

U.S. Food and Drug Administration (FDA)

Public Meeting:

Requirements for Additional Traceability Records for Certain

Foods: Proposed Rule

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Moderated by Barrett, Kari

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A P P E A R A N C E S

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Michael Kawczynski, Project Manager, FDA (by videoconference)

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Center for Food Safety and Applied Nutrition (CFSAN) (by
videoconference)

Frank Yiannas, FDA Deputy Commissioner for Food Policy and
Response (by videoconference)

Katherine Vierk, Division Director, Office of Analytics and
Research, FDA CFSAN (by videoconference)

Karen Blickenstaff, Response Staff Director, Coordinated
Outbreak Response and Evaluation Network (CORE), FDA CFSAN (by
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A P P E A R A N C E S (cont'd.)

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Coordination Staff, FDA Office of Policy, Legislation, and
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Dr. Yuhuan Chen, Interdisciplinary Scientist, Division of Risk
and Decision Analysis, FDA CFSAN (by videoconference)

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Dr. Aliya Sassi, Senior Economist, Office of Policy,
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Commissioner (by videoconference)

Andrew Kennedy, New Era Technology Team Leader, FDA Office of
Food Policy and Response (by videoconference)

A P P E A R A N C E S (cont'd.)

Erik Mettler, Assistant Commissioner for Partnerships and Policy, FDA Office of Regulatory Affairs (ORA) (by videoconference)

Natalie Krout-Greenberg, Director, Inspection Services Division, California Department of Food & Agriculture (by videoconference)

Randy Treadwell, Program Manager, Rapid Response & Emergency Management, Washington State Department of Agriculture (by videoconference)

Dr. Rebecca Buckner, Senior Science Advisor to the Center Director, FDA CFSAN (by videoconference)

Dr. De Ann Davis, Senior VP Science, Western Growers (by videoconference)

Lisa Weddig, VP Regulatory & Technical Affairs, National Fisheries Institute (by videoconference)

Greg Ferrara, President & CEO, National Grocers Association (by videoconference)

Sandra Eskin, Project Director for Food Safety, PEW Charitable Trusts (by videoconference)

A P P E A R A N C E S (cont'd.)

Dr. Susan Mayne, FDA CFSAN Director (by videoconference)

Kelly Nuckolls, Policy Specialist, National Sustainable
Agriculture Coalition (by videoconference)

Shaun Kennedy, Director, Food System Institute (by
videoconference)

Wyllys Terry, Shellfish Solutions (by videoconference)

Angela Fernandez, VP, GS1 US (by videoconference)

Paige Smoyer, Manager Food Safety & Scientific Affairs, National
Confectioners Association (by videoconference)

Elie Cohen, Senior Advisor Sales Americas, Connecting Food (by
videoconference)

Patrick Smith, President, Soil & Environmental Consultants (by
videoconference)

Beth Lowell, Deputy VP for U.S. Campaigns, Oceana (by
videoconference)

A P P E A R A N C E S (cont'd.)

Bob Wolpert, Corporate Senior VP and President and President
Quality Custom Distribution (QCD), Golden State Foods (by
videoconference)

Ron Tanner, VPP Education, Content & Advocacy, Specialty Food
Association (by videoconference)

Dr. Jennifer McEntire, VP Food Safety, United Fresh Produce
Association (by videoconference)

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MS. BARRETT: -- as we work out all the details for today but we do want to welcome you to today's public meeting, which 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's Food Safety Modernization Act, which we also call FSMA. And this is the third of three public meetings that we have held on this topic.

So we do hope that today you'll find the meeting very useful in evaluating the proposed rule, providing more clarification, and really in facilitating the 00:00:39 process.

So my name is Kari Barrett and I lead the Public Engagement Team at FDA Center for Food Safety and Applied Nutrition and I will be moderating today. Over the course of the day we'll walk through an overview and the key components of the proposed rule; we'll have a Q and A; we'll hear from our state partners and some external stakeholders; and then we'll receive public comment at the end of the day.

So before we begin, a few quick agenda items. All

of you should have the agenda; it was posted on the FDA website. We also have speaker biographies there as well so today we'll be very brief on introduction.

The meeting today is being transcribed and it is also being recorded; the recording should be posted fairly shortly -- within a week or so -- but the slides and transcripts may take a little bit more time. We'll have all of that up in December.

So with that that concludes the housekeeping part of the meeting as we start off and at this point I'd be pleased to introduce Mr. Frank Yiannas, who's our Deputy Commission for Food Policy and Response.

And Frank is going to offer some introductory remarks so Frank, I'll turn to you.

MR. YIANNAS: And thank you. Well good morning to each and every one of you and thank you for joining us today and being part of what I think is going to be a very important conversation.

I recognize these are challenging times and I appreciate the fact that you've taken time out of your busy schedule to pause for a moment with us and look towards the

future and consider how we together can further strengthen food safety protections for generations to come.

You're going to have a full day I'm sure and find it extremely valuable but I wanted to start -- when we talk about food traceability what we're really talking about is the ability to track a food at every step in its journey through the supply chain continuum and by every step we mean from the time a food leaves its source or origin to when it lands on your plate.

The draft rule we'll be talking about today is critical; one can also say it's foundational in our work to achieve that kind of end-to-end traceability throughout the food system.

In the FDA Food Safety Modernization Act -- also known as FSMA -- Congress always anticipated the need for enhanced tracking and tracing of certain foods. We've used the framework provided to us by Congress to propose this food traceability rule; a draft list of foods for which additional recordkeeping requirements would apply.

Please note that we're not calling it a high-risk foods list because any food can be hazardous if the right steps haven't been taken to ensure its safety and we believe that by

using the term "high risk" we could mislead consumers; so instead we're simply calling it the food traceability list.

While limited to only certain foods we believe we're laying the foundation for a standardized approach to traceability recordkeeping, paving the way for industry to adopt, harmonize, leverage, and -- very importantly -- scale more digital traceability systems in the future.

The proposed rule -- while under the auspices of FSMA -- is also part of a bridge to the New Era of Smarter Food Safety -- which I hope you're familiar with -- and the blueprint that Commissioner Dr. Steven Hahn and I announced in July of this year.

In fact tech-enabled traceability is one of the foundational pillars of the New Era initiative in which we plan to use new and emerging technologies and new tools and approaches to create a more-digital, traceable, and safer food system.

This draft rule is the first step -- the very first one -- in our work to harmonize the key data elements and critical tracking events -- KDEs and CTEs -- which you'll be hearing more about today -- needed to enhance traceability.

In fact today you're going to hear a lot about the what of the proposal or what's in it from my colleagues in FDA and other experts in the public and private sectors.

So in the brief moment that we have together this morning I'd like to spend more time on the why of this proposal -- why it's critical and why it's needed.

In the fact the why of the proposal is so important because we all know it's the why that serves as the antecedent -- the actions that we'll take and we'll take them together.

Now you'll be hearing a lot of talk about data and standards; it's important to remember that this is ultimately all about protecting consumers from contaminated foods. It's also about creating a more-transparent food system.

In other words it's about getting rid of the anonymity that sometimes -- in fact I could say often -- exists as we try to investigate outbreaks of foodborne illnesses. Everything -- and I mean everything that we're doing is to bend the curve of foodborne illness.

That's worth repeating. Everything that we're doing is to bend the curve of foodborne illness in this country

and to give consumers the confidence they deserve in the safety of the foods they eat and they serve their families and friends.

So let me quickly elaborate a few points on why this is so important. I believe that better food traceability is a game changer for food safety. I don't think I'm overstating that. It's preventative in nature and we'll talk a little bit more about that; oftentimes people think "well better traceability is reactive" and while I think those comments are well-intended they couldn't be further from the truth.

So let's begin. Why is better food traceability needed? Well one reason; it's all about food safety modernization. I think everyone on this webinar knows we've made great strides in implementing FSMA; most compliant dates have arrived. There have been extensive training and inspections conducted; guidance documents and other resources have been provided; and enforcement actions have been taken.

Today's food system is pretty impressive -- our modern food system -- when you think about the wide variety of different foods -- generally very safe -- available to you for a fraction of your hard-earned dollar. In fact our food supply while challenged because of the pandemic has remained amazingly

resilient throughout the whole COVID pandemic.

However many of you have heard me say I believe that today's food system -- while impressive -- has one major Achilles heel and that's a lack of traceability and transparency.

The records involved in moving food through the supply chain are still unfortunately largely paper-based; this creates a system in which it's necessary to take one step forward to identify where the food has gone and one step back to identify the previous source.

This along with insufficient -- and let me emphasize -- a lack of standardized data identifying the product along the supply chain creates an inability to rapidly track and trace foods and during an outbreak when this matters and costs - - this actually can cost lives; it can cost millions of dollars in avoidable product loss; and certainly damage the consumer trust.

I cannot state this strongly enough. When there's an outbreak of foodborne illness it's critical to rapidly identify where that contamination occurred and having this information allows us to alert the public and the food industry

about which food to avoid, remove contaminated food from the market, and evaluation what may have caused that contamination so that actions can be taken to prevent it from happening again.

And all this requires extensive investigation; collaboration; working as necessary with state, local, and sometimes international health officials -- certainly partners such as the CDC and the USDA.

And these investigations cannot be effective without timely access to accurate information all along the food supply chain continuum and that's why food traceability is so essential to food safety.

When we look at the current state of traceability across the food supply we could find that even though some companies and retail chains have adopted more-modern and effective traceability systems -- and we're happy about that -- rarely are these systems compatible with each other and still many food companies have not 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 and we can -- no, I should say we must do better.

The second reason why it's time for a new era of better traceability is because quite frankly it's an idea whose time has come.

I think many of you know food safety's been my life's work for over 30 years -- first in the private sector and now I'm so happy to be at FDA. And while there's no question in my mind that there's a strong public health -- a business case for better food traceability.

Let me tell you what I think the future looks like. I was once involved in a blockchain pilot -- distributed ledger technology -- to see if by applying technology we could enhance food traceability in the retail sector. That pilot traced mangoes back to their source so I'm going to use it as an iconic example.

I call it the life journey of a mango. Mangoes had a complicated supply chain like many other foods that we consume beginning with seedlings that take five to eight years to mature once they're planted; once those trees -- five to eight years later -- mature and start bearing fruit and the fruit are ripe farm crews will go out and harvest and transport those mangoes to a packing shed; from a packing shed they can

get shipped because they're grown in Central and South America and this time it's speared by airline; received to the United States; and once in the U.S. they could go further processing -- in this example they can get washed, peeled, sliced, put in the clamshell, and sent to stores across the nation.

In this pilot I actually purchased a package of sliced mangoes from a retail store and came into my staff meetings when I was in the private sector, put it in the center of the conference room table, and I told my team at that time "the traceback tester study starts right now. Tell me from where these mangoes in this beautiful package of sliced mangoes came from."

In working with stakeholders and supply chain it took my team at that time six days, eighteen hours, and twenty-six minutes to identify the farms from which the mangoes in that package came from. Now that's pretty good when the average traceback can take weeks or even months.

Fast forward to the pilot that we used -- or conducted using distributed ledger technology with small growers that collected information in very simple user form and standardized format along the entire continuum.

At the end of the pilot we scanned a package of sliced mangoes and we were able to trace it back to source with specificity in 2.2 seconds -- reducing traceability to the farm from 7 days to 2.2 seconds.

Now that's what I've referred to as food traceability as the speed of thought -- an ability to deliver accurate real-time information about how food -- how it's produced and how it flows from point of origin to the point of consumption and that's a game changer for food safety. We won't get there overnight but that's an example or a vision of what is possible.

The draft food traceability rule was developed independently of any specific technology so that it will remain relevant well into the future. We imagine that in the future methods of capturing, storing, and sharing traceability data will continue to evolve; however the basic principles of traceability will remain consistent.

And we recognize that there will be many solutions. Now FDA will remain technology agnostic; we will be very focused on helping to ensure that technologies can work well together by paying attention to these issues of

interoperability, governance, and common structure data and terminology such as the key data elements and critical tracking events that we've referred to and we're all going to become very familiar with.

We also need to help to ensure that food companies of all sizes -- whether they're small or medium enterprise -- can utilize these new tracing technologies with cost proportional to the benefits and we'll be very focused to working with technology firms on this.

And we need to insure that the lessons learned about food safety through insights gathered by better traceability are shared with all of the continuum and even broader; that's what we mean when we talk about democratizing data and information so the entire food system gets better and wins together.

We must create a digital and traceable food ecosystems that create what I refer to as shared value for all participants involved and for companies of all sizes. And we can and will do this.

Industry has already taken the lead in this question of better traceability. Why? Well because industry

knows that it's good for their customers and their customers are demanding it and it's a very good and important business practice.

Now real quickly let me just pause or talk a little bit more on why -- the last why and why the time is now for better food traceability; it's because traceability will lead to better foodborne prevention.

I know sometimes -- I referred to it earlier -- people think that "well traceability is reactive in nature and we want to stay focused on preventative measures." It is a preventative measure.

Let me try to persuade you. You don't have to look too far to find deadly outbreaks that have defined what a lack of better food traceability has cost us in society -- whether it was the outbreak of E. coli O157:H7 in sections tied to bagged spinach in 2006 -- if you remember that outbreak; 2006. Greater than a decade ago.

What happened there? We knew there were illnesses associated with bagged spinach. You will recall at that time in 2006 the public health advisories that called for all spinach to be removed from supermarket and restaurant shelves.

And it took the FDA two weeks to trace that spinach back to source and when it was all said and done it was one producer, one day's production, one lot number. A lack of better traceability.

More recently you could think about PCA -- the Peanut Corporation of America -- in 2009 and the fact that it produced about 2 to 3 percent of the peanut paste produced in this country yet it made its way into literally thousands of different food SKUs and some of those recalls after the outbreak was known came in literally months after the original outbreak was declared. A lack of better traceability.

Or more recently you can think about romaine lettuce in 2018.

Better traceability will have the benefit of only not helping to solve outbreaks sooner and potentially prevent additional illnesses by shortening the epidemic curve -- a form of prevention often referred to as secondary prevention; so it's prevention -- but it will also help us get back -- source quicker in these instances to conduct the much-needed root cause analysis to prevent such outbreaks from occurring again in the future.

So that will be a form of primary prevention. We have seen these food vehicles that are repeatedly implicating in foodborne outbreaks. And our inability to do rapid root cause analysis is a challenge.

You see, better traceability will result with that question and better foodborne illness prevention -- primary prevention.

It would also help food producers from being unfairly impacted by contamination events that they had nothing to do with -- and we've seen this all too often and it's tragic and we can do better; just think of romaine lettuce as a perfect example.

But lastly, let me say that better traceability is a game changer for prevention because at the end of the day what it will do is create greater transparency in the food system and I can't overstate the importance of greater transparency in the food system.

