in general, can improve food safety. And, also its ability to help make recalls more efficient and effective. I think we also heard a little bit about that, but welcome comments from anyone who wants to start, Joe? Go for it.

MR. SCIMECA: All right, I'll break the ice. And, I'm sure my fellow panelists will jump in there.

So, I see traceability as an important tool in the food safety arsenal, along with other tools such as having a robust food safety plan based on validated preventive controls, use of sound, auditing by qualified auditors, appropriate and relevant training, and then perhaps most importantly having a food safety culture.

All right, so I am often asked how to define food safety culture. And, food safety culture is knowing why something is being done to help ensure the safety of the food, and then ensuring that it gets done even if nobody is watching. Now, however we all know that despite everyone's best efforts food safety mistakes can occur.

And, when this happens traceability systems help speed the time to identify and remove the adulterated food from the marketplace and trace back the adulterated ingredients to prevent a potential other future food-safety issues that could be occurring with that same ingredient.

MS. BUCKNER: Great, thank you. Yeah, Frank Yiannas will be very excited that you got in the food safety culture mention there. Other folks? Jason? Randy? Or, Mitzi? On this issue.

MR. GRAHAM: Yeah, I'll speak to it briefly. I think that it's important not only for the consumer but for the producer. I mean, the faster you can trace back a problem and get it stopped, the more confidence the consumer will have in the product, say, they eat and drink, and also the better the image of the producer as being really caring about the quality of the product they put forth and making sure that their systems are strong and ensuring the safety for everybody.

So, it's a win-win really for everybody.

MS. BAUM: I agree with all of the comments. You

know, traceability does help improve food safety because the faster and more efficiently and effectively you can trace a product, the quicker the consumers will get information. And, as I mentioned in my previous comments it's 37 days right now, and if we can reduce that to six days, that really has an impact on the supply chain, food safety at the retail level, and then ultimately the consumer.

So, they go together; I don't think they're mutually exclusive at all. And, you really can't have one without the other when there is some type of adulteration or contaminants that's been identified.

MR. CULOTTA: Yeah, that's right. Whether it's protecting a brand name, obviously the sooner an adulteration situation occurs being able to withdraw that product from supply chain, if not the point of retail is crucial for the industry to pull off and ensure that we're not allowing that threat to linger out there.

MS. BUCKNER: Yeah, we so much agree and we're really excited about the possibility -- the real possibilities of improving food safety with this rule making. I think that, as you all have said, the improvement of consumer confidence is important as we had a whole series of foodborne outbreaks which resulted in this rule making, among other things.

And, so the ability to really improve that situation -- I think there's also a feedback list, right? As we

are getting to problems faster we can learn lessons from that which hopefully prevent future outbreaks which I think is the really important part of this. Also... and, hopefully also assisting with the consumer confidence etc. is avoiding the really broad recalls which we think may be another benefit of this rule making, is that we can really hopefully avoid having to make a broader statement associated with outbreaks if we can actually identify where the contamination is faster.

MS. BAUM: I agree on that Rebecca, and also with the traceability that with snowballing of recall -- you know, you identify one product and then three weeks later...

MS. BUCKNER: Why do you think traceability is important to consumers in terms of what they have to deal with? Rolling recalls is one of them, right? That whole, like, this product and then that product, etc.

MS. BAUM: Consumers rely upon the system to work for them, and I think that's a simple expectation when you're purchasing a product at the store that, A) it's not going to harm me, and B) if there is a problem with the product that I'll be notified, or there's some system to pull this product from commerce as quickly as possible and identify who the producer is, and do some kind of root-cause analysis to identify the problem and prevent it from occurring again. I think that's a reasonable expectation, and that includes retail food establishments complying with the rules.

You know, one of the things I don't think consumers would understand or have a really deep knowledge of is, part of the rule is allowing national or multinational retail chains or establishments, producers that have multiple location that have 10 or fewer employees to be exempt from the rule. And, I think they'd have a hard time with that speaking from a consumer perspective.

And, I asked a variety of individuals about that and they didn't understand how there could be a proposed exemption for a multimillion maybe a billion-dollar company to get an exemption, because they have fewer employees. And, really a lot of the feedback was: wouldn't that incentivize these companies to have 10 or fewer employees?

So, they didn't have to comply with the rule. It's important for traceability at every single level, especially at the consumer to business level. We all want to consume safe products, but ultimately in the end who pays the most can be a consumer with their health or their life.

MS. BARRETT: All right, anybody else on this topic? Go ahead.

MR. SCIMECA: Yeah, I want to certainly agree with Mitzi that the primary real driver behind traceability should be, rightly so, food safety. But, we shouldn't overlook that consumers, and companies for that matter, have interest beyond food safety that traceability can help further. Right?

So, there are the insurance of certain factors associated with foods such as the place of origin, or certain standards like dietary standards like kosher or halal, other claims on sustainability of the product, and so forth that can also be supported by a traceability system.

So, I agree that food safety is the driving factor but there are other benefits of a strong traceability system.

MS. BUCKNER: Yeah, thank you. I think that's a group point, we agree. I think you heard Frank say this morning the issue of, yeah there's more organic food sold than there is produced. And, so you have some issues like that that traceability can potentially help with. Other thoughts on this before we move on?

MR. CULOTTA: Yeah, I guess I just re-mentioned how important it is to other -- between the companies who sell ingredients another company before the final product, having a record or proving the traceability system is intact and works can often be a key lynchpin in one of those contracts between companies.