If you think about this concept of transparency and how powerful it is in terms of the motivator for prevention what we have today is the opposite of transparency in a lot of the food system. We have anonymity and anonymity as a concept is

not a good thing in areas of life where it matters.

Do you want anonymity in how people do banking?
Do you want anonymity in the classroom when you want to ensure that students aren't cheating and taking the test legitimately?

Same is true for food safety; this concept of greater transparency -- the ability to shine a light if you will -- on all nodes or aspects of food production I think is a powerful idea -- one that allows people to self-govern and moderate their behaviors because they know that all that they do is transparent for all and so they self-govern their actions and behaviors and move from accountability to an area of just being responsible because they care.

Let me also talk about the lessons learned of food traceability. When you look how other industries today as we speak are tracking through digital means the real-time movement of planes -- you know this. When you're flying, ridesharing, or packaged goods; if you get online to order a packaged good -- a non-perishable good -- you probably know at any certain point of time where that good that you ordered is and when you're likely to receive it at home.

We can do this in the food system too. And we

will. And the food system -- I believe it's inevitable that the food system becomes more traceable and tracked with digital means.

So the benefits to me personally have been clear for a long time but the need for better food traceability and transparency clearly have been highlighted through the pandemic. What we learned through the pandemic is that better traceability could help us create the type of transparency that would've been extremely beneficial at the height or the start of the pandemic and the public health emergency when we saw that we didn't have a food supply issue but we had a supply chain logistics issue with too much food in the wrong places and helping to divert it. It might help FDA and others in the course of normal events but certainly in a crisis like the pandemic.

Consumers have an interest in this too; they want to know more about their foods; they want a better understanding of how foods are produced. And enhanced traceability will do that.

And so after 30 years of experience I can tell you that consumers want this more today than ever before. There was a time when they primarily wanted great values but even

today consumers are asking more about where their food comes from and how it's produced.

And so if you see all the pros and why that I've answered today and you think about the cons of improving food traceability I think without the question the pros are outweighing the cons. And I hope you see it that way too.

In closing I think you're going to have a very fruitful and productive day. This is the third of our public meetings and I plan to stay logged in and listen to all of it; that's how great I think they are.

But I want you to close this morning's section with this. Follow along with me.

I want you to imagine a world -- just imagine a world in which you can scan a product at your favorite grocery store before buying it and know immediately where it was produced or if it's involved in a recall.

I want you to imagine if the FDA could trace a food vehicle suspected to be the cause of an outbreak -- have you seen us do in the past -- from shelf to source in minutes instead of days or weeks how that would benefit today's food system.

This draft rule I'm convinced is an important bridge between FSMA and the new era of the smarter food safety - - one that will bring us to full end-to-end traceability in our food system. We're working together towards that goal every day but we cannot -- and I emphasize -- we just can't do it without your input and without your help.

Speaking of which we have been asked to provide additional time for stakeholder input and considering request to extend the public comment period for this proposed rule beyond the current closing date of January 21st. And while the comment period for the information collection provisions closed on November 23rd we intend to reopen it. I'll have more to report on this soon.

I've learned from working with the FDA from the other side of the fence in the private sector that there's a lot industry can do to advance food traceability. I've learned that there's a lot the public sector -- government -- can do to advance food safety -- whether it's the states' or federal governments.

But what's crystal clear to me -- to all of my friends and colleagues listening in by Webex -- is that there's

so much more that we can do together. Ultimately whether you're in the private or public sector we're all working for the same boss -- the American consumer.

So let's work together to keep their food safe and they're counting on us to do so and I know we will. Thank you very much.

MS. BARRETT: All right. Thank you so much Deputy Commissioner Yiannas and thank you so much for your time and for laying out such a compelling vision of traceability and really setting the stage so well for today's program.

So we'll now go to our next speaker --who is Katherine Vierk; she is our CFSAN division director, Office of Analytics and Outreach. And Katie will provide an overview of the proposed role. So Katie, take it away.

MS. VIERK: Thank you, Kari. And good morning, everyone -- or, almost afternoon to some. I want to thank you everyone for being here today; we certainly appreciate the time you've taken to join us. And also want to thank Frank for his opening remarks.

We have been thinking about and imagining that vision for faster traceability and hope to help the stakeholders

understand today how this vision has been translated into the proposed rule.

So we know many of you have looked forward to the proposed rule and we're excited to publish it and look forward to today's meeting and your comments.

I'd like to also thank the FDA staff who contributed to drafting the proposed rule for their hard work and their commitment, considering the various intricate issues involved and including the various challenges that come with a proposing rule that encompasses a variety of commodities, entity types, and domestic as well as foreign firms. Everyone at FDA worked very hard to consider all the diversity among the entire supply chain.

One of the goals with this proposed rule is flexibility; we want to maintain flexibility throughout the supply chain -- making sure the chains of traceability information are unbroken. But we also want to be flexible to enable the requirements to work for different business models.

As you listen to presentations today you will likely have a lot of questions; there is a lot of information and many of you will be listening with an ear towards how it

affects you and your business and your role in the supply chain.

An important part of the rulemaking 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 and business models, and for food safety and traceability.

In those areas where you have questions or see challenges in the proposed rule it is important for you to provide your comments in writing and especially to provide details about specific scenarios and real-life examples for us to consider; couldn't tell how important that is for us as we try to understand your role in the supply chain.

These details help us understand your complexities and will help us as we move to ensuring a safe and traceable food supply.

So a little bit of overview of how we have gotten here. In September 2011 the FDA asked the Institute of Food Technologists to execute two product tracing pilot projects; I.F.T. carried out those pilot projects at the direction of FDA.

In 2013 FDA released I.F.T.'s report on the pilot projects and in November of 2016 FDA issued a report to Congress

that described the findings of the pilot projects and that also included the agency's recommendation for improving the tracing and tracking 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 lists of high-risk food.

And then in September of this year -- 2020 -- we published the proposed rulemaking to establish recordkeeping requirements including the publication of the designated food for which the additional recordkeeping requirements would apply and we were calling that the food traceability list. And that's where we're at today at the last of our three public meetings.

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

And these are just a few examples of the things included in Section 204 that needed to be considered during the

rulemaking process.

So as we draft the proposed rule we knew that there was a better way for traceability. Better traceability can and needs to be achieved individually as well as collectively and we believe it is a mindset.

So as Frank mentioned there's a bigger picture here to consider. Transparency is in demand and consumers want information about their food. Food technologies and information technologies to help the way businesses run are being introduced quicker. And businesses are pulled in many directions on what technologies to use -- especially for traceability. And we know that 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 the industry and across all industries. We need that conducting information -- the linkages throughout the supply chain; information to know the scope of the problem and to understand how affected foods move through the supply chain.

And we need technologies to be interoperable. There are new ideas and tools popping up in traceability

technology. 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. Information included in the proposed rule provides that foundation to allow for interoperability.

And we believe it's about interconnectivity -- taking it from a responsibility handled in its own way by each segment in the chain to a solution that connects the points in a 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. The identifiers to link incoming product to outgoing product throughout the entire supply chain are just not consistently there and it has a big effect.

Lack of interconnectivity affects timeliness because if there are no linkages the investigations take longer and affect public health. It affects specificity; a lack of specificity can be detrimental to businesses -- that if we're unable to narrow the scope of a recall. And the response to an incident can be affected; resources can be misdirected if we

have a larger scope of potential product affected and because traceability information didn't allow us to narrow that down.

And if affects communication; we have a difficult time determining appropriate communication because we are waiting actionable information and this is to everyone's detriment.

So while limited to only certain foods the proposed rule lays the foundation of the standardized approach to traceability and recordkeeping. We recognize that to fully realize the public health benefits and vision by FSMA we need to improve our ability to rapidly identify and trace foods that may be causing illness.

We need to quickly and effectively trace the movement of a listed food through the supply chain and identify and remove contaminated food from the marketplace.

So the food traceability proposed rule was published on September 23, 2020 and we are currently accepting public comments for 120 days through 2021. And as Frank mentioned FDA intends to extend the comment period for the information collection provision and also concerning whether to extend the comment period for the rule.

As I mentioned in the beginning we encourage you to provide public comment. Once the public comment period is closed we will review the comments and work to develop a final rule.

We are also under a consent decree to submit a final rule to the Office of Federal Registrar [sic] by November 7th of 2022.

Not to go over this in too much detail as I think we've heard Frank outline and myself as well a little bit already but the benefits of the food traceability rule has -- there are a number of benefits intended; being able to more-quickly and identify the source of the contaminated food; to help reduce impacts of foodborne illness; having more-accurate information to help identify the source of contaminated food and focus recall efforts.

More-efficient traceability is facilitated when each point in the supply chain is maintaining the same information so harmonizing and standardizing that information allows FDA to establish linkages along the supply chain more quickly than we can do right now.

And 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 and we would have more information to help inform root cause analyses to identify and apply lessons learned from the outbreaks.

Here's an overview of some of the key concepts for the proposed rule; these will be discussed in greater detail throughout the day. Proposed rule covers any persons who manufacture, process, pack, or hold foods on the food traceability list.

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

The proposed rule applies to certain designated food, which will be presented in greater detail today. The requirements also apply to both foreign and domestic firms alike.

There are some exemptions and partial exemptions and two options being proposed with regards to retail food establishments that will be also discussed in more detail.

So our -- traceability in the proposed rule is one that is consistent with current best practices in the industry. We have identified key points along the supply chain where it's most important to collect traceability information.

These were called critical tracking events -- or CTEs -- and include the points where food is grown, created, transformed, shipped, and received. At each CTE we are requiring traceability information essential to understanding what happened to the food at that point.

These pieces of information are called key data elements -- or KDEs -- and they'll provide us with the data necessary to make those linkages across the supply chain. The KDEs required by each entity depend upon the critical tracking event that is performed at that entity.

Importantly the records required at each critical tracking event would need to contain and link the traceability lot code of the food to the other relevant data elements. By identifying the required KDEs of key data elements this will also help standardize the data that industry maintained for traceability.

An important concept in the proposed rule is

placed on the traceability and lot code. At every CTE KDEs -- key data elements -- must be linked to each traceability lot code of the food shipped. This will help make those linkages.

The traceability lot code and the traceability lot code generator key data elements will help the FDA go quickly 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. So in general the entity who originates or creates the food assigns a traceability lot code and this should stay the same until another entity transforms the product and when that transformation occurs a traceability lot code should be assigned.

This will help enable FDA to stick points in their supply chains that minimally handle the products and quickly identify the points that can provide FDA with the information leading to the source of the product. There will be more discussion on this -- on the traceability lot code -- later by Angela Fields.

So just to help illustrate that -- and to

visualize how the proposed rule can help in efficiently identifying the source of a product here is an example of a 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.

We gather non-standardized information in paper and/or electronic format; resolving differences in terminology and lack of connectivity and ask the infirmed clarifying questions at each point. This takes a lot of time and requires a lot of resources.

Under the proposed requirement FDA would be asking for key data elements related to an entity's critical tracking events for certain time period; gathering standardized information in paper and/or electronic format; obtaining the traceability lot code and traceability lot code generator in order to skip back to the source faster; going to those points that handle the product, those that create or transform in order to get to the source efficiently; reducing clarifying questions by having access to the traceability program records that explain a firm's traceability recordkeeping process.

This is the vision of the proposed rule and illustrates how industry and regulators can work together to have more-efficient and accurate traceability.

I will wrap up by mentioning that we know that this proposed rule is only the first step towards our efforts to advance traceability across the food supply. 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 rule could use those same elements to enhance the traceability effort.

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

So today you'll hear from the subject matter experts that were instrumental in developing the proposed rule along with some of our federal, state, and industry partners and then we look forward to hearing some comments from the public.

So again thank you for joining us today and

handing it back to you, Kari.

MS. BARRETT: Great. Thank you so much, Katie and thank you for your presentation.

Now we're going to turn Karen Blickenstaff who's a CFSAN response staff director, Coordinated Outbreak Response and Evaluation Network. And we also have Laura Gieraltowski from CDC joining us; she is the lead for CDC's Foodborne Outbreak Response Team, Outbreak Response and Prevention Branch within the Division of Foodborne, Waterborne, and Environmental Diseases.

So the two of them are going to discuss the impact of traceability during foodborne illness outbreaks. We're going to start with Karen and then we'll go to Laura. So Karen?

MS. BLICKENSTAFF: Great. Thank you, Kari and good morning and good afternoon to everyone and we thank you all for joining us today.

So as Kari stated my colleague Dr. Gieraltowski and I will be talking a bit more today 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 investigations.

The FDA's Coordinated Outbreak Response and Evaluation Network was established in 2011 in order to manage the surveillance, response, and prevention activities related to incidents or outbreaks of illness linked to FDA-regulated products to include food, cosmetics, and dietary supplements.

CORE consists of several multidisciplinary teams including three individual response teams. Response teams are charged with coordinated 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 that CORE responds to include ones where an in-depth investigation is needed -- including coordinate of inspections and investigations, sampling, and of course traceback investigations.

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

There are multiple federal agencies at play when it comes to responding to foodborne illness outbreaks -- the

Center for Disease Control, the FDA, and then USDA's Food Safety and Inspection Services.

Our partners at CDC lead disease surveillance, outbreak protection and investigation; additionally they are involved in education and training of public health staff and you'll hear from my colleague Dr. Gieraltowski in a few moments regarding CDC's specific roles in outbreak response.

The regulatory agencies -- both FDA and USDA -- are charged with establishing food safety policies for foods that falls under each agency's regulatory authority; inspecting those facilities to ensure they are in compliance with the regulations; we coordinate product recalls when necessary -- for example when it is determined that a product may present a health hazard to consumers; and of course we coordinate the traceback investigations to determine the distribution and source of a product.

Finally, we conduct investigations at farms and production facilities and specific to outbreaks these investigations occur if there was an indication that they could be tied to an outbreak or determined to be the source of an outbreak.

So at this point I will transition into more detail surrounding the FSIS and the traceback work that CDC and FDA carry out during foodborne outbreak investigation and some specific examples on how traceability impacts the overall investigation.

So at this point I'm going to turn it over to Dr. Laura Gieraltowski from the CDC's Outbreak Response and Prevention Branch.

DR. GIERALTOWSKI: Thank you, Karen.

There are several challenges public health officials face when collecting epidemiologic data. Due to delays in surveillance ill people are often interviewed about what they ate two to four weeks after their illness began. It can be difficult for ill people to remember exactly what they ate and where they purchased their food.

Also, it's difficult to determine if the proportion of ill people eating commonly-eaten foods -- such as leafy greens, chicken, and beef -- is higher than we would expect.

We may not routinely ask about some new or uncommon foods on our standard questionnaire and ill people may

not remember eating stealthy ingredients that are added to foods -- such as onions, peppers, herbs, and spices.

And there is often a lack of brand or product information for produce, chicken, and beef. This information is important for our regulatory partners to be able to trace products to the source.

And finally, subclusters of illnesses where two or more ill people who don't 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 provide critical clues about the source of an outbreak.

When several unrelated ill people ate or shopped at the same location within several days of each other it suggests that the contaminated food was served or sold there.

Now I walk through two case studies that are examples of outbreaks where the epidemiologic data collection was challenging and traceback data was necessary to identify the source.

CDC, FDA, and state and local health departments investigated a multistate outbreak of over 1,100 salmonella infections from 48 states linked to onions. Onions are a

stealthy ingredient and difficult to implicate with patient recall alone.

Initially we identified nine subclusters and red onions were served at all nine subclusters. We utilized the invoices from restaurants and other points of service to identify a common onion grower. Traceback evidence led to the company voluntarily recalling red, yellow, and white onions.

Some of the investigation challenges I mentioned on the previous slide -- which is that onions are commonly eaten and stealthy so it's difficult to trace back and recall the many foods affected and provide clear public communication. We learned that it was critical to rapidly interview ill people to identify those subclusters.

My next example is a multistate outbreak of 425 salmonella infections that 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 amongst sushi eaters.

With the evidence pointing to spicy tuna a traceback investigation was conducted by state and local health

departments with FDA. The tracing efforts focused on fresh and frozen tuna supplied to four of the five restaurant subclusters.

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

Again the epidemiologic data alone cannot identify a source of the illnesses; tracebacks were needed to confirm spicy tuna was the single ingredient in common among the sushi items ill people reported eating and to determine the source of the raw tuna. This led to action to protect public health, such as an FDA import alert, product recalls, and public communications to consumers and retailers.

Karen, back to you.

MS. BLICKENSTAFF: Great. Thank you so much, Dr. Gieraltowski.

So I'm going to talk more in depth now regarding traceback and some of the challenges that we face when doing a

traceback.

So when traceback investigation is initiated it means that we have ongoing foodborne illness outbreak. Time is of the essence and we must 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 and as Dr. Gieraltowski pointed out an upfront challenge is poor consumer recollection of consumption history and the lack of specific product information. Understanding the consumer's exposure is a critical first step that needs to happen for a traceback to be initiated.

At times multiple varieties of a certain product or multiple ingredient items are identified, which makes it hard to determine which exposures or ingredients should be prioritized for a traceback. And at times we trace multiple products to help tease out what could be causing illness. Additionally points of sale can and usually do have multiple sources of the same product.

Poor recordkeeping at firms and throughout the distribution chain is an ongoing challenge we face; in fact in

some instances we receive handwritten records or records that are difficult or even at times impossible to read.

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

Currently there's varying amounts of tracing data across the supply chain, which means we must piece together information from numerous sources and numerous types of documents in order to extract the useful data to follow the product all the way through the supply chain and this can be an extremely time-consuming step.

Each of these challenges greatly impact the efficiency and the effectiveness of the traceback investigation.

I'm going to highlight traceback finding from the E. coli O157-H7 outbreak linked to romaine lettuce that occurred in the fall of 2019. This particular traceback investigation was initiated on November 18th in conjunction with state partners. In total the traceback 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 available for the specific products

that were purchased; so because of this we needed to request the tracing data to identify all growers who supplied any romaine lettuce used in products reported by the consumers and available for sale during the time period of September 15th through November 18th -- so we're looking at almost a two-month time period.

For these 13 out of 15 points of sale without lot code data available it took approximately 1 month to collect, analyze, and identify the growers that supplied lettuce to the points of sale.

Now on the other hand we did have two points of sale where we had lot code data for the products that were purchased and in those instances a much-narrower scope of data could be requested and the growers were identified within 24 hours or less.

I do want to note that lot codes currently are not typically available at the points of sale during outbreaks and I'll go into a little bit more detail on how we obtained the lot code data on the next slide for this particular instance.

But it is important to note that while this traceback was ongoing the case count was rapidly increasing; so

a broad public advisory targeting a regional area was issued on November 22nd as it was the most efficient way to ensure contaminated product was off the market while we continued to work through the traceback investigation.

So this slide just kind of emphasizes again the difference in timing for when we have lot code data available versus when it is not available. So for the 13 points of sale where lot codes were not available the requests for data were initiated on November 18th and it wasn't until December 13th -- or 25 days later -- that we were able to identify all the growers that supplied romaine to the points of sale during the timeframe of interest.

Without that lot code data in hand we had to go to each step in the supply and linking shipments one by one to get to the sources.

Now on the other hand there was a Maryland point of sale where we had the lot code data; that information -- the grower label information was requested on November 18th and we have it in hand later that same day.

Similarly for the Wisconsin point-of-sale location we also had lot code data and that information was

requested on December 4th and we had it in hand the following day on December 5th.

So how do we get the lot code data in this particular situation? As our investigation was starting on November 18th the Maryland Department of Health informed FDA of E. coli O157-H7 contamination in an unopened package that -- collected from a consumer's home.

So with the availability of a lot code on the product packaging Maryland Department of Health was able to provide FDA with the corresponding growing information later that same day.

Similarly for the second instance on December 4th the Wisconsin Department of Health Services reported E. coli O157-H7 contamination had been detected in an unopened bag of leafy green romaine collected from an ill person's home in their state and that corresponding grower information was obtained the next day on the 5th.

So for 2 separate products -- which were separate brands I'll add -- the FDA was able to obtain that grower-level data within 24 hours or less compared to 25 days when no lot code data was available.

So 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 grower-level data can be obtained when we do have that lot code data.

Based on combined years' experience doing tracebacks we feel if lot code data and other key data elements are available throughout the supply chain it would likely enable FDA to identify common product sources in five to seven days; this time would account for the time necessary to request, obtain, and analyze tracing data across the supply chain in the absence of packaging with lot code data.

Having this data readily available could result in swifter product action and better-scoped product action.

We will be able to have more-refined record requests, avoiding the need to ask for large quantities of records spanning months and these large requests are both time consuming for firms to pull and they're also very 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 illnesses, and investigate the reason for contamination in a timely manner.

So that concludes what I have to present today so I'll turn it back over to you, Kari. Thank you.

MS. BARRETT: Great. Okay. Thank you, Karen and thank you, Laura for your remarks.

We're going to go up next to our next speaker, who is Brian Pendleton; he is our senior policy advisor, policy engagement and coordination staff in the FDA Office of Policy, Legislation, and International Affairs.

So welcome, Brian; Brian will discuss the scope of the proposed rule and the exemptions. I'll turn to you.

MR. PENDLETON: Thanks. Thanks, Kari. Good morning, everyone and good afternoon and thanks for the opportunity to talk with you today about the scope of the proposal on food traceability -- that is the farms and the firms

that would subject to the rule as well as exemptions from the requirements that we have proposed.

Who would be covered under the rule? As Katie noted the rule applies to persons who manufacture, process, pack, or hold foods on the food traceability list -- or the FTL -- and that includes the foods that are specifically listed -- that is that they actually appear on the list -- and foods that contain listed foods as ingredients.

And this applies to entities throughout the supply chain -- from farms and manufacturers, food processors to distributors, wholesalers of food 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 the rule would apply to food that is grown or produced in the United States as well as food grown and produced elsewhere and imported into the United States.

This slide presents an overview of the exemptions that I'll be talking about, some of which are set forth in the statute Section 204 of FSMA; these would include the exemption for farms that sell food directly to consumers and food that's

produced and packaged and labeled in a certain way on the farm and some additional exemptions that we have proposed on our own initiative -- including for certain very small farms, for produce and shell eggs that receive certain processing, produce on FDA's rarely-consumed-raw list, and transporters of food and non-profit food establishments as well as those who manufacture, process, pack, or hold food for personal consumption.

There are also certain partial exemptions, some of which are set forth in the statute; for example for certain comingled raw agricultural commodities -- although this would not include fruits and vegetables -- for fishing vessels and for farm-to-school programs.

The statute also proposes an exemption for grocery stores that receive food directly from a farm and we have proposed due broadness to all retail food establishments.

It's also important to note an additional partial exemption for food -- and for food on the food traceability list that receives a kill step; under the proposed rule if a person applies a kill step in its processing that significantly minimizes the pathogens -- such as cooking or pasteurization of the food -- to food on the food traceability list they wouldn't

be required to keep records required under the rule for their subsequent shipping of the food as long as they kept their record of the application of the kill step and the subsequent recipients of the food to which the kill step had been applied would not be required to maintain the records otherwise required under the proposed rule.

The first exemption I'll talk about is for certain small originators of food and the proposed rule defines an originator as a person who grows, raises, or catches a food, or who harvests a non-produce commodity -- and that would include egg collection and taking seafood in an aquaculture operation.

Farms or farm activities of farming-type facility would be exempt 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 Section 112.4A -- and basically that means that applies to farms with no more than \$25,000.00 in average annual monetary value of their produce that they sell.

Also exempt would be shell egg producers with fewer than 3,000 laying hens at a particular farm and other

originators of food with no more than \$25,000.00 in average annual monetary value of the food sold would be exempt -- and this would include small aquaculture farms and potentially small farms that grow non-produce foods if such foods were to be added at some time to the food traceability list.

We have proposed an exemption for farms when the food is sold directly to consumers; this exemption would apply to a farm with respect to the food that's produced on the farm - - including food that's also packaged there -- that's sold directly to a consumer by the owner, operator, or agent in charge of the farm. This would apply to sales at farmers' markets, roadside stands, internet food sales, and sales through community-supported agriculture programs.

The rule also wouldn't apply to food that's produced and packaged a certain way on a farm; so that would be that the food's packaging would have to remain in place until the food reaches the consumer and the packaging that's maintained the integrity of the product and prevents other contamination or alteration.

In addition, the food's labeling that reaches the consumer would have to supply the name, complete address, and

business phone number of the farm; we would waive this requirement to include the business phone number to accommodate a religious belief of a farm owner.

An example of a food that might be eligible for this exemption would include iceberg whole-head lettuce that's harvested and packaged for the consumer in the field with individual non-vented cellphone wrapping that maintains the integrity of the lettuce and prevents subsequent contamination or alteration.

But not eligible for this exemption would be for example produce that's packed or packaged in containers such as clamshells with holes, cardboard boxes, vented crates, plastic bags with holes, or netted bags; those types of foods would not be eligible for the exemption.

The rule also wouldn't apply to produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance provided that the requirements in the produce safety regulation of Section 112.2B are met; that refers to the application of the commercial processing, disclosure that the food isn't processed to adequately reduce the presence of microorganisms of public

health significance, and written assurance from the customer that it or a subsequent entity in the food supply chain actually did perform the commercial processing.

And this exemption would apply to all who manufacture, process, pack, or hold such produce -- not just the farm that grew it -- and it would apply both before and after the processing takes place.

In addition, the rule wouldn't apply to shell eggs wherein all the eggs that are produced at a farm receive a certain treatment in accordance with the regulation on the production storage and transportation of shell eggs and in that regulation it specifies that this kind of treatment is one for which the technology or a process that achieves at least at a five-log destruction of *Salmonella enteritidis* for the shell eggs or the shell eggs are processed in accordance with the Egg Products Inspection Act.

We're also proposing to exempt produce that's rarely consumed raw; the FDA produce safety regulation specifies several types of produce that are deemed to be rarely consumed raw -- I won't go into all of them here but this would include produce such as beets, sweet corn, potatoes, and several kinds

of beans so produce rarely consumed raw would exempt.

We have proposed a partial exemption for comingled raw agricultural commodities; so the rule generally wouldn't apply to what's defined as a comingled raw agriculture commodity and that's any commodity that's combined or mixed after harvesting but before processing -- very importantly this would not include fruits or vegetables that are raw agricultural commodities that are subject to the produce safety regulation. So fruits or vegetables would not be eligible for this exemption.

Let's say that the shell eggs are the only potentially comingled raw agricultural commodity on the proposed food traceability list and shell eggs are the example of such a comingled raw agriculture commodity that we talk about in the preamble to the proposed rule but it may be that there are some other -- I mean seafood maybe meets the definition of a comingled raw agriculture commodity and there are some types of seafood that are on the list so we may need to adjust that.

And that would be the general exemption but if a person manufactures, processes, packs, or holds a comingled raw agricultural commodity if they also have to register with FDA as

the food facility with respect to that commodity then the person would have to keep the records identifying the immediate previous source and immediate subsequent recipient of that commodity in accordance with existing food traceability regulations in subpart J of part 1.

But some of these facilities are already subject to the subpart J traceability requirements; those who aren't would under this rule be required to keep these one-up/one-back records.

We had proposed an exemption for small retail food establishments; we're actually -- this is a co-proposal with two different options. And the small retail food establishments we have defined as 10 or -- with having 10 or fewer full-time equivalent employees.

So under option one, there would be a full exemption; so the small retail food establishments would be completely exempt from the rule.

Under option two they would be exempt from the requirements and -- to make available to FDA in certain circumstances an electronic sortable spreadsheet that contains traceability information that we request for certain foods and

certain date ranges.

Now we might -- examples of when we would request such a spreadsheet would be when we're conducting an investigation to help prevent or mitigate a foodborne illness outbreak; when we are assisting with a recall implementation; or when we're otherwise trying to address 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.

Some examples of some pros and cons for the two options with respect to the full exemption. Because of the lesser volume of food that's handled by these smaller retail food establishments their compliance costs might outweigh the benefits of the rule and we might be able to obtain the information that we need from larger firms that sold the same food using the same distributor.

On the other hand this full exemption could result in delays in obtaining information that we need when we are investigating outbreaks and it could hinder our ability to narrow the scope of implicated products during an outbreak investigation.

With respect the exemption, with respect to the electronic spreadsheet, smaller firms might be less likely to have the resources to easily produce the spreadsheet so exempting the small retail food establishment from this requirement would ease their burden -- at the same time keeping them within the scope of the rule would retain the traceability benefits of having all these firms covered.

So we've requested your comments on which of these options you think might be appropriate for small retail food establishments or some other alternative approach you think might be appropriate for these entities.

The rule generally wouldn't apply to retail food establishments regarding -- that is, all retail food establishments regardless of size -- regarding food that's produced on a farm -- including food produced and packaged there -- and sold directly to the retail food establishment by the farm's owner, operator, or agent in charge.

However the retail food establishment would have to keep a record for 180 days of the name and address of the farm that was the source of their food.

Somewhere in there is an exemption for farm-to-

school programs -- a partial exemption. The rule generally wouldn't apply to an institution operating a child nutrition program authorized under the Richard B. Russell National School Lunch Act or Section 4 of the Child Nutrition Act of 1966 or any other entity conducting a farm-to-school or farm-to-institution program regarding the food produced on a farm and sold directly to the school or institution; so a general exemption.