MS. BUCKNER: Thank you. I think these are all great points, and thank you. All right, moving on to a different topic. We're still on traceability, obviously. What steps are you aware of that have already been taken to implement traceability systems? And, how would the proposed rule further

enhance this?

I think a couple of you spoke to some situations that you're aware of in your opening remarks. But, we really welcome thoughts around what people have done, where people are now with traceability, versus how they will need to move to that in the future and I would love examples if you have them. Joe, you want to start?

MR. SCIMECA: Yeah, thank you.

So, I think one example that I would look to is, as required under FSMA under the supplier verification requirement, our members have vendor approval processes that include verification of traceability systems. And, in many of these vendor approval require also on-site audit.

So, this is an important part of ensuring that traceability is being implemented throughout the value chain. Part of approving your vendor is ensuring that you vendor is also conducting appropriate vender approval. And, that those secondary suppliers also have traceability systems.

So, this is kind of tightening the network through the existing vendor approval process that's required under FSMA. The one thing I would point out is that there is a certain degree of transparency that can occur in this process of verifying your supplier's systems. And, particularly when you start to go back to the secondary and tertiary supplier you can, I think, understand that there is a certain concern, a

competitive concern in revealing suppliers to your customer -- suppliers or suppliers to your customer.

So, while the systems need to be connected and interoperable there is a certain guard rail that we'll have to put into the proposed rule to protect certain confidential business information around the supply chain so that we're not violating that trust among the supplier.

MS. BUCKNER: Yeah, that's an excellent point and certainly one that we're aware of and have heard from others with FSTB and some of the other FSMA rule makings that have required some level of information to be passed through without suppliers.

So, definitely something that we will keep in mind. Other folks on this, Jason or Randy who are involved with producers?

MR. GRAHAM: Yeah, I will say that FSMA has already led to a lot more record keeping at the farm level, even down to very, very specific locations and dates and names of harvester-specific people, and that sort of thing. That really wasn't in place before, so I think as far as looking at step-back process there's already a lot more that's been going on on the farm level to allow very, very specific tracing to... I mean, practically the specific tree or block or trees where, say, a fruit comes from -- in our case, apples.

And, so some of that information is already being

collected by the producers, and that's good because that will mean that much less of a learning curve as we get more tighter and stronger in these systems.

And, we've also seen FSMA lead to stricter vendor approval requirements and that sort of thing. You know, it's driven both ways; it's driven by the consumer, it's driven by the industry.

So, a lot of the growers have changed practices, I would say, a lot. The bigger growers are probably already doing some of this, but the smaller producers -- especially if you were strictly retail -- you really weren't doing some of that stuff in the past because it was pretty much the consumer came to the farm, they got the product, and left. But, now it's a lot more detailed than it was.

So, some of this stuff is already being implemented and this will probably enhance that.

MR. CULOTTA: Yes, as Randy mentioned, a lot of our producers -- or, processors I should say -- in their dealings with the growers with whom they contract, they now require -- they have to know about when were fertilized applications made, and what was that. Or, and herbicide that was applied -- different than a pesticide that the processor may apply, but all these things have to now be part of the record so that if there is some issue that arises further in the chain, we can identify that.

So, I think Randy's right. I think there's more sophistication on the part of the larger growers. And, I know that with our industry there are a number of folks who have been farming a lot of years and they've been growing the same or a similar mix of product and have to change the way that they've done business. It's an important hurdle to overcome in order to make sure that we have that information.

MS. BUCKNER: Great, thank you. All right, I think in a similar vein I would just ask if people were talking about, I would say some of the successes and the fact that people are already doing some of this stuff and they really had to implement this, or have chosen to in terms of the other FSMA rules. Could you all speak to challenges that you're aware of that folks have faced in implementing any tracing systems?

MR. SCIMECA: Well, if no one else is going to go first then I'll start again.

MS. BUCKNER: Go for it.

MR. SCIMECA: I think a couple of challenges that we have identified are the foreign supplier, right? And, that's always a challenge just by the nature of the distance. But, a good example -- a specific example that we have in the dairy industry is with specialty cheese producers.

So, many of these producers in various parts of the world -- for example, Europe, are rather small producers of these specialty cheeses. And, they sell their product to

consolidators. And, the consolidator cuts and repackage the cheese, and then sell those to distributors that eventually export it to the United States. And, currently the ability to trace back to the original producer of the cheese through the consolidator is pretty much limited to a one-month supply of cheese.

So, getting down to the individual producer of a cheese is going to be a challenge there. And, there's so many small ones.

So, that's one example I can give as a specific supply chain that will be problematic. Another one I would say is, like dried dairy powder.

So, for example whey powder -- whey is produced from cheese production, but it could include production from several different batches of cheese made from several different facilities, and that whey is dried down and then commingled with other dried whey, and then commingled together and provided to a customer.

So, like any commingled product it gets to be challenging to trace the product through that comingling. I would also say that while the agency and the proposed rule has focused on pathogens and not so much on chemical contaminants, but we do know there are chemical contaminants that do pose a food safety concern, and that it will be extremely difficult to manage the traceability of products that are commingled, and

ensuring that the safety of those chemical contaminants are being met. And, if they're not to be able to conduct the necessary traceability exercise.

Unlike a biological contaminant, you may have a kill step and the proposed rule allows for a certain halt in the traceability process, that is not going to be the case with a chemical contaminant. And, so I think this is another challenging area that the proposed rule (inaudible) directly address, and it will require I think a lot of thoughtful impulse to handle not only comingling but also chemical contaminants.

MS. BUCKNER: Thank you. Yeah, comingling is always a challenge. Right? I mean, there's -- certainly understand that it's an important factor in the way things are produced. But, it does result in a challenge for whom you're tracing. Randy, or Jason?

MR. GRAHAM: I would speak from the small grower's perspective. I think Jason touched on it earlier that resources are challenges oftentimes for small producers. A lot of these people wear many, many hats already. And, for them it may seem like a small thing to keep additional records, but that's why I think that some standardization or templates and things that could be filled out and kept electronically -- even a template spreadsheet or something -- would be very helpful because I know in going through the FSMA training, the produce safety training, a lot of growers just struggle to understand

exactly what was being required and how best to maintain the records that were necessary.

And, with the goal being food safety, and I think everyone shares that same goal, the easier we can make it and the more clear-cut and obvious that those records can be. I think that would be the best, particularly for small growers who are already wearing a lot of hats and doing a lot of jobs.

And, as Jason mentioned earlier people don't have IT staff so to speak or even a specific person assigned to traceability. A lot of times they're doing almost everything themselves. And, so it's one more thing that they need to learn.

So, that learning curve needs to be as brief as possible and as clear as possible because sometimes it's confusing just to understand. I think the translation from a written rule to the actual day-to-day record can sometimes be a difficult translation.

So, I think having input in that process from people who would actually need to comply would be an important step in making it streamlined as best as possible.

MS. BAUM: I agree with your comments, Randy, with regard to uniformity in the system and a lack thereof. And, that certainly creates a lot of inefficiencies. And, for the smaller growers that you work with it has to be a challenge. And, the proposed rule talks a lot about electronic record

keeping but it does provide for paper records.

But, it seems to me that the way the rule is written that it's setting a lot of the smaller folks up for failure because the requirement would be to submit a spreadsheet in the electronic filterable spreadsheet with all of that information within 24 hours. Do you think that's something that your growers could do?

MR. GRAHAM: It would be very difficult unless they had a package deal, basically, that everything fits together well and they say, "Okay, here's the spreadsheet. Here's what it looks like. If you maintain this data and make it readily accessible, then you're good." You know?

I think that's the biggest confusion that small producers have is, they start to implement a system and wonder am I doing everything that's required? And, until they have an inspection or some kind of a dialogue directly with an inspector, they don't know what their deficiencies may be.

So, I think if we had something going in that was presented -- okay, here it is, here is what you need to do, and this is how you verify the step back, this is how you verify the step forward, that would be very helpful.

MS. BAUM: And, I completely understand that it's a process. And, as Rebecca mentioned, I worked in food banking for 23 years and part of what we did with non-profits was moving them to electronic record keeping, specifically with inventory.

And, it is a long process and there's a lot of hand-holding that's necessary. And, I think it may have been too... I think you also made the point as well, Joe, that the translation from paper to action can be difficult.

So, I agree, resources are probably necessary there.

MS. BUCKNER: Yeah, and this is Rebecca, yeah thank you for those comments. Certainly, it's not our goal to set people up for failure with this rule making of any size. And, I would say it is certainly our intent, as you all are saying, to provide materials that are going to be helpful to people.

We certainly have heard from others that templates and things like that would be very useful. We've done it with other rules. I think certainly we will be looking at what is most useful here with an eye towards the fact that that sortable spreadsheet could be a challenge for people, especially anybody who is thinking they want to keep paper records. And, you know, I think we welcome comments on that, we welcome understanding people's situations, but it is absolutely our intent to be very clear with the minimum folks could do to meet those standards of this rule in terms of providing this information.

And, so I think we will certainly -- we stand ready to do our part to help people really understand what this

should look like in practice. Because, we do understand there are challenges especially for smaller producers in figuring out exactly what it is.

And, I did love the comments about the difference between the written rule and it's actual implementation in real life because that is, for any rule making, always a challenge to go from kind of how FDA is envisioning a process working, or any regulatory agency for that matter is envisioning a process working, and then how it actually translates.

MS. BAUM: I should clarify: I appreciate the 24-hour turnaround -- I certainly appreciate that. I think in real application, it would be a struggle.

MS. BUCKNER: Well, I mean we'll see. You know, and again we welcome comments on that, we welcome understanding how people think this is doable. Certainly, we only anticipate seeing a lot of company step up to provide packages and software etc. that will help people do this.

I think the important thing here with this rule making is the establishment of the common data standards and the language which will then allow other people to step in and produce products to help producers meet the requirements.

So, I think hopefully that is where we're headed down the road with the -- is a real group effort to sort of scale to smaller businesses and get everybody on the same page. Let's see... oh, we're running short on time. I'm looking at

my questions... actually, kind of in keeping with this I would ask about affordability.

We just heard this will be challenging for smaller producers. I am interested for folks who are aware of systems that have already been implemented. Are there returns on investments for businesses in pursuing traceability outside of food safety? I mean, we've heard from some people that it fits with inventory control and things like that. I'm just wondering about your awareness or experience of some of those types of benefits of tracing.

MR. SCIMECA: Well, Rebecca, I think there are some examples of partnerships between retailers and suppliers that have created a very effective interoperable system that allow traceability that provides benefits to consumers, around either organic or some other element attribute of the food that the consumer is seeking.