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

Another partial exemption is for fishing vessels; the rule generally wouldn't apply to the owner, operator, or agent in charge of the fishing vessel with respect to foods through use of the vessel.

So that would be the general exemption but if such the owner, operator, or agent in charge of the fishing vessel has to register with FDA as a food facility with respect to that seafood produced through the vessel -- for example because vessel just not only catches the food but the food is processed on the vessel -- then the person would have to keep the one-up/one-back records under the existing traceability

regulation.

So other exemptions that we are proposing; for transporters we believe that the type of records that we would require under the proposed rule we most likely can get from others in the supply chain for that food so we think that we could exempt transporters from the proposed rule.

Other exemptions include for non-profit food establishments, for those who manufacture or 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 that they hold and they're not in the business of distributing food.

So for example this could include persons such as a hotel concierge, a reception desk staff in an apartment building, and staff in an office complex who receive and hold foods on the food traceability list for a consumer but they aren't parties to the purchase of the food and they are not in the food distribution business.

So that presents a brief overview of the scope of the proposed rule and the exemptions from the rule that we have proposed and I look forward to your questions on these issues

later this morning. Thank you.

MS. BARRETT: All right, Brian; thank you so much.

And we're going to now conclude our first group of subject matter expert presentations with our next two speakers.

We have Yuhuan Chen, who is a CFSAN interdisciplinary scientist, Division of Risk and Decision Analysis.

And we also have Christopher Waldrop, the CFSAN senior health scientist, Office of Analytics and Outreach.

And Yuhuan and Chris, 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. I'll turn it to you, Yuhuan.

DR. CHEN: Thank you so much, Kari, and greetings, everyone.

To inform the designation of the food traceability list we've developed a risk-ranking model for food tracing. Thank you for the opportunity today to give an overview of the risk-ranking model.

In the overview I will 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 example.

In FSMA Section 204(d)(2)(a) Congress lays out the requirements on which the designation of high-risk foods must be based. It must be based on -- briefly -- the known food safety risks, including the history of outbreaks; the likelihood of microbial and chemical contamination and whether the food will support pathogen growth; the points 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 impacts -- 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 strived to have a transparent process that engaged stakeholders and a broad range of subject matter experts. We put together a project advisory group and developed a draft approach, which was published in 2014 for comment. We then revised the approach, collected data, and developed a model.

As is the case for our risk assessments, we conducted peer reviews of the model and the underpinning data. Throughout this process the project advisory group helped 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 as the food traceability list was to create a data-driven model, use it to score food hazard pairs based on the risk factors specified in FSMA, and aggregate 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 practices in decision 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 industrywide intervention; consumption; and cost of illness.

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

So how do we classify food? 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.

The commodity categories are adapted 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 a commodity hazard pairs based on data and expert knowledge. The model then scores each pair independently; to do that we need scoring definition.

Let me take a moment to go over a couple of

examples. Here is the scoring definition for criterion one; it's a matrix with the frequency of outbreaks on the X-axis and the occurrence of illnesses on the Y-axis.

For each food hazard pair based on data a score of one, three, or nine is assigned. For example 10 outbreaks in 1,000 cases would give a score of 9; on the other hand if 1 outbreak and 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 the scoring definition for criterion three -- the likelihood of 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 greater than 1 percent the score would be 9. Sampling data are also weighted for relevance.

So we developed scoring definitions for all seven criteria and have the definitions peer reviewed.

The model utilizes data from a wide range of sources, including the published scientific literature,

government surveys and investigations, and most of all expert solicitations to fill data gaps. We also use data and information submitted by stakeholders.

The model draws on a vast amount of data to score many commodity hazard pairs. Here is a quick look at how the model distills all the 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 identified approximately 770 commodity hazard pairs that involve 210 commodities and 60 hazards. Overall the model uses over 10,000 data points.

Let me draw your attention to the leftmost of the slide and walk through the scoring process.

These circles represent data points and C1 through C7 on a branch indicate the seven criteria. Remember each of the criteria is scored using data and well-defined definitions.

The branch shows how the model calculates a list for a commodity hazard pair, such as commodity A, hazard one. It's by summing the seven criteria scores.

The model evaluates each commodity hazard pair independently so it does the evaluation multiple times for commodity A because it's associated with multiple pairs.

From there the model aggregates the scores for the pairs to calculate a risk score for the commodity; that's how it generates commodity A with score.

Now there are about 210 commodities in the model so this data evaluation and scoring process -- it's repeated 210 times so that's how the model generates results.

We see two examples on this slide. 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 contributions from the criteria scores.

The figure on the right shows a ranked list of a subset of commodities; the longer the bar the higher the risk score.

To facilitate understanding of the model we've created a user-friendly tool; it's a webpage that can be accessed at the URL on the slide. The tool is interactive; it allows you to view the results as tables and figures, by commodity, by commodity category, or as a whole. It also

facilitates the review of the methodology and walks you through a calculation example.

In summary to inform the designation of the food traceability list FDA developed a risk-ranking model that is aligned with the FSMA 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: All right. Thanks, Yuhuan; appreciate that.

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 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 a marine finfish 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 recordkeeping 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 to not include results from the model related to food allergens; typically consumers with food allergies can identify the food or ingredient that most likely caused the allergic reaction -- including the brand and packaging of the food in most cases.

FDA can then rapidly identify the source of the allergen-containing food and take appropriate regulatory action; therefore enhanced recordkeeping for traceability would not greatly enhance FDA's ability to identify and respond to undeclared allergens in food.

Third, as we reviewed data used for the model to generate the food traceability list we decided to not include results for certain food hazard pairs that were attributed to contamination 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 retailer point of service, such as lack of time/temperature control, ill food workers, or improper cleaning and sanitizing of food surfaces.

Once the retailer point of service location is identified as the source of contamination there's really no need to further trace the source of the food; as such enhanced recordkeeping requirements would not significantly improve traceability in these situations.

FDA considered different levels of granularity in characterizing food for the food traceability list, such as commodity and commodity category; an example -- the food at the commodity level would be tomatoes while food at the commodity category level would be the broader produce or agricultural commodity. We determined 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 pairs produced by the model were ranked, as Yuhuan as described. The commodity was included if there was sufficient evidence of a significant public health risk based on the data in the model. More information about how this was done is available in a memo accompanying the proposed rule and available 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 includes all varieties or types, such as all varieties of tomatoes -- including Roma, beefsteak, cherry, et cetera -- or all varieties of peppers -- such as sweet peppers, poblano peppers, jalapeno peppers, et cetera.

For some foods there are a few exceptions; for example the category of finfish would not include Siluriformes fish such as catfish as those 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'll publish a final version of the food traceability list when we publish the final rule.

In one other note, we have received a number of inquiries seeking more information about specific foods or types of foods that are on the food traceability list. We are currently considering ways to help clarify that and we'll 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 don't anticipate updating the list very often.

If we do determine we should update the list

we'll do so via notice in the Federal Register providing the public with an opportunity to comment. We will then review those comments and post a notice 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.

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

MS. BARRETT: All right. Well thank you so much, Yuhuan and Chris.

And the next part of our agenda -- it is now time for us to take some questions and I do see that a number have come in.

So let's bring up our morning panel and we'll begin that process. As Michael said earlier too please -- if you haven't already and you have a question please submit it to the chat.

All right. I think we're ready to get started. What I'll do -- again this Kari Barrett -- I'll read the

questions out loud to earlier presenters. We also may have some others -- I see Becky Goldberg has joined us, who is a member of traceability team -- and we'll get started.

So it looks like the first question is for Brian Pendleton and the question is "are food importers subject to the proposed rule?"

MR. PENDLETON: Thanks, Kari. Good question and importers are subject to the proposed rule to the extent that they manufacture, process, pack, or hold food -- and maybe most likely it would be the holding of the food if they don't process the food after they get it.

But in the preamble to the proposed rule we talk about the need for -- if you don't physically possess a food and you're not engaged in holding and it's defined under the proposed rule. So an importer would have to physically possess the food upon importation to be subject to the rule.

For example when we talk about in the preamble to the proposed rule that if you're coordinating the import of food but you never take physical possession of the food then you would not be subject to the rule.

So importers depending on -- and the importer's

defined differently in different FDA regulations and for customs purposes so -- but if you physically possess the food at importation those would be entities that would be subject to the proposed rule because they hold the food.

MS. BARRETT: Great. Thank you so much.

And before I go on I do want to note -- because I'm looking at the questions that we've received and there does appear to be some that we have received in previous meeting.

And when we haven't been able to get to all the questions we've suggested that people send them to our TAN for an answer and so some of these I know have been submitted to the TAN; it may be that we'll cover a couple of them but I just want to assure folks if you're submitting a question that you've already submitted to the TAN you will get an official response through that process.

So even if we answer it today you'll still hear from our subject matter experts if you've submitted to the TAN.

So with that I'm going to ask the next question; I know it's one of a great deal of interest to folks and it has to do with extending the comment deadline.

So Katie Vierk, I think this one is for you and

the question is "did Deputy Commissioner Yiannas indicate that FDA is considering extending the January 2021 written comment deadline?"

MS. VIERK: Yes. So FDA has been asked to provide additional time for stakeholders to provide input and we're considering those requests to extend the public comment period beyond the current closing date of January 21, 2021. So if that is to be extended that will be done through the Federal Register.

However the comment period for information collection provision has closed so while that's closed and that did close on November 23rd, we intend to reopen it and that will be announced in the Federal Register shortly.

MS. BARRETT: Great. Okay. Thank you so much.

Let's go now to our next question and let's see. That one looks like it may be for Becky Goldberg and the question is "can you talk more about how traceability aspects will reduce food waste? What is the relationship there?"

MS. GOLDBERG: Sure. Yes. Thanks for the question.

So of course reducing food waste is not the

specific purpose of the rule; the rule is --

But it does seem reasonable to expect that it might have a positive effect on the -- thing -- fair example would be if you imagine that if we're able to have more-targeted recalls and more-targeted public -- that the only food that's getting -- shelves is the food that actually -- which is something that, you know, hopefully will be an outcome of the improved traceability.

If that happens it also seems like it would reduce food waste compared to a situation -- taking our commodity of the shelves; in other words from because they don't feel confident that they --

So it seems reasonable to --

MS. BARRETT: Okay. Yeah. Thank you. Great questions.

The next question; again Katie Vierk, this one is for you. "Are any of the food centers" -- let's see; let me get this right. The question is "are any of the Centers of Excellence working on recordkeeping templates?"

MS. VIERK: Sure. So we're happy to provide templates if that would be helpful but we also want to emphasize

that there's flexibility for people that want to develop records as they wish.

So we are committed to providing materials that industry will find helpful for compliance and that could include templates so -- and that could come through FDA working with Centers of Excellence or just from FDA.

MS. BARRETT: Great. Thank you. All right. The next question looks like it's for Chris Waldrop; "could we have the name of the traceability list development memo you referenced in the docket?"

MR. WALDROP: Sure. So that's titled the Risk-Ranking Model for Food Tracing Application but also if you go to our website or if you search under "FDA" and "food traceability list" that should give you a webpage on our website that has everything about the food traceability list, including links to all the memos and supporting documentation going with that list.

MS. BARRETT: Great. Thank you, Chris.

And Karen Blickenstaff, this one is for you I think; "if you had lot code data for some of the salads why was the broad advisory still needed?"

MS. BLICKENSTAFF: All right. Thanks, Kari.

Yeah; so regarding a specific outbreak scenario that I presented, that initial positive sample result and the corresponding traceback data records were available on November 18th and this was the same time we were initiating our traceback and just investigating at multiple other points of sale.

And from the records we were reviewing we noted the evidence comingling of romaine in finished product so that means that one lot of finished product contained romaine sourced from multiple growers.

So even while we had grower-level data for a specific lot it did not clearly pinpoint one grower; we were identifying multiple growers within a region. Additionally, there were discrepancies noted in the grower and the harvesting information providing at the processor level.

So ultimately the lack of standardized KDEs really hindered our ability to quickly narrow the scope of the traceback to one particular grower or ranch so in order to prevent additional illnesses we had to go out with a more-broad public advisory on November 22nd.

And that second positive sample I mentioned -- which provided additional insight into the source of

contamination -- was not identified until December 4th; so a couple weeks after the advisory had to go out.

MS. BARRETT: Okay. Thank you, Karen, for that detail; that's very helpful.

The next question is on exemptions so Brian Pendleton, this one is for you and it's "may interested persons request that other entities or foods be exempt from the proposed rule?"

MR. PENDLETON: Thanks, Kari. And yes; of course people can -- in their comments on the proposed rule they could suggest or recommend that entities or food types other than what we have proposed should also be exempted and they can do so in their comments on the proposed rule.

And also note that the proposed rule itself includes provisions in accordance with Section 204 of FSMA allowing a person to request an exemption or modified requirements from the requirements from the regulation for a food or type of entity when the application of the requirement isn't necessary to protect the public health.

So we have proposed provisions allowing for a request for an exemption or a modification from the requirements

as well as we also have proposed provisions allowing firms to request a waiver of one or more of the requirements in the rule when application of those requirements would result in an economic hardship for an individual entity or a type of entity and certain other conditions are met.

So we also have proposed provisions for requesting a waiver that are set forth in the proposed rule.

MS. BARRETT: Great. Thank you, Brian.

Our next question is for Yuhuan Chen and this is "would a single outbreak cause a food to be added to the food traceability list?"

DR. CHEN: Thank you for the question.

It depends; I think it would depend on the magnitude of the outbreak and the characteristic of the food and the hazard implicated. Other similar outbreaks could also have an effect.

In the risk-ranking model outbreaks are considered in criterion one; there are six other criteria. So risk score for the food hazard pair is affected by data across all seven criteria, as is the risk score for the food itself.

The risk-ranking model is flexible; it can

accommodate new data to update the risk score. As you have heard there is a process in place to decide when we would update the model and then once we have the updated risk scores there is a risk-management process in place to decide given the updated risk score whether the food should now be considered to be included on the food traceability list.

So Chris, would you like to add something to that?

MR. WALDROP: Thanks, Yuhuan. Yeah, that's correct. So there is a process and that's a public process and so we would -- you know, the public would be aware of any kind of changes we've been making to the list. Thanks.

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

And it looks like we have time for one more question and Becky Goldberg, I think this is for you; "will eggs going to a liquid market be exempt from this rule since they are modified and no longer in their shell?"

MS. GOLDBERG: All right. That's a great question.

So first of all as the question points out the liquid egg is not a shell egg. Right? So shell eggs are on the

list; liquid end-products are not on the list so that's one piece of the puzzle.

But the other thing to understand; sometimes there are shell egg operations where all of the eggs are on the farm are intended to go for processing and we are proposing an exemption that parallels a partial exemption -- egg rules -- think -- and farmers will already be aware of the partial exemption -- farms that send all of their eggs for processing.

We are proposing -- operation -- from the requirements of this -- so what that would mean is that they'd be exempt from the beginning, even when they are still in the shell. They would already be exempt because they are -- processing.

That's not how other parts of this proposed necessarily work but that is a specific -- so -- partial --

MS. BARRETT: Great. Thank you. And again a round of applause for our morning speakers and our folks who have answered questions during this part of our agenda.

We are now at time to take a break. We're going to take a 15-minute break and start up again at 1:30 Eastern. And so folks, please do come back in 15 minutes and we'll start

right on time.

So thank you again and we'll be back with you shortly.

MR. KAWCZYNSKI: Do we have all of our people elevated for the next half?

Just a reminder; we still are on a live feed so as we're checking audio and checking camera -- De Ann, are you there?

DR. DAVIS: Yes.

MR. KAWCZYNSKI: Whose phone number ends in 1024?

MR. A. KENNEDY: That's me; Andy Kennedy.

MR. KAWCZYNSKI: Okay. All right. I'll connect you. All right. Okay. Fix that. I'll fix that. Thank you.

All right. There go. Andrew, can you give me a sound check again please?

MR. A. KENNEDY: Yep, I'm still here.

MR. KAWCZYNSKI: There we go. Got rid of that echo. All right. Perfect.

And okay. I just want to make sure. I'm going to bring the camera on. We'll let you guys all check your cameras quick for our second group.

All right. So Brian, yours works; Angela, there we go; Andrew, perfect; and we know Kari's works. All right.

So we're done with that. You are all set. Looks like we have everybody else; Cailyn, do you see anybody else that needs to come up? Okay.

Got it. Okay. I think we are good. All right. We'll play some background music in a minute here. Guys, I think we're on time -- I don't even know if we're on time anymore. Is it 1:40 right now -- Eastern? Because that's what my computer clock says.

That makes more sense. That makes more sense. Remember we talked about having I.T. problems? Even my computer clock is off. All right. I can fix that.

Thank you, John; I appreciate that as well. Let's see.

MS. BARRETT: All right. Welcome back, everyone. This is Kari Barrett and I want to welcome you back. We're going to now start a series of presentations from our second group of subject matter experts and first up we have Angela Fields; she's our CFSAN senior consumer safety officer in CORE and Angela's going to walk you through the requirements of the proposed rule.

So Angela, you go ahead and take it away.

MS. FIELDS: Thanks, Kari. So this presentation will cover the proposed record requirements under this rule. We will discuss what records would be necessary for the traceability program, what the key data elements -- or KDEs -- that would be required for each critical tracking event, how we are proposing to qualify for an exemption or waiver, and how 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 traceback investigation. Obtaining as much detail from firms regarding interpretation of records can assist in alleviating time delays that can result as a lack of understanding.

The proposed rule would require every person who manufactures, processes, packs, or holds food on the food traceability to establish and maintain traceability program records. These records would be intended to help FDA understand a firm's recordkeeping process, which is significantly valuable -- especially in foodborne outbreak illness

investigations.

Additionally, person that would be subject to these requirements may enter into agreements with individual firms to help 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. It should also be noted that these and all of the other records that would be required under subpart S to be kept by these other firms.

While most of the proposed records would need to be retained for 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 where 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 records. A description of the relevant reference record -- while it is encouraged that the required traceability information be maintained in a single electronic system FDA recognizes that

there are firms that do not currently have product-tracing systems that enable them do this.

As a result a firm's KDEs might be kept on various types of records, such as bill of lading, purchase orders, or production logs.

A firm's traceability program records would need to include a description of the reference records on which the firm's maintains the required KDEs. This description would explain where on the reference record the traceability information appears and if applicable a description of how reference records for different tracing events for food are linked, linkage of incoming to outgoing products -- such as a product description -- and to the next firm.

We're also proposing a list of foods on the food tracing list that are shipped. The proposed rule would require anyone who ships food on the food traceability list to keep a list of which listed foods they ship, including the traceability product identified and traceability product description for each food.

In situations where product tracing or other product action are necessary access to a firm's food tracing

list can help FDA and the firm more-quickly identify associated foods. This potentially would speed up timing on product action.

This list can also assist a firm in identifying foods that a firm manufactures, processes, packs, or holds that would be subject to this rule. The list of foods would indicate which food on the food tracing list a firm generally ships -- even if there are gaps in those shipments.

We'd like to propose a description of traceability lot codes are assigned. The traceability lot code allows a food to be uniquely identified through the supply chain. As a part of the firm's traceability program records firms would be required to describe how they established and assigned lot codes.

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

Also, other information may be needed to understand data provided within the records. The proposed rule would require a firm's 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, glossaries, and abbreviations; this would help regulators understand the terminology, methods, and systems a firm uses in its traceability operation.

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 -- which were referred to as traceability lots in the proposed rule.

It should be noted traceability lot codes should stay the same throughout the supply chain unless certain activities are performed, which I'll be discussing next.

Additionally, the proposed rule 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 code could be a firm's only code or in addition to other lot codes used with that firm's internal traceability system.

Also, for foods on the food traceability list there is no proposed requirement to place or print KDEs on 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 critical tracking events performed by that firm.

Firms that ship foods on the food tracing list would also be required to send certain KDE information -- including the traceability lot code -- to the receiving firm.

The traceability lot code and the other KDEs would not need to be written on the package of the product; it could be sent in other ways -- such as via an e-mail or the private document that accompanies a shipment, such as a bill of lading.

As mentioned, traceability lot codes are an essential part of this proposed rule and should only be manipulated in specific situations to avoid creating confusion that could hinder tracebacks or traceforward efforts. Therefore

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

In situations where a first receiver receives a listed food where the originator has not assigned a traceability lot code the first receiver would be required to establish and maintain a record of the traceability lot code for the food.

Prohibiting when a traceability lot code can be changed would potentially expedite the amount of time needed to trace a produce; this could create an ability to skip steps or avoid unnecessary record collection from firms where 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 could reduce time necessary to review records from multiple firms.

Additionally, by limiting when a traceability lot

code can be changed there would be better tracking of traceability lot codes across the supply chain as well as within a single firm.

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

At the heart of the proposal is a requirement for those who manufacture, process, pack, or hold a food on the food traceability list to establish and maintain records associated with specific critical tracking events. For each CTE entities would be required to establish and maintain records containing key data elements.

The CTEs include the points where food would be grown, where food would be transformed either by changing a food on the food traceability 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, i.e., cutting, cooking, comingling, repacking, or

repackaging.

Also, where food on the food traceability list would be first created -- making or producing a food on the food traceability list through manufacturing or processing -- using only ingredients that are not on the food traceability list. The definition further states that creating does not include originating or transforming a food.

And finally, where food would either be shipped or received from one in the supply chain to another.

The proposed recordkeeping requirements would apply to all foods on the food traceability list, which includes products that contain listed foods as ingredients. Firms can elect how they would like to maintain their KDEs; however they would be required to be linked to the traceability lot code.

Our first CTEs are related to growers. Many farms in rural locations that lack street addresses -- in addition, many farms have multiple fields in which the same commodity is grown. Therefore for persons who grow foods on the food traceability list the grower would need to keep a record of the growing area coordinates of their farm and the shipment record information and name of the transporter.

The grower would also need to provide KDEs to the next point in the supply chain, linking these data points to the lot code of the product. This would also include information about the harvest, cooling, and packing of the food -- which will be discussed later in the presentation.

It should also be noted that the growing area 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.

And sprouts pose unique food safety concerns, as reflected in the special provisions for sprouts in the produce safety regulation. Additional KDEs would be required for growers of sprouts. These KDEs would create linkages between sprouts and the seeds used to produce them.

Requiring sprout growers to keep records on seed lot codes assigned by seed harvesters, conditioners, processors, and repackers, along with the dates of seed harvesting, conditioning, processing, and repacking could help to better scope a sprout recall event and identify the seed lot used to grow the sprouts involved in the contamination event.

An additional critical tracking event part is shipping. For shipping -- there would be the other KDEs that all firms in the supply chain would be generally responsible for, with the exception of most retail food establishments.

The records we propose to require shippers of listed foods to keep are similar to the records that receivers of food would have to keep and by requiring that most of those records be passed along from the shipper to the recipient the rule would avoid duplication of effort and ensure that those requirements for the receiving CTE could be met.

As with the requirements for receivers of food, if an imported food was to subsequently transform a shipper for the food produced through transformation would not be required to keep or send forward a record of the entry number for any imported food that is a component of the food.

To help ensure that those who receive listed foods would be able to obtain the information they would be required to keep under the proposed rule we propose to require persons who ship listed foods to provide their customers with certain information related to the foods they ship and this information might not always be provided under current

commercial practices.

Our next CTE is receiving; the receiving CTE would be another one of the CTEs that all firms in the supply chain 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 they may find recordkeeping 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 for any imported food that is a component of the transformed food.

Our next CTE that we identify is the first receiver. In addition to maintaining receiving KDEs, certain

firms would be required to maintain first receiver KDEs. A first receiver of a food would be the first person other than the farm who purchases and takes physical possession of a listed food.

Examples of first receivers could include manufacturers, processors, buyers of seafood from fishing vessels, and distribution center. Only listed foods that are originated -- i.e., grown, harvested, or a non-produce commodity -- raised or caught -- would have a first receiver.

The concept of the first receiver was created because the foods on the food traceability list includes foods in several different commodity types of varying growing and production practices and associated business relationships.

Because of this the first receiver would be the person who is best positioned to maintain comprehensive information about the origination and subsequent handling of a food; this includes the information identifying the persons who originated, harvested, cooled, and packed the food.

It does define the first receiver and defining it in this way would ensure that comprehensive records relating to the origination and handling of the food were maintained by a single person who both owns and possesses the food.

First receiver records include information about farm maintenance of these records by first receivers of a listed food that would likely help prevent delays in determining who grew and physically handled a product by alleviating the initial need to visit an entity performing farm activity.

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 a traceability lot code you would need to establish a traceability lot code for the food and maintain a record of the traceability lot codes linked to the KDEs.

However in situations where a food tracing list food is made exclusively from non-FTL ingredients -- which is a CTE identified as creation -- there would not be a first receiver.

Since unique tracing information is relevant for seafood products obtained from fishing vessels we are proposing to adapt separate recordkeeping requirements for first receivers of listed seafood products obtained from fishing vessels; these KDEs would give FDA a better sense of the general harvesting trip a fishing vessel made for the identified seafood.

Here we have an example of a first receiver as it

would apply to cantaloupe. In this example a farm grows cantaloupe which is on the food tracing list. The farm sends the cantaloupe to an on-farm cooler who sends it to a distributor.

Since the distributor is the first person other than the 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.

In this next example of a first receiver we have mango. In this example farm number one grows mangoes which are on the food tracing list. Farm number two purchases and take physical possession of the mangoes from farm number one. Farm number two sends the mangoes to an on-farm packer who sends them to an on-farm cooler.

The mangoes are then sent to an importer/wholesaler. Since the importer/wholesaler is the first person other than a farm who purchases and takes physical possession of the mangoes the importer/wholesaler would be considered the first receiver in this scenario. The importer/wholesaler then sends the mangoes on to a retailer.

In this next example we have shell eggs and this

example of farm-harvest shell eggs which are on the food tracing list. 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 will be considered the first receiver. The distributor then sends the shell eggs on to a retailer.

Our next identified critical tracking event is transformation. Transformation of a food on the food traceability list would involve taking a listed food and changing the food and/or its package and labeling such as by processing it, combining it with other ingredients, comingling it, or repackaging it.

There are two important things to consider as it relates to transformation. Transformation only applies to foods on the food traceability list. Also, this requirement would not apply to retail food establishments with respect to the listed foods they sell directly to consumers.

Another CTE that we have identified is creation. Creation of a food on the food traceability list would involve making or producing a listed food -- such as through

manufacturing or processing -- using only ingredients that are not on the food traceability list. Similar to transformation, RFCs 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 food tracing list. 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 from the immediate previous sources of any of the ingredients that are not on the food traceability list; therefore a firm would not be able to satisfy the proposed KDEs for transformation. Because of this the concept of creation was made to serve as the starting point for subpart S record requirements.

In this example we have the supply chain for soft cheese. The diagram shows soft cheese which is on the food tracing list. This diagram of a creation event because the ingredients of this particular soft cheese -- milk and salt -- are not on the food tracing list. The requirements under the proposed rule would begin at the point of creation.

Then since soft cheese is on the food tracing list recordkeeping requirements would apply throughout the rest of the supply chain all the way to the retail food establishment.

In this next example we have the supply chain for romaine. Romaine is on the list so it would be covered under the proposed rule. This slide shows the relevant CTEs for each point in the supply chain and the KDEs that would be required at each point.

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

Next we have an on-farm packer; the packer would need keep receiving KDEs based on what they received from the cooler. The packer would also need to keep and send shipping KDEs to the next point in the supply chain.

In addition, because the grower, cooler, and packer are all farms each one of them would have to send certain

information forward to the next point in the supply chain -- specifically a statement that the shipper is a farm; the location identifier and location description of the originator of the food if not the shipper; the business name and points of contact and phone number of the harvester of the food if not the shipper; and the date and time of harvesting; the location identifier and description of -- foods that also cooled and packed if not the shipper; the date and time of cooling and packing if they both had already occurred; and the location identifier and location description of the place where the food was cooled and packed if not by the shipper.

Next we have a produce processor. The produce processor would be considered the first receiver in this scenario because they would be the first person other than a farm who purchased and took physical possession of the listed food.

The produce processor would need to maintain the receiving KDEs as well as the specific first receiver KDEs based on what they received from the on-farm packer.

Since the produce processor is transforming these romaine heads into fresh-cut romaine they would have to maintain

transformation KDEs and the produce processor would have to keep and send shipping KDEs to the next point in the supply chain.

Next we have a distributor. The distributor would need to keep receiving KDEs based on what they received from the produce processor. The distributor would also need to keep and send shipping KDEs to the next point in the supply chain.

And then finally, we have the retailer, who would be required to keep receiving KDEs on what was received from the distributor.

In this next supply chain example we have seafood -- this is specifically applied to finfish. Finish is on the FTL but the proposed rule establishes modified requirements for the fishing vessel which catches the fish.

Purchaser of the finfish would be the first receiver and would have to maintain specific KDEs related to seafood obtained from a fishing vessel; then recordkeeping 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 for an exemption or for a food or type of entity. FDA will consider whether to modify

requirements or grant exemptions on our own initiative or based on a citizen's petition by an interested party.

Based on the information in the petition FDA will determine whether application of the identified requirements is not necessary to protect the public health.