So, there are example out there. I don't know about the cost or the return on investments. Ultimately, I think they must demonstrate that if the product is to continue to remain on the marketplace. And, I also think that as these IT systems like FAP and other similar ones continue to improve and adopt the software that allows for traceability, and the inputting of key data elements, that the cost will come down.

I will have to say that while we're standardizing the type of data that needs to be collected for an effective

traceability system, there's still the issue of the formatting of that data. All right?

So, you know, you may have the product code but that product code could be formatted in many, many different ways. And, as of yet, that is not standardized.

So, that will really fall to the supplier customer and how they decide that arrangement.

So, that's one area that if we can drive towards more standardization that will help really increase the adoption of these systems.

MS. BUCKNER: Excellent point, thank you. Others on this subject? Awareness of any side benefits of tracing?

MR. GRAHAM: I would say that one side benefit is not only improved consumer confidence, but producer confidence as well. I think if you have a better means of producing a safe product and you know that that product is safe, or you have mechanisms in place that you can trace back any problems that might arrive, that gives the producer more confidence also.

MS. BUCKNER: Great point, thank you.

MR. CULOTTA: Yeah, I think that what Randy just shared I think has been the experience of our processors who have adopted their own proprietary system, but then they do end up seeing benefit in areas that they may not have anticipated when they put the system together.

MS. BUCKNER: Great. All right, we are almost --

we've only got a few minutes left, so I think I would ask the panelist any sort of final remarks from anybody? Don't feel like you have to, but jump in if you have any final thoughts.

MR. SCIMECA: Yeah, I actually do have a lead, and I think you'll get input on this from many different directions how the agency will... and, that is the FDA's traceability list includes many different foods that aren't particularly well-defined either in regulation, or by other standards. Right?

So, for example the cheese commodity group is not particularly well-defined in U.S. regulations. And, so the traceability list excludes other hard cheese, right? But, we don't have a really clear definition of what a hard cheese is.

So, it's kind of hard to tell within that particular food grouping what's in and what's out. And, similarly there are other food categories that there's a lack of clarity. Right?

So, there's a tropical tree fruit category, and then there's a fresh and vegetable...

MS. BUCKNER: A way of understanding foods that are not on the list.

So, that's one helpful hint that the list is available as part of the materials for the school. But, yes, we are very aware that people would like more clarity about our list.

MR. CULOTTA: I would say be very intentional

about providing sufficient resources for compliance even down to the smallest level, the smaller farm. Because, I don't know too many people who are excited about keeping paper records anymore, I mean most people have electronic. But, a lot of times your supplier will hand you a paper record and then you have to input that record somehow.

So, a lot of it starts out as paper whether you use paper or not.

So, I think sufficient resources in order to get the smaller producers going and starting and knowing that they've got what they need to comply will go a long way to reaching this down to all levels of producers. I know a lot of the big suppliers, big producers already have systems in place, and (inaudible) might be tweaking the broader systems. But, the smaller suppliers some of them are starting from scratch.

MS. BUCKNER: Thank you (inaudible), it's always good to be reminded of that and we focus on (inaudible) it is positively our intention to provide the (inaudible) that we can to everybody, especially to our smallest producers.

So, (inaudible) to very small. All right, we've got like a minute left. Jason, are we missing any final thoughts?

MR. CULOTTA: I was going to say, just allowing the flexibility of the producer to comply and FDA does already. I think making sure that feature is built into what final rule

is brought forward will ensure the best compliance and the best information that can be provided to consumers and producers alike.

MS. BAUM: Thank you, I appreciate that the FDA is forward-focused, and has stated in the document that these types of records can be used throughout all of the supply chains, and not just the products on the traceability list.

So, forward thinking I think is really positive and I appreciate everything the industry has done, the leaders that are doing traceability at this point and those that are participating in this process to make sure that the rule makes sense, and it can be implemented and executed.

MR. CULOTTA: Rebecca, I just want to add, I think all my panelists would agree that we really appreciate the agency's transparency during this process, the willingness to get input from stakeholders, very collaborative and I'm sure collectively we'll come up with a better solution than we would have individually trying to do it.

So, thank you.

GROUP: Agreed.

MS. BUCKNER: Yeah, I was just going to say, that will be the wrap up right there. And, I'd really, really like to thank all of you for this great discussion and hearing your experiences and perspectives is so useful as we report in this dialogue, and we want the dialogue to continue about this rule

making and all of our efforts on tractability. Again, we really appreciate your time today. We know you're very busy. And, with that, Kari I'll turn it back over to you.

MS. BARRETT: All right. Boy, what a wonderful panel. This is a big round of applause for all of you. That was an excellent discussion and, again, like Rebecca I really appreciate your time and your thoughtfulness this afternoon.

So, at this point in our agenda we are going to take a quick break.

So, folks, we're going to break now and come back at 3:50 for our open public comment session.

So, thank you.

SPEAKER: All right, thank you. Now, for all my public commenters do me a favor and go ahead and raise your hand. It makes it easier for me to find you and then I can start dialing you in, those of you that are in the meeting room already.

Top of your screen, thank you so much. And, then I will start calling you in. Welcome everyone back, and let's get everything set up. All right, welcome back from break. Kari, you want to take it away?

MS. BARRETT: I sure do.

So, let me just welcome everyone back as well and we are going to start our public comment session. At this point, we're here ready to listen to stakeholder reaction and

perspective on the proposed rule. I do want to welcome all of our public commenter presenters, and thank them in advance for taking the time to prepare their remarks and to offer the public comments. We have I think about seven or eight folks who are ready to give comments.

Please ensure for all those who are giving comment that you're situated so you're ready to go once your name is called. And, I will start out -- I will call you individually by name, and then as noted you will have three minutes to present your remarks. Please do be respectful of the time; I know that you have a clock that you can keep an eye on. We really are strict about the three minutes, so if you should go over three minutes then I will ask you to wrap up and submit the full comment to the docket.

So, again, very appreciative that you're here taking the time and we look forward to what you have to say.

So, with that Michael if we could put up the slide for our first commenter, which is James Kinchilo, Center for Science and the Public Interest. James.

JAMES: Thank you for the opportunity to comment on the proposed rule. I speak on behalf of the Center for Science and the Public Interest, or CSPI, which advocates for science-driven equitable policies to increase food safety.

A comprehensive system of traceability is crucial to ensuring the safety of the food supply, and benefits all

stakeholders. Good traceability allows foodborne disease investigators to quickly identify contaminated products, therefore limiting consumer illness. For food producers and retailers, effective traceability can limit the amount of products and operations which would need to be recalled or investigated.

Wider recalls and prolonged foodborne outbreak investigations result not only in losses of products, but in continued loss of consumer confidence.

Finally, traceability creates further accountability for food safety at every level of the supply chain, which leads to an increase in the attentiveness to food safety and decreased amounts of contaminated products reaching consumers. This new rule will harmonize information requirements and resolve many of the problems with the current systems which has created delays and inefficiencies in trace-backs, and cause documented harm to stakeholders. Overall, CSPI applauds the proposed traceability rule and the FDA's efforts in developing it.

The FDA has also considered entities and products which may deserve waivers or exemptions. We are also supportive of FDA's acknowledgement of the need for some flexibility within the rule, as long as the risk to public health is minimal. For small retail food establishments, we support the proposed Option #2 of partial exemptions to the rule.

In general, when possible the FDA should focus on identifying ways to make compliance more successful for small businesses rather than giving full exemption from policies that have public health benefits. Certain populations in the U.S. may be primarily served by these small retail establishments, and to fully exempt them may disproportionately affect these populations.

Finally, as Rarely Consumed Raw products are exempt from the proposed rule, we support the FDA's efforts to re-evaluate the Rarely Consumed Raw list. The whole population data sets and criteria used to develop the Rarely Consumed Raw list may not be sensitive to detecting important non-traditional products for certain populations which are not consumed raw, and thus subject these products to needless regulatory burden. Alternatively, the Rarely Consumed Raw list may include products which are consumed raw by certain underrepresented populations, or due to changing dietary trends and thus these should be subject to the traceability rule.

In conclusion, while there may be some aspects which warrant additional attention, CSPI again applauds the FDA for this comprehensive traceability rule, and looks forward to the benefits it will provide to public health and the food industry. Thank you.

MS. BARRETT: Great, thank you so much for your comments. We'll go on to our next commenter which is Kate

Tynan. Yeah, so the Northwest Horticulture Council. Yes, go ahead Kate.

KATE: Thank you to FDA for today's opportunity. My name is Kate Tynan, and I'm speaking on behalf of the Northwest Horticultural Council, which represents the growers, packers, and shippers of apples, pears, and cherries in the pacific northwest. We all share the goal of keeping consumers safe, which includes allowing for the swift removal of contaminated products from the marketplace.

This requires a traceability system that provides regulators with the information they need quickly, and is simply enough for the food industry to implement effectively. The NHC believes that this is best done by building on existing traceability majors, and targeting reforms to the areas within the supply chain that are currently failing.

Our industry has fairly effective traceability systems in place that allow for shippers to immediately determine what orchard a box of fruit came from. While we can't control what happens once the fruit leaves the dock, the vast majority of producers participate in the produce traceability initiative that has intended to provide a more system-wide approach. The NHC is working with industry experts to develop detailed written comments in response to the draft rule.

I'd like to take the opportunity today to highlight three specific areas. First, the proposed rule

requires information be shared throughout the supply chain to the level of specificity of the date and time of harvest, cooling, and packing. While we recognize the value of having this information available to regulators in the event it assists with a trace-back investigation, we question the necessity of requiring that it be shared with others in the supply chain.

This is not only burdensome, but also begs the question of why the government should be requiring such information to be shared with other private sector entities.

Second, the NHC asks FDA to reconsider the requirement that the originator must issue a traceability lot code. While we recognize that this could be beneficial for many within the food industry, in the case of tree fruit it could actually complicate traceability efforts.

Current practice within our industry is for packers who often pack for a number of other growers in addition to their own fruit to assign growers and their individual orchard locations their own lot code, and retain that traceability information on both the fruit they own, and those that come from other growers.

This would actually save FDA a step in the trace-back investigation. Therefore, we ask the FDA allow the originator to defer this responsibility to a packer when appropriate. This leads to the final issue; farms are, for obvious reason, an important part of this proposed regulation.

however, the agricultural industry is still awaiting clarity on how FDA defines a farm. It is our understanding from previous statements made by FDA officials that the agency plans to take regulatory action to revise the farm definition in the near future. I cannot emphasize enough the importance of providing this clarity before a final traceability rule becomes effective. Otherwise, the agency will only be further complicating these traceability efforts, both for industry and the regulators attempting to enforce this new rule.

Thank you again for this opportunity today.

MS. BARRETT: Great, thank you very much. Thank you for your comments, and we'll go to our next commenter which is Lawrence Lynch, national restaurant association.