Requests should meet the requirement for citizen's positions [sic] in 21 CFR 10.30 and would need to include specify the food or type of entity to which the modified requirements or exemption would apply; if the petition requests modified requirements specify the proposed modification to the subpart S requirement and present information demonstrating why application of the requirements requested would be modified or from which exemption is requested is not necessary to protect the public health.

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

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 and the waiver would 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 consequences or death to humans and the receiver would not otherwise be contrary to the public 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 point of contact of the individual entity to which the waiver would apply for the individual entity waiver 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 requested 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 prevent or mitigate a foodborne illness outbreak; and information demonstrating why

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

Additionally, the proposal would also require that records be maintained as either original paper records, electronic records, or true copies. They all must be legible and stored to prevent deterioration or loss. Records must be kept for two years from the date they were created.

Traceability records must be provided to FDA as soon as possible but no later than 24 hours after a request is made. Firms must provide FDA with an electronic sortable spreadsheet containing relevant traceability information within 24 hours of a request when necessary to assist FDA during an outbreak, recall, or other threat to public health.

So in summation I would like to review some of the key concepts of the proposed rule. The traceability lot codes should carry throughout the supply chain and can only be established and assigned when origination, transformation, or creation occurred. All proposed KDEs would be required to be linked to the traceability lot code.

Where possible firms can reuse KDEs provided by the immediate previous source to meet proposed requirements,

such as traceability product identifier. Traceability program records would be required to explain terminology used in the firm's internal traceability system that may differ from the terminology of 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 records request. FDA would not visit the third-party location to collect the requested information. The third party could be a separate business or could also be someone who is part of the firm's supply chain.

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 last part identifies the fact that foods created would not have a first receiver.

Any firm can be a first receiver and the first receiver KDEs are more specific; it's dependent on the structure of the product supply chain and the first receiver again is the first non-farm that purchases and takes physical possession of

the food. Additionally, transformation includes repacking.

Our goal for the proposed rule is to ensure that KDEs -- especially the traceability lot codes -- can be maintained across the supply chain for more efficient and effective tracing while providing firms flexibility with their existing tracing systems.

We realize that the examples we have provided are simplistic and do not reflect the full range of business models used by various industries. So with that we are seeking comments that provide examples of business models that may not be compatible with the proposed rule with an explanation of why and identify and explain if there's any confusion within the proposed rule.

So with that I'll pass it back to Kari.

MS. BARRETT: Great. Thank you so much, Angela. Great job and I know that was a lot to walk through. I know you'll hang around for questions later.

So let's go on to our next speaker. We now have Aliya Sassi and she is the senior economist in the Office of Policy, Legislation, and International Affairs in the FDA Office of the Commissioner. And Aliya's going to provide us with an

overview of the regulatory impact analysis of the proposed rule.

So Aliya, I'll turn to you.

DR. SASSI: Okay, Kari. Good afternoon, everyone; I'm happy to be here to talk about our preliminary economic impact analysis.

This is an outline of -- today stock; I'll start by going over the estimated entities covered by this rule; then discuss the estimated benefits, costs, impact on small businesses, and international effects.

There are two co-proposed options when it comes to covered retail food establishments -- or RFCs -- and the option one of the co-proposal -- retail food establishments with ten or fewer full-time-equivalent employees would be fully exempted.

And the option two -- these retail food establishments would be exempted only from the requirement to provide FDA under certain circumstances with an electronic sortable spreadsheet containing the requested information.

During today's talk I'll present the estimated impacts to both options side by side.

Entities that will be affected by this rule 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 the preamble.

Here you can see both the estimated number of covered firms and the number of establishments of facilities by size. One firm can operate several establishments.

Under option 2 the rule currently proposed would cover approximately 422,000 firms operating 566,000 establishments. Under option 1 the total number of covered establishments and firms would be lower -- 188,000 firms operating 332,000 establishments.

This is a summary of quantified costs and benefits of the rule. The cost and the benefits are annualized over 10 years at 7 percent discount rate and present in 2018 dollars. This proposed rule is an economically significant regulatory action as defined by Executive Order 12866.

We estimate that annualized cost of the rule under co-proposed option 1 would be \$411 million per year. Annualized health benefits would be \$567 million per years based on an estimated 84 percent traceback improvement.

Under co-proposed option 2 the annual cost of the rule would be \$535 million per year and annualized health benefits would be \$626 million per year.

In addition the estimated costs to foreign entities are about \$295 million per year -- a portion of which could be passed through to U.S. entities and consumers via price increases.

Using example from three product recalls we estimate that additional non-health benefits for both options 1 and 2 of avoiding overly-broad recalls could range from 1.7 billion to \$5.6 billion per year.

We lack complete information on other benefits and discuss them quantitatively.

This slide shows a breakdown of cost by option and industry sector. Compared to option 1 costs for option 2 are greater by \$124 million and benefits are greater by 60 million.

This is because under option one fewer retail food establishments would need to comply with this rule; however by exempting RFCs with ten or fewer full-time-equivalent employees -- and that's our option one -- the time limits, precision, and accuracy of traceability efforts can be impacted.

Under option one FDA ability to narrow the number of lots in recalls and the ability of these RFCs to have data to quickly identify and remove contaminated products from shelves will be lessened. We believe that non-quantified benefits will also be lessened under option one compared to option two.

Requiring recordkeeping by all RFCs regardless of their size allows for more-consistent, organized, and specific information that covers the entire supply chain of listed foods.

The proposed rule may result in public health benefits if foodborne illnesses directly related to outbreaks from listed foods are averted. The primary public health benefits are the value from the reduction of the foodborne illnesses or death because records required by this rule are likely to reduce the time that a contaminated listed product is on the market.

These health benefits could be generated if the following two conditions hold. First, a foodborne outbreak occurred and a second, the traceability records required by this proposed rule help FDA to quickly and accurately locate a commercially-distributed quality product and ensure that it is removed from the market; this may also lead to more efficient

use of FDA and industry resources needed for outbreak investigations but potentially resulting in more-precise recalls and also by avoiding overly-broad recalls and advisories for listed foods.

Additional non-health benefits may include increased food supply; system efficiencies -- such as improvements in supply chain management and in inventory control; more-expedient initiation and completion of recalls; avoidance of costs due to unnecessary preventative actions by consumers; and other efficiencies from a standardized approach to traceability including an increase in transparency and trust and potential deterrence of fraud.

We lack complete information that would enable us to quantify these benefits or to quantify the difference between the two co-proposed options; in the P.L.I.A., we discuss them qualitatively.

These many public health benefits are based on the model provided by the 2012 pilot study report by the Institute of Food Technologists. We included five of the eight case studies from the IFT report plus ten additional case studies using data from the CDC along with investigation and

intervention data from FDA as explained in appendix C of our analysis.

We focused our analysis on four pathogens Cyclospora, E. coli, Listeria monocytogenes, and non-typhoidal salmonella. Outbreaks caused by these 4 pathogens represent over 90 percent of all illnesses associated with the listed foods.

According to FDA experts access to lot codes and other key data elements throughout the supply chain would likely enable FDA to identify common product sources in about five to seven days or an average of six days as opposed to thirty-seven days that it takes right now.

We used this information to estimate the resulting 84 percent improvement based on the reduced time to trace the implicated product.

In sum we estimate the burden of foodborne illness 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 we borrowed from the FDA cost of foodborne illness model.

This slide shows our upper and lower estimate of public health benefits. Both option one and two estimates vary

by wide range. We estimate that annualized benefits of the rule under co-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 two of the co-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-size food recalls may result in social benefits from avoiding overly-broad recalls. Although recalls of rightly-implicated foods come with necessary costs, overly-broad recalls that involve loosely-related or unrelated products is unnecessarily costly. There are no benefits from removing unimplicated products from the market and therefore avoiding removing unimplicated product is a benefit.

Using three case studies in supermarket common data we estimate that social benefits at the value of forgone sale during each recall event, which is two-times serious, assuming that four weeks is the shortest length of a class I recall and that's our best-case scenario and thirteen weeks is

our longest length of class I recalls and that's our worst-case scenario.

You can see that the last two columns on this slide represent the estimated low and high forgone sale.

This proposed rule is finalized with both compliance cost on covered entities by increasing the number of records that are required for listed foods. Certain entities would incur recurring costs to establish and maintain traceability records.

Some firms may also incur capital investment and training costs in 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 of reading and understanding the rule.

This slide shows our upper and lower estimates of costs. We estimate that annualized costs of the rule under co-proposed option 1 would range from approximately 34 million to \$2.4 billion per years with a primary estimate of \$411 million per year.

Under option 2 of the co-proposal the annualized cost of the rule would range from approximately 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 by provision and the difference between the two co-proposed options. The highest costs would be capital investment costs -- especially under option two -- and shipping records costs; you can see those are highlighted here.

This slide shows our estimated lower and upper-bound costs for small business by industry types. These costs are similar for the two co-proposed options.

Using Small Business Administration definition of a small business and U.S. Census data we estimate that about 90 percent of firms covered by this rule are small businesses. Because some small firms may have annualized costs that exceed 1 percent of their annual revenue we find that the proposed rule will have a significant economic impact of essential number of small entities but not on all small entities.

We estimate that this rule would affect about 212,000 foreign entities and that the annualized costs to foreign entities would be about \$259 million per year. A portion of these costs could be brought through to U.S. entities and

consumers via price increases so they may experience higher costs. We can -- concerning the portion that may be passed through.

However requirements of this rule apply to all domestic entities in the same manner regardless whether their suppliers are foreign or domestic.

To estimate these costs of the proposed rule on foreign entities we extrapolate from the main costs estimates but by comparing the number of foreign entities in FDA's food facility registration model to the primary estimated number of domestic establishments minus retail food establishments. We estimate that the number of foreign retail food establishments affected by this rule is negligible.

There are several areas where we are seeking comment on information to help us improve our estimates and narrow the ranges; for example the number of covered entities, degree to which entities already satisfy the requirements, percentage of remaining traceability investments needed by industries, and the corresponding additional expenditures.

We expect the benefits due to complexity of predicting the health benefits of averted shorter foodborne

disease outbreaks, the current number of foodborne illnesses caused by listed foods, and overall our estimates of costs and benefits and the extent to which these costs may already be internalized by covered entities.

This concludes my presentation. Thank you very much and with that I'll turn it back to you, Kari.

MS. BARRETT: Great. Thank you so much. All right.

We'll now move on to our concluding segment within this part of the agenda and we have up next Andrew Kennedy; he's the New Era Technology Team Leader for the FDA Office of Food Policy and Response.

Andy's going to walk you through our real-world application of the proposed traceability rule. So Andy, I'll turn it to you.

Andy, I can't hear you; you may be on mute.

MR. A. KENNEDY: Got it. Okay. Can you hear me --

MS. BARRETT: All right.

MR. A. KENNEDY: -- okay now?

MS. BARRETT: I can. Thank you.

MR. A. KENNEDY: Perfect. Thank you.

So today we're going to walk through a basic example of a salad kit prepared with tomatoes and iceberg lettuce and the focus is going to be on the tomato grower, the salad kit maker, distributor, and retail store.

This presentation shows abbreviated data due to time constraints. To see the detailed supply chain records in spreadsheet format a link will be provided when the presentation is posted online.

The following example is intended to illustrate how several types of firms in a supply chain might meet the requirements of the proposed food traceability rule and how that information 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 non-FTL ingredients. For the purposes of this scenario it is assumed that the tomatoes are the commodity of interest in the traceback so the iceberg lettuce farming information will not be shown.

This chart provides a quick snapshot of the data I'll be walking through; specifically I will show the farm's program records and shipping KDEs -- including the originator,

harvester, cooling, and packing KDEs to the extent of 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'll represent the information in a technology-agnostic manner but I developed the examples based on what I imagine the sortable spreadsheets might look like for each actor in the supply chain.

For discussion purposes just imagine that the farm is providing paper records to the produce processor who then digitizes the information upon receipt and stores it in their receiving system.

The processor then captures the ingredients in finished production in their manufacturing software, which is used to produce an electronic advanced shipment notice for the distributor -- incorporating the shipping KDEs; and the product itself is labeled with the traceability product I.D., description, and lot code.

The distributor receives and verifies the information in their warehouse management system then shares

their shipping KDEs to the retail food establishment via their proof-of-delivery system. The product itself retains the original label from the processor.

Please note this is only one example and by no means is intended to be the only way data can be kept and shared.

Tom's Produce is a large produce-growing company that contracts with several companies to grow, harvest, pack, and ship fresh produce -- including cherry tomatoes. They retain ownership of a crop from planting to shipment to customers and have agreed to keep and send records on behalf of the organizations they work with; those include Tom's Tomato Farm owned by Tom Junior; Harry's Harvesting, who harvest the tomatoes; Patty's Packers, who cools and packs the tomatoes; Johnson's Storage stores and ships packed tomatoes for Tom's Produce.

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

Program records are critically important for our understanding of traceability KDEs. The first type of required program record is a reference record description. This example

shows the bill of lading listed in the first column under "reference record"; the second column is the listing of rule KDEs; and the third column shows the corresponding name on the actual document or electronic record.

A good example is the transporter name KDE, which is equivalent to the term "carrier" shown on the bill of lading.

Columns four and five show linkages to other records and linking KDEs. Please note this example does not show the entire bill of lading or all reference records.

The next type of required record is the list of FTL foods the organization ships. Please don't confuse this with the shipping CTE; this is a master listing of traceability product identifiers and associated KDEs -- including category, brand, commodity, variety of pack size, and style.

If the products shipped are multi-ingredient the product name KDE would be used instead of the commodity and variety KDEs.

The point of this program record is twofold; first, this enables firms to reference the traceability product identifier in critical tracking events instead of incorporating all of the KDEs in every shipment received in transformation.

Second, this enables investigators to quickly determine what types of products a firm produces without combing through production and shipping records.

Traceability lot code assignment method -- as you heard from Angela -- is incredibly important for investigators to understand how lot codes are determined and assigned by the traceability lot code generator because this gives us a sense of the scope of the lot code.

The example shown here is very specific, indicating the commodity, variety, packing location, and pack date. Other lot code assignment methods are less specific.

The important thing to consider is how the traceability lot code combined with other KDEs can be used to identify a certain quantity and type of food and narrow the scope of an investigation.

Although not required under the category of other information, firms may want to create a master listing of location. This shortens the number of KDEs required in critical tracking events by linking the full list of location description KDEs to a location identifier. Typically firms maintain electronic location and product master listings in their

business software.

For each FTL food grown the grower of the food would be required to establish and maintain records linking the traceability lot code of the food to growing area coordinates shown above. Your actual records may include more information -- like branch, field, block, sub-block, et cetera. The main idea here is that we can physically identify where the food was grown.

It is not required that our growers send this information to their trading partners but in many cases it is a common practice to do so.

This is the starting point in shipping information the farmer would need to keep and send to the processor; so imagine all of the orange boxes are part of the same tab of the spreadsheet.

To begin with the farmer would provide product information -- including the traceability product identifier, quantity, and unit of measure linked to the traceability lot code.

To make the critical tracking event easier to read I've included an abbreviated traceability product

description; the full traceability product description was shown before in the program records and is referenced in this example by the traceability product I.D.

The next three columns in our spreadsheet tab include the traceability lot code generator information; in this case Tom's Produce assigned the lot codes so they are listed as the contact for the traceability lot code generator.

Continuing on to the ship-to information, the I.D. for fresh processor plant number 16 -- and in this case an abbreviated location description -- are kept and sent. The location I.D. references the location master information shown in the program records so I only included a short description on this slide.

In a similar way the location from where the product was shipped along with the shipment date and time are kept and sent to the processor; I abbreviated the ship-from location description -- Johnson's Storage warehouse number four -- and referenced the detailed location information in program records using the location identifier.

The last component of the farmer's shipping KDEs are intended to be kept only; they include the reference record

type and number and transporter name.

The following five slides illustrate the data that should be sent from the farmer to the first receiver. Step one is to let the processor know the shipper is the farm; this alerts them that they are first receiver.

Next the farmer communicates the originator's location identifier and description for each traceability lot code sent to the processor. In this case I've referenced the location master list in program records. The harvester's business name, contact information, and harvest date and time are sent.

In this example the same packing company provides cooling and packing so the information shown here is the same as the next slide except for the date and time.

This shows the packing date and time along with the packing shed location I.D. and abbreviated description. This completes the records the farmer is required to send to the processor. Next up we'll see the processor's records.

So the quick reminder of this scenario. The fresh processor receives tomatoes from Tom's Produce and iceberg from Lizzie's Lettuce. Once the processor creates the salad kits,

they're shipped to the distributor and on to the retail food establishment.

For the sake of time I've abbreviated the processor's traceability records; they're very similar to the farmer's 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 will include the distribution center the processor ships to.

Since the processor was notified that they are first receiver by the farm they are required to capture the first receiver KDEs listed here for each traceability lot code received. This information should be provided by the farm with the shipment either electronically or via paper records.

The processor also records the receiving KDEs shown here; they're virtually the same as the shipping KDEs from the grower except the receiving date and time. Once the ingredients have been received the processor completes the transformation. This slide and the next show the required KDEs.

First are the foods used in the transformation; in this case iceberg lettuce and cherry tomatoes. The next step

captures the foods produced through the transformation, including the new traceability lot code; quantity and unit of measure; traceability product I.D.; and abbreviated product description -- I included the UPC in the example based on industry best practices but it's not required --additional information captured by the location and date where the transformation took place, and the work order number.

The next five slides show the shipment KDEs for the salad kit that was produced in the prior step. Similar to the farmer's shipping KDEs we have the product information; the new traceability lot code generator and their point of contact - - which is now the fresh processor; then we have the food distributor's ship-to location; and the ship-from location and shipment date and time. Finally, we have the reference record and transporter, which is kept only.

Okay. Halfway there. Next up the distributor receives the salad kits and ships them to the retail food establishment, which in turn sells to the consumer.

So again the program records are similar; however if the distributor does not repack or process they may not have a lot code assignment method so it'll be a little shorter.

The receiving KDEs are simpler because they are not the first receiver so they only capture the product information, ship from and to, traceability lot code generator, and transporter.

The next five slides illustrate the distributor passing the information that they received from the processor to the retail food establishment. First the processor's traceability lot code, product I.D., and description, along with the quantity and unit of measure are kept and sent. The processor's location I.D. description and point of contact are kept and sent under the role of traceability lot code generator.

Next we have the ship-to location, which is kept and sent and the ship-from information, ship date, and time are all kept and sent. Finally, the reference record and transporter are kept. So that kind of wraps up the shipping records.

The last link in the supply chain is the retail food establishment. The retail store receives the salad kit and sells it to the consumer. The retailer's program records may be even simpler since they do not assign lots or ship product. Other than program records their only other records are receiving records, which mirror the shipment records from the

distributor with the exception of the receiving date and time.

Note that the traceability lot code generator and lot code have been received at the store along with product information. This completes this supply chain scenario.

To understand how this simplifies traceback imagine that investigators know the location, UPC, and date of purchase. From the retail food establishment they can request information on traceability lot codes and traceability lot code generators related to products that were received around the time of purchase.

Investigators can use this information to contact the processor directly and ask about the ingredients and ingredient lots used to produce the salad kits of interest.

In this example investigators have determined that tomatoes are the likely cause so they can use the first receiver information to contact the farm regarding the physical location or locations where the tomatoes were grown.

Along with the packing, cooling, and harvesting information the investigators are starting with a pretty good idea of where to look for possible contamination. If contamination is discovered at the growing location, cooler,

packing shed, or processor, the same type of traceability records used in traceback investigation can also enable the supply chain to initiate and complete a quick and effective traceforward and recall.

Thank you very much for your attention and I look forward to your questions.

MS. BARRETT: Great. All right. Well thank you, Andy, and our speakers in this segment.

We are a little early but I think we'll go ahead and jump into our questions and we'll go for our 15 minutes.

So why don't we take a look and see what's in the chat. If folks have a question please do put it into the chat; we'll give you a minute.

And just as I did before -- again this is Kari Barrett -- I'll read the questions out loud and if we can direct them our speakers.

Okay. It looks like we have an initial question for Aliya and it's "could you please explain what you mean by 84 percent traceback improvement?"

Aliya?

DR. SASSI: Sure. Can you hear me?

MS. BARRETT: Yes, we can.

DR. SASSI: So based on the outbreak case studies that we looked at the average number of days to identify a product source without a lot code is about 37 days.

And then according to FDA experts if the proposed rule is finalized it would take about 6 days to identify a common product source and -- which we estimated would be 84 percent traceback improvement so that with fast identification of a common product source it's basically translate into FDA's ability that reduced time of a contaminated product will be on the market and shorter outbreaks and that would translate into more illnesses prevented.

MS. BARRETT: Great. All right. Let's take a look and see what our next question is. The questions here. Okay. Bear with me one second.

Okay. This is on recordkeeping; the question -- and I'm not sure who to direct this to -- but it's "what recordkeeping is necessary for entities downstream from a qualifying kill step?"

MS. GOLDBERG: Hi. And this is Becky; I can take that one.

There is not any recordkeeping required for entities downstream from a kill step. -- for products that have already received a kill step; if you're someone who subsequently receives that product you do not have to keep any records for that product.

MS. BARRETT: Great. All right. Let's see. This one looks like it's for Angela and the question is "if the farm is the grower and also the cooler and packer are they still required to maintain KDEs on the cooler and packer steps?"

MS. FIELDS: Thank you, Kari. So to answer the question yes, they will be required to maintain information but the farmer would only need to maintain the growing record -- so the growing area coordinates that are linked to the traceability lot code.

And additionally they would need to keep and send the shipping KDEs that were outlined in the presentation and make sure that those are sent to the next -- that's in -- 1350.

And so subsequent KDEs would include information that has to do with harvesting and packing and cooling. So again that information would move forward in the supply chain.

MS. BARRETT: Great. Thank you, Angela.

MS. FIELDS: Additionally, with that --

MS. BARRETT: Please go on; sorry.

MS. FIELDS: Additionally, with that there wouldn't necessarily be a requirement for them to maintain the information about the cooling or packing the KDE specifically per the proposed rule but they would have to ensure that that information made it to the first receiver. Thank you.

MS. BARRETT: All right. Thank you. Let's see. Our next one looks like it's for Becky Goldberg, which is "fishing vessels are exempt but about aquaculture farmers?"

MS. GOLDBERG: Great. Thanks for that question.

So you know, the key issue is whether or not you fit the definition of a fishing vessel. So there's nothing -- you know, we don't define aquaculture farmers. People might use that term in different ways.

But the definition that we used for fishing vessels is directly from the Magnuson-Stevens Fishery Conservation and Management Act, which I think the industry is already familiar with -- it's the same definition that I believe NOAA uses in some of their regulations.

So you know, if you fit the definition of a

fishing vessel then you're eligible for that partial exemption and if you do not fit that definition then you are not eligible for that exemption.

MS. BARRETT: Thank you. Andy Kennedy, this one is for you; the question is "I'd like to request publication of the real-world application slide set. It's very helpful."

MR. A. KENNEDY: Well thank you. It's always good to hear positive feedback and I believe after, you know, this public meeting we're publishing the slide deck; is that correct? We'll be publishing that soon?

MS. BARRETT: We will. We will. Yes; I know the slides have at times slightly evolved because of the conversations that we've had through these public meetings so we did want to wait until the third and final public meeting was complete before we posted them.

So we will be posting the slides for all of the fans of the slides. They'll be coming.

So Angela Fields, this one is for you; "does repackaging require new traceability lot code?"

MS. FIELDS: Thanks for that question, Kari.

So yes, under the premise of transformation

repackaging would be considered a transformation, which again would require some additional KDEs to be kept.

MS. BARRETT: All right. And our next question is for Andy Kennedy; "in the salad kit example does the lot of tomatoes -- 150 cases -- have to stay together and be handled together until they are packaged with the lettuce to the kits?"

MR. A. KENNEDY: So it depends on how you identify that lot of tomatoes. So it depends on your aggregation level. So that's really a business decision on the best way that you can keep those together so they remain identifiable.

So if it's in a case or in a bin as long as that bin can be, you know, identified as part of that lot you could have multiple bins or multiple cases in your inventory and you can just pull on the match you need.

So you don't actually have to keep, you know, all of them together. So as long as there's some sort of way of segregating them.

You know, typically in the produce traceability initiative it's -- you know, they're labeled at the case but for tomatoes that haven't been put in a case, you know, field bins and other types of mechanisms to keep them, identify, and

segregate them.

Hopefully that answers the question.

MS. BARRETT: All right. Thank you. Our next one is for Aliya Sassi, which is "what kind of small business definition did you use?"

DR. SASSI: Well the Small Business Administration publishes size standards for industry categories by North American Industry Classification System codes -- also called NAICS codes.

So for each of these NAICS codes it defines small business thresholds either in terms of sales revenues or the number of employees per firm.

We used these Small Business Administration thresholds for each NACIS codes to estimate the number of small business by industry sector.

Now by the way for retail food establishments the small business threshold is based on annual sales and not the number of employees and you can see section three of our P.L.I.A. document for more details.

MS. BARRETT: Great. Thank you. The next one is for Andy Kennedy; "Andy mentioned that location description

information can be abbreviated because the processor maintains a master list. Can you elaborate on that?"

MR. A. KENNEDY: Yeah. So when we asked the processor for their sortable spreadsheets, you know, the critical tracking events that they capture -- the receiving, transformation, and shipping -- will reference locations.

And so technically in those records if you just list the location I.D. in those records and then provide us a list of your location I.D.s and what they mean and all the associated KDEs then those individual, you know, shipment records or receiving in the sortable spreadsheet, they only really need to point to the I.D. that points to that location.

So if you provide us just a list of the facilities you ship to or receive from and that your processing locations, the I.D.s and then all the required KDEs, you just do that a one-time list.

And that's typical for business software when you set up your vendors and you set up your customers; those are master lists. But then the individual receipts and sales and so forth you reference those lists.

So that's the idea. So we want to as much as

possible leverage how business systems work today and not make you do something different. So we're trying to be flexible in what information goes in the actual rows of the sortable spreadsheet.

Thank you.

MS. BARRETT: Okay. Thank you. Angela Fields, a question for you; "what are the requirements" -- I'm sorry; let me get to it -- "what are the requirements for the traceability lot code and how does this relate to the current use of lot codes?"

MS. FIELDS: Thanks, Kari. So there are no current requirements for the traceability lot code outside of that traceability lot code must be unique. So the KDEs that you're maintaining must be linked to your traceability lot code.

The traceability lot code is a term that we're using that would be represented to what industry is currently calling a lot or a lot code; we identified this term of "traceability lot code" to ensure this unique identifier could travel through the supply chain and be used to easily identify products -- especially during a traceback event or other recall event.

The traceability lot code again does not have to be printed on the food product; it just needs to be provided within the records and identified.

And one other thing is that that traceability lot code can only be changed or established and assigned during certain circumstances; so that's origination, creation, or transformation. And then outside of that we would expect that that traceability lot code not be adjusted in any other situation and again travel through the supply chain.

MS. BARRETT: Great. Thank you very much.

Okay. This next one is for Becky Goldberg; "can you please make an example of the various steps needed for a foreign imported product -- for instance cheese from abroad -- and how is that different from current practices?"

MS. GOLDBERG: Sure. Thanks. Of course current practices I think vary a lot throughout industry but the important thing to know from a big picture is that the proposed rule would apply the same to foreign entities as to domestic entities; or in other words it would apply the same to imported products as it would to domestic products.

The only thing that's kind of import-specific is

that once a product has an import entry number that becomes one of the key data elements that gets maintained and passed along during shipping and receiving.

But other than that, you know, yes, that's kind of the only import-specific thing. But basically the requirements are the same for both foreign and domestic entities.

MS. BARRETT: Great. Thank you. Andy Kennedy, we're going to come back to you. "How would companies use P.T.I. labels in your scenario?"

MR. A. KENNEDY: Yeah. Great question. So an example would be for the tomato packing shed; if they wanted to, you know, as part of their -- the way they communicate with their customer, the traceability lot code and traceability product identifier and description is they print all of that onto a P.T.I. label and include a bar code with traceability product I.D. and traceability lot code.

So that could be the way that they communicate that information to, you know, the subsequent recipient.

And then, you know, the next step in the chain -- the processor could take advantage of for example P.T.I.'s

message standard. So that can be how they share traceability information to the distribution center, you know, from the processor.

So there's lots of different pieces within P.T.I. that can be used to, you know, share this information; identify products in the supply chain uses P.T.I. labels that could be then leveraged by receivers to capture that information.

And so I think there's a variety of different ways and different aspects of P.T.I. that could help meet this rule. Okay.

MS. BARRETT: Great. Thank you. All right. Let's see. Angela, we have another question for you; "how will a distributor know if it is the first receiver?"

MS. FIELDS: Thank you, Kari. So again the first receiver is the first non-farm entity that takes physical possession and purchases a product. -- in that case you -- the entity -- would know that you're not a farm.

Additionally, as identified in shipping -- KDEs there is a statement that is required to be sent forward from a farm to indicate that they are a farm and shipping the product to the next entity.

So the entity receiving that product if they are the first receiver would be receiving a statement that says that they received product from a farm.