LAWRENCE: Kari, thank you and the FDA for this opportunity to present this afternoon. My name is Larry Lynch, and I'm the Senior Vice President of Science and Industry for the National Restaurant Association.

The National Restaurant Association is the largest food service trade association in the world. We represent an advocate on behalf of more than 500,000 restaurant businesses. I'm here today during a most challenging time in our industry. Restaurants more than most industries in the nation have suffered some of the most significant sales and job

losses since the COVID-19 outbreak began. We've seen 1 in 6 restaurants close, approximately 100,000 shuttered businesses for either the long term, or permanently.

In addition, even with the rehiring of many restaurants employees the industry is still at a net loss of 2.3 million jobs due to COVID-19. And, finally the restaurant industry as a whole is expecting $240 billion in losses in the 2020 calendar year. It's in that framework while looking forward that we present to you here today.

While working through the harsh realities of the pandemic, we continue to hear from our members that quality assurance and food safety remains the top priority for the entire restaurant industry. Well, conversations with our industry's food experts are ongoing; our members are concerned this proposal would create an extremely high burden for restaurants. And, we ask the FDA to consider the following recommendations as it continues its work on the proposal.

First, the association asks the FDA for additional time to review the proposed rule by extending the comment period to at least March of 2021.

Second, we ask the agency to consider hosting a fourth public meeting on this topic where FDA can summarize feedback they have received from] the food industry to date, and allow stakeholders to provide oral comment in the new year.

Third, the association request extending the two-

year implementation timeframe and the proposed to four years, following publication of the final rule in the federal register.

Restaurants are the last stop in the supply chain before food products reach consumers, and in order for restaurants to become compliant they must be able to determine how their suppliers will change their business practices to become compliant, as well as how restaurant suppliers will share the proposed required data and tracking information with restaurant businesses.

If the supplier does not come into compliance ahead of the two-year mark, the supply chain entities downstream like restaurants will not appropriately achieve rule compliance. Thus, we respectively ask the FDA to allow for four years so that all supply chain entities, but especially those downstream in the supply chain, can comply with the requirements to final rule.

The final request is for implementation flexibility. The restaurant industry represents a wide variety of businesses, widely diverted menus, varying business sizes and layouts, and variegated business concepts from non-profits to franchise corporations, require a wide variety of different food resources and operational logistics.

As a result, restaurants need flexibility by which their data and records are stored, organized, and maintained. In the case of required sortable spreadsheets, as

proposed this may be outdated in some restaurants and a huge advancement for others. More flexibility in how this information is maintained and provided, the better the restaurant industry will be able to comply.

We ask the FDA to provide as much flexibility as possible regarding the format that must be used for records provided in the agency upon request. I thank you for the opportunity to share these recommendations with you, the industry looks forward to preparing more detailed written comments in the months to come.

MS. BARRETT: Okay, thank you Larry. And, just noting your remarks, again, how much all of us appreciate all that the food industry is doing during this very difficult time.

So, thank you for your comments and we'll get to our next commenter.

LAWRENCE: Thank you.

MS. BARRETT: Melissa Suprin, who is with Northeastern University. Melissa.

MELISSA: Thank you. My name's Melissa Suprin, I am a doctoral candidate and researcher at Northeastern University with an additional 25 years of experience in manufacturing quality risk management, and research and development.

I'm asking today that you consider three things related to food traceability rules. Implement traceability so

that it drives prevention, eliminate exemptions or be transparent to the public about which producers operate outside of requirements, and consider alternative forms of regulation that are less complicated and more preventative.

According to the FDA's website, the Food Safety Modernization Act was meant to transform the nation's food safety system by shifting the focus from responding to foodborne illness to preventing it. And, that's my theme for today. Year to date, recalls for biological contamination have increased over 20% and that's with data reported only through September of 2020.

In addition, we continue to see large multi-state outbreaks. Recent outbreaks related to peaches, bagged salads, and onions resulted in significant numbers of illnesses and hospitalizations, and included 47 states.

Recall and continued widespread outbreaks are indications that we have more to do to prevent foodborne illness. The good news is the causes of foodborne illness are generally understood and most are preventable, meaning if risk controls are put in place to intervene at the cause, foodborne illness can be prevented.

While traceability is a helpful risk control, it does not prevent outbreaks; it detects outbreaks after they have reached multiple consumers and only if they have been detected as outbreaks.

So, for your additional consideration the traceability rules will be most impact as they create accountability for the whole food supply chain. If a food facility can't afford to handle food safety, they can't afford to make food.

We need to consider whether current exemptions are keeping FSMA from being as effective as we might have hoped. Next, traceability is most impactful if it connects the responsible food facilities to deterrents to supply tainted food to consumers.

And, last data generated from tracing has to be used to advance understanding of root causes of foodborne illness cases for future preventative actions. I don't disagree that there are benefits associated with establishing traceability through the food supply chain.

But, I am asking that FDA carefully review the investment and traceability from a cost/benefit perspective with a focus on prevention. How do FDA and CDC create the process, or do they create the process? Or, do they just create the requirements? Perhaps it is FDA's rule to require food facilities to be able to trace products to and from the consumer, but not necessarily to implement a specific process for methods for tracing.

FDA resources may be better spent on methods that have been proven effective in other similar areas, like those

used by USDA and on FDA's pharmaceutical side, where faculty capabilities are assessed before they are permitted to introduce products to the market, and retailers maintain responsibility for delivering safe products to the hands of consumers. Agency resources are used on more preventative activities like inspections of operating facilities. Thank you for the opportunity to comment.

MS. BARRETT: All right, thank you very much for your comments. We'll now go on to our next commenter, Johnathon Esien who is with the International Food Service Distributor's Association. Johnathan.

JOHNATHAN: Thank you, my name is Johnathon Ishan and I’m Senior Vice President of Government Relations for the International Food Service Distributors Association. IFDA represents food service distributors to supply food and related products to restaurants, hospitals, schools, and other food away from home providers.

IFDA has worked closely with FDA throughout the FSMA implementation process, and we've appreciated the agency's work to ensure these rules were focused on reducing risks while providing industry with strong and clear guidance on compliance.

If the members strongly support FDA's goal of improving public health and building a better trace-back system to quickly and efficiently identify and remove adulterated products from the supply chain.

We will be filing detailed written comments, and I'd like to take this opportunity to raise three key points regarding the proposal. First, our largest concern is around the complexity of the proposal and the sheer volume of additional records it will require.

Food service distributors carry tens of thousands of products sourced from thousands of suppliers and deliver more than 8.7 billion cases each year. This makes understanding the requirements this will create for distributors an extraordinary undertaking.

Determining which items fall within the scope of the rule, how the rule would apply to each item, and what records will be required, will likely require an analysis of each individual product. Beyond this determination, a different record keeping system for only the items covered by the rule create significant additional issues.

The proposal also creates an entirely new terminology that in many instances could add to the confusion and hamper compliance. The requirements for first receivers provide an example of how difficult these determinations could be. In the examples on the FDA's website, a first receiver can vary under different supply chain scenarios. Distributors would need to make this determination for each covered product, and the answer could change depending on how a product is sourced.

Given the high volume of transactions, this could

make it difficult to understand the regulatory requirements and ensure compliance. The final rule should ensure the distributors can clearly understand their obligations. Second, we encourage the agency to reconsider the scope of products that are subject to the proposed rule.

The proposal covers not only foods on the Food Traceability List, but also products made with listed foods which could require a review of every single sub-ingredients in the product distributor's handle.

As written, the proposal would also include products that are manufactured with the clear intent that they will be subject to a kill step prior to consumption, such as a frozen pizza with cheese and vegetables. Other products may come in various forms, sometimes with a kill step in between, sometimes without such as refrigerated salsa.

Given the large number of products in a distributor system, determining which products incur the additional record keeping requirements would not be a simple process. Third, if they would like to request an extension of the overall comment period, as it will take significant time to digest the proposal's implication for distributors.

We are committed to providing FDA with substantive and detailed feedback to help the agency achieve its critical goals. Given the rules, complexity, the pandemic, and the upcoming holidays additional time is necessary to allow a

thorough review and provide meaningful comments. Thank you.

MS. BARRETT: All right, thank you very much for your comments. We'll now go to Julie McGill. Julie is with Food Logic.

JULIE: All right, thank you.

So, good afternoon. I appreciate this opportunity to provide comments today. My name is Julie McGill and I am the Vice President of Supply Chain Strategy and Insights at Food Logic. Our mission is to map the world's food supply chain, and make it as safe as possible.

I don't see if the clock is on... oh, there we go. As deputy commissioner Frank Yiannas commented in his opening statements during the first public meeting, end-to-end traceability is being realized today. At Food Logic, our customers are gathering key data elements, sharing critical tracking events, and connecting their supply chain.

We now have over 50 million critical tracking events in our platform. This number has doubled since the beginning of this year. I would be remiss if I didn't address the impact of the global pandemic. This has magnified the need for better connectivity across food systems, and we experience this first-hand through our customers as they address stressors placed on their food chains during COVID. With real time event data, they were able to access detailed views of their inventories at the batch-lot level to better understand product

level, shortages, and avert product spoilage.

With this increased understanding, they were able to act swiftly to hold, withdraw, and redirect product in their supply chain. Through our customer implementation at food logic, we obtain first-hand the critical investments that need to be made in systems, resources, and processes] to make end-to-end traceability a reality.

We understand that these changes do take time, and that they require collaboration across supply chain partners. We commend the FDA for placing emphasis on three main areas that we have deemed critical for our customer success with traceability. First, is data standards. Global data standards such as GS-1 are absolutely critical for end-to-end traceabilities to function.

Second, the emphasis on taking a phased approach -- we highly recommend rolling out traceability in phases. Community education, and clear communication of the record keeping requirements will be vital to engaging the industry to make the shift in processes and practice.

And, lastly the emphasis on tech-enabled traceabilties. We believe in a connected food chain driven by technology -- technology that is interoperable with other systems as well. Implementing digitized traceability programs allows companies to have this data at their fingertips, reducing the time that it takes to investigate issues from days and even

weeks down to seconds.

This is why we are here; 10 years ago we participated in the first round of FDA traceability pilots, and we are thrilled to see these next steps taken for the industry. Consumer safety is our utmost concern, and we are confident that food companies can adopt processes and interoperable technologies to make end-to-end traceability across the food chain a reality. Thank you.

MS. BARRETT: All right, thank you very much for your comments. And, then our last commenter today is Walter Ram with the GUMAR Company. Walter.

WALTER: Thank you Kari. My name is Walter Ram, and I'm the Vice President of Food Safety at the GUMAR company. We supply about five dozen different items to the marketplace as growers, packers, shippers, importers, exporters, and more. We support the food traceability rule, and its goal of strengthening traceability in our food supply. We applaud FDA for the efforts at creating a risk-based rule that promises to have positive impacts on public health.

Although we believe that FDA got a lot right, I would like to comment on two concerns. The Food Traceability List takes a risk-based approach focusing on foods that have elevated probabilities of causing foodborne illnesses.

We applaud this risk-based approach, but neither the rule nor the risk-ranking tool used to develop it contains a

mechanism for removing a food once it is on it. Since regulations are very difficult to amend on they're enacted, it is strongly recommended that such a mechanism be included in this rule before it is finalized.

There are many scenarios that would warrant food being removed from the list, such as an effective mitigating strategy that is being developed and adopted by the industry. Even if such a mechanism is rarely used, it would not lessen the public health protection that the rule provides. A separate concern is the inclusion of watermelons with all melons in the Food Traceability List.

Watermelons are substantially different than cantaloupes and other muskmelons, and as raw agricultural commodities watermelons are rarely responsible for recalls. Since 2010, nearly all watermelon recalls have been for fresh cut watermelons, or related to food preparation issues. Watermelons are botanically different as well, and they even belong to a different genus than cantaloupes and honeydews.

These fruits are not just found in different genera, their morphology is substantially different as well. Watermelons have smooth, hard rinds and skins, not meta-skins like cantaloupes. Watermelons also don't have internal feed cavities like cantaloupes and honeydews. More importantly however, whole fresh watermelons are not generally associated with foodborne illnesses.

There have been numerous recalls of fresh cut or pre-cut watermelons, but the Food Traceability List already includes all fresh fruits and vegetables. Accordingly, we ask that whole fresh watermelons be excluded from the traceability list. We support activities that will protect public health, but we believe that the inclusion of whole, fresh watermelons would be a misallocation of finite food safety resources for both industry and government. Thank you very much for this opportunity to speak at this session, and we'll be providing more detailed comments in written form.

MS. BARRETT: Great, thank you so much for your comments. And, for all of our commenters this afternoon we do look forward to your full comments being submitted to the docket. And, again we really appreciate your time and your thoughtfulness in presenting this afternoon.

So, now I'm going to switch to our last segment of the agenda which is to conclude today's public meeting. And, in that regard I would like to welcome Dr. Susan Mayne who is our FDA CFSAN Director. Dr. Mayne has been actively engaged in this rule making process, and we look forward to her remarks today.

So, Dr. Mayne we'll turn it over to you.

MS. MAYNE: Great, are you able to hear my Kari?

MS. BARRETT: I can hear you, but let me get the webcam on.

SPEAKER: We have to turn it back on now. We just had to turn it back on, because we just went to the next layout.

MS. MAYNE: Let's get it back on... there we go.

MS. BARRETT: All right, perfect.

MS. MAYNE: Got it? Okay. All right, you can hear me, you can see me. Thank you.

So, good afternoon everyone. I know all of you have been with us virtually for many hours today so I'm going to 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 as we all try to manage things like work, home, and school under the constraints created by COVID-19.

And, so I just want to thank you all for making the time to join us today to discuss our food traceability proposed rule. Second, I want to thank all of our panelists for participating. The perspective and feedback that we heard during today's public meeting, as well as during the other public meetings and throughout the comment period, are vitally important during our rule making.

You've all given us a lot to consider, and I hope the discussion today has also helped all of you listening to think about the requirements that we've laid out in the proposal, and how they may affect your interests. Based on the feedback we have heard so far, we understand that additional

clarification about some of the concepts in the proposal would be helpful.

We all recognize that we have introduced some new concepts, and that there are many different supply chain structures that these requirements will apply to if finalized. We are committed to ensuring that the regulated industry understands how these requirements could be implemented. As part of this commitment, we continue to make available additional resources on our website, and we are carefully listening to determine whether the materials might be helpful.

I also want to emphasize how important it is that when you are submitting comments, you provide thorough examples of how your supply chain works, and how these proposed requirements might apply.

Our goal is for this role to be flexible and workable across many different supply chains, and so we need your help to ensure we consider all of these situations as we finalize the rule. Although I know that this kind of virtual public meeting isn't our ideal solution, your feedback is so important to this process and I am glad that we had this opportunity today to discuss and support this rule making.

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 SYNA 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 again to be a tremendous barrier in our ability to rapidly respond to outbreaks.

The traceability systems we have today far too often leave us scrambling for information during the critical hours, days, and weeks after 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 deaths.

It's for all 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 move this rule forward. Thank you again.

MS. BARRETT: Thank you Dr. Mayne for your remarks, and for concluding our meeting today. It has really been a tremendous day, and really again I want to thank everyone for joining us.

I want everybody at FDA and the external presenters who helped in the planning preparing for this meeting. And, we do look forward to continuing to work with all of our stakeholders as we move forward. I do want you to know that there is one last opportunity to participate in a traceability public meeting in December, so if you know someone who has not been able to join but who would like to, then please

encourage that. And, with that we will conclude and have a wonderful evening.

So, we are adjourned. Thank you again.

CERTIFICATE OF NOTARY PUBLIC

I, Damaris Hamilton, the officer before whom the foregoing proceedings were taken, do hereby certify that any witness(es) in the foregoing proceedings, prior to testifying, were duly sworn; that the proceedings were recorded by me and thereafter reduced to typewriting by a qualified transcriptionist; that said digital audio recording of said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

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Damaris Hamilton

Notary Public in and for the

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