MS. BARRETT: Great. Thank you. Becky, we have another question for you; "what KDE recordkeeping would apply to a bulk tanker of pasteurized liquid dairy product that is then placed in a bulk tanker and shipped to another processor?"

MS. GOLDBERG: Thanks. So liquid dairy products are not on the food traceability list so there would not be any requirements.

Also, if it was pasteurized -- as a second matter; I guess it's not relevant since it's not on the list but just for greater awareness -- when something has received a kill step then any subsequent parties who deal with it don't have to keep records.

MS. BARRETT: Great. Okay. Thank you. Andy Kennedy; "is blockchain a good method to comply with this proposed rule? Also, what technology would FDA recommend?"

MR. A. KENNEDY: Got you. So we are completely agnostic to technologies; you know, from back in my days of implementing systems, you know, what I found is always effective

is start with what you have and see what it can do.

So that's always the least-costly option so I would take a look at your existing systems and see how they could potentially meet this rule.

And then in terms of blockchain, you know, blockchain is being used effectively by a number of different solution providers and companies to do traceability but it's not the only way; so there are many different solutions out there but you may find it's an effective tool but there's lots of good tools out there.

We kept the rule pretty simple and since it's -- you know, we've identified three basic use cases where you need to keep data -- you know, keep records for yourself; send data between trading partners; and then generate the sortable spreadsheet.

So another way to think about it; it's like three different tasks. You got to be thinking about how do you automate that within your operation to make it most effective.

So anyway; a couple recommendations. And then the last one is taking the data you have and then put it into the CTEs and KDEs and do a gap analysis and see -- you know, you

probably have most of this data already and then talk to your trading partners about what they're thinking about doing and how they intend to meet the rule.

So that's couple thoughts.

MS. BARRETT: Great. Thank you, Andy. Angela Fields, we're going to come back to you; "in the event of an outbreak who would be responsible for contacting RFEs in order to obtain KDEs?"

MS. FIELDS: Thank you, Kari. So in a typical situation in contact retail food establishments oftentimes you'll find the local or state health department or agriculture department but state public health officials would be contacting the retail food establishments.

There could be some situations where FDA may reach out to obtain the information as well. So it just depends on the degree of information that's needed and who is going to be able to contact that retail food establishment initially.

MS. BARRETT: Great. All right. Thank you.

And I know we're going a little longer than 15 minutes. Here is another one, Angela; "I may have missed this but does the retail store have requirements for receipt records

from their D.C.? How is traceability applied to direct store delivery?"

Oh I'm sorry; I think I said that wrong. "I may have missed this but does the retail store have requirements for receipt records" -- yeah -- "from their D.C.? How is traceability applied to direct store delivery?"

MS. FIELDS: Thanks, Kari. So retail food establishments that would be covered under the rule would be required to maintain receiving KDEs. So the expectation would be that from whomever they are receiving product from, they would be provided information but would be required to maintain specific KDEs that are related to the shipments that they've received.

MS. BARRETT: Great. Thank you. And I think we're getting close to wrapping up the Q and A but Becky Goldberg, we have another one for you and it is "not in all cases entities take physical possession and purchase produce at the same time" -- and in parentheses -- "(business models vary). FDA should consider that."

MS. GOLDBERG: Yes; thank you for that. We're definitely aware there's a lot of different business models out

there and as I think we've said we definitely encourage people to submit comment if they feel like their specific business model -- sort of they can't figure out how it fits within the rule or have concerns about how it fits within the proposed rule.

I'll say to that specific question we are aware of that discrepancy that purchasing and taking physical possession sometimes don't both happen; you might have one of those things happen but not the other thing.

And actually that's why we drafted the proposed definition for first receiver the way that we did; because the proposed definition for first receiver involves both purchasing and taking physical possession and we specified both things because we know they don't always happen at once but you're not a first receiver unless you did both things.

So again though we do encourage people -- if you feel like you're not sure how your business model fits into the proposed rule or you're worried that it's difficult to fit it in that's the sort of details about different types of business models -- those are the sorts of details that are very helpful to receive in the comments.

MS. BARRETT: Great. Thank you, Becky. I think at this point we are going to go ahead and move on to our state perspectives panel. So I do want to thank all of you for the questions that you answered; again another round of applause and really appreciate your participation today.

So we will conclude our Q and A and we're going to go ahead and move to our state perspectives panel.

Before we do that I do just want to remind folks if you have additional questions and you didn't get them in or they got in and we're not able to answer them in the last session please do submit them to the CFSAN Technical Assistance Network -- or TAN as it's called; that way you are guaranteed to get an answer and we're also able to track the questions that we're receiving as well as responses.

And that helps too sometimes when we see a question that comes in multiple times -- you know, it may be that we need to do more widespread communication on that particular topic; so it gives us good information. So please recommend that you use the TAN if you have questions or if leaving today you have questions that you'd like to address to the agency.

So with that we are now going to move into our state perspectives panel. We have moderating this session Erik Mettler; he's our assistant commissioner for partnerships and policy in the FDA Office of Regulatory Affairs.

So welcome, Erik, and your panel; I'll turn it over to you and we look forward to hearing remarks.

MR. METTLER: Perfect. Thank you very much.

With me joining is Natalie Krout-Greenberg and Randy Treadwell. I think most of you know these folks but I'll introduce them anyway.

Natalie serves as the director for the Division of Inspection Services at the California Department of Food and Agriculture and Randy is the response -- sorry; Rapid Response Emergency Management Program [sic] manager for the Washington State Department of Agriculture. So thank you, both, for joining us.

Let me just start out by saying it's an absolute pleasure to work with both of you and all the states; we really could not do this without you. Our public health mission would not be complete without our partners of the states. So you guys are just absolutely essential to everything we do. So thank you

very much.

So I'll just sort of ask two questions really and, you know, Natalie, I'll sort of start with you and then we'll bounce it back and forth from there if you don't mind.

So the states are really the boots on the ground; you guys are the folks that see it -- sort of live this day in and day out and really sort of close knit with community there.

So based on your experience how has the lack of consistent recordkeeping hindered your investigations in an outbreak situation?

MS. KROUT-GREENBERG: Thanks, Erik. Can you hear me all right?

MR. METTLER: Yep, absolutely.

MS. KROUT-GREENBERG: Very good. Okay. Well thank you and thank you for having both Randy and I as part of the panel today.

And I guess let me start just with that question from a high-level perspective and then we can drill down a little bit; and then California I think we're in a unique situation in that we have 21,000 different farms that are subject to the Produce Safety Rule.

And realizing that not all the commodities that those farms produce are necessarily subject to the food traceability list but a good portion are; we produce over 400 different commodities in this state.

And so as our goal at C.D.F.A., we're part of a rapid response team -- just like Randy is in Washington state -- and that means it's comprised of C.D.F.A., our partners at the state department of public health, and FDA.

And when we are faced with situations of outbreaks, you know, obviously for us -- just like it calls out in the introduction of the rule -- speed and precision are key in tracebacks. Speed leads to fewer sick individuals and allows us to get those important touchpoints in the supply chain like fields, the processors, or harvesters faster.

And then it really allows us to understand what happened and to then prevent that from happening in the future -- not only for that particular entity but lessons learned for entities as a whole.

And so that really is key. Precision really helps us both in the office and with our field staff as well. All of the time that's wrapped up into traceback takes time; it's a

person behind the scenes looking through paperwork, corresponding with entities. It's also time with our farms as well as our handlers.

And so when we can get to a level of traceability where we can be faster and be more precise it narrows the scope and really allows us to be effective when it comes to root cause evaluation and improving overall food safety practices as we move forward.

MR. METTLER: Perfect. Thank you. So Randy, it's sort of the same question but stated I guess a little bit differently.

How would a harmonized traceability enhance your ability to improve outbreak investigations in regards to a product tracing and listing of foods?

MR. TREADWELL: Can you hear me, Erik?

MR. METTLER: Randy?

MR. TREADWELL: Yep. Yep.

MR. METTLER: We can hear you now.

MR. TREADWELL: Great. Great. Thank you. Sorry about that; having a little bit of an audio problem.

But anyways. So was the question based on the

lack of consistent recordkeeping; is that what I heard?

MR. METTLER: It's basically how would a more-harmonized traceability system enhance your ability to deal with outbreak situations, specifically around --

MR. TREADWELL: Yeah, I --

MR. METTLER: -- tracing -- yeah or product tracing.

MR. TREADWELL: Absolutely. Yeah, that's a great question.

So like Natalie mentioned, here in Washington state we have a rapid response team since 2009 and we actually based it heavily on the California model so thank you, Natalie and team.

But since then, you know, we've had our fair share of outbreaks and other food-related emergencies in that time where a large piece -- like we heard from California -- have an investigational puzzle that's tied to product traceback.

So you know, during these responses we try to be, one, fast; and two, accurate. And so when product traceability records aren't standardized or in some cases not even present it takes us as regulators and the firm considerable extra time and

effort, you know, to hunt down that information so -- you know, when we could be working on that time and effort for -- you know, both industry and regulatory partners working on removing any implicated product from distribution.

So you know, as the recall coordinator who's been doing this for some time I definitely like the concept of not only an enhanced but a standardized traceability process so, one, we can, you know, really quickly identify the products of interest; confirm the correct distribution pattern; and then be able to communicate that information to public health partners with minimal guidance as to explaining what they're looking at.

So making sure that we're including all the partners from local health jurisdictions all the way up to our federal partners and industry partners in that process.

So in a way of being able to harmonize the traceability aspect I think it really comes down to that piece of standardization that we would be looking at so we're not reinventing the wheel every time and learning as regulators as we go to see, you know, what the process is for that particular industry partner and then being able to communicate that to all of our partners for a more-efficient response.

MR. METTLER: Fantastic. Thank you and I think you sort of led me into my next question.

You know, I think this really sort of helps us and I sort of touched on this a little bit in the very beginning but, you know, us being sort of an integrated system where we're all working together at the end of the day.

So these systems can really work well -- you know, I think, you know, in an individual state or another but how important is it to you to actually have something like this that, you know, if it's happening in California versus Washington the same system that you guys can sort of, you know, work back and forth and also with us?

From our standpoint, you know, it's very and extremely important.

Natalie, how about you go first and then Randy, you can sort of follow up on that?

MS. KROUT-GREENBERG: Certainly, Erik. So it is really important; it's one of those things that we could not do the job that we need to in California without our partners across the nation. There are so many times that we are interdependent on one another; what is happening at a local

level then moving up into a state level, working obviously with CDC and CORE.

And then ultimately, you know, and what I always tell my team. Statistically unfortunately it's likely that it came from California just because of the amount of product we produce in this state.

So with that said having those systems ready and being able to know exactly where we need to go -- we have a finite level of resources and at the end of day we only have so many field staff -- both on the federal side and on our state partner side.

And so for us it's vitally important that we're at the right place and that we're able to get to the bottom of the situation. In addition to that it's vitally important that we're not going to operations and expending industries' time and energy in places that we don't need to be.

So when we look at standardizing a system it goes through and through not only from a local perspective but up to a state level and then also just funnels into -- like a ripple effect -- into our industry partners because everyone's time and energy when it comes to food safety resources is precious but we

know it's the most important thing that needs to be at the top of our list.

MR. METTLER: That's great. Thank you, Natalie. Randy?

MR. TREADWELL: Yeah; just to kind of mirror that sentiment as well. I mean due to the variability of the regulated firms that we're seeing -- including, you know, size, complexity of processing, number of products manufactured -- we tend to see some pretty good variability in the recordkeeping as well.

But to Natalie's point of making sure that we're all kind of singing to the same sheet of music; you know, it does take considerable amount of time in these traceback-type efforts -- particularly time that we may or may not have in an outbreak-type situation or other food-related emergency -- where, you know, you don't really reinvent the wheel of you're trying to figure out having the regulators communicate what's needed to our industry partners but requesting that our industry partners, you know, explain their process to the regulators and then have both the regulators and the industry partners then be able to pull out the necessary data to make a successful

traceback.

So being able to really crunch that time in and being able to make it more efficient -- most efficient as possible is what I'm trying to say -- is definitely a help to the outbreak response piece of it.

MR. METTLER: Fantastic. Thank you. I know this is sort of a short timeframe that we had here together but any sort of closing or words of wisdom that are watching us now?

I'll let either of you go first. We'll go with Randy first and then Natalie, you can wrap it up.

MR. TREADWELL: Okay. Sounds good. Thank you, Erik, again for the invitation.

You know, I think that there are -- like I said it's a really great concept. I think that with a really high level of awareness and education and outreach around, you know, which KDEs -- key data elements -- are needed and where to find them and how to best record them -- I think that this concept of a standardized data element approach for these critical tracking events is going to be really, really helpful for all of the partners -- not just FDA and not just industry but our state and local partners as well -- to make sure that we're, you know,

really increasing the speed and the effectiveness of our outbreak response situations to food emergencies.

So -- and I'm in support of that.

MR. METTLER: Fantastic. Thank you. Natalie?

MS. KROUT-GREENBERG: And Erik, yeah; I would just add to what Randy said. I certainly agree; ongoing education is really important as we work through this -- realizing that we have so many different sizes of farms in California and across the nation. It'll be really important that everyone understands how they fit into this particular rule and have the support that they need in order to do that.

On the heels of that comment though I just want to acknowledge that we've had recent incidents where we've had to exercise this and we had really good information from the point of purchase and there was, you know, quick speed in getting back to the actual ranch we needed to be at.

And I commend the industry because there are systems that are already out there that are working. And so I think it's just important to build upon those and continue to celebrate the wins where we have them, realizing that we have more work ahead but that we're on the right path together.

And then just the final point I'll leave you with is this also has applicability -- and especially like in our state; we've seen policy initiatives move forward with regards to reduction of waste going into landfills. And when we can improve traceability components it does help reduce elements within the supply chain where we can have tighter supply chain management and ultimately reduce the amount of food waste in the system, which helps us, you know, ultimately achieve those policy goals that some of us are facing with new initiatives in the state.

So with that thanks so much for having us; we enjoy continuing to be a partner and working with industry as we move through this.

MR. METTLER: Absolutely. Well thank you, both; and Kari, we'll pass it back over to you.

MS. BARRETT: All right. Well thank you; what a great session. Really wonderful to hear all of you speaking and your comments today. So thank you again for participating.

And at this time we are going to I'm going to say take a lunch break for those of you on the West Coast; over here on the East Coast maybe it'll just be an extended tea break but

we are going to take some time.

So we're going to follow the agenda. We're breaking a little bit early but we are going to come back at the 4:35 Eastern Time with our panel of external stakeholders on traceability.

So please enjoy a nice break and come back at 4:35 Eastern and we'll continue our program. Thank you.

MR. KAWCZYNSKI: For those of you who we just coming back from our break and we should be now back on time with our agenda; we made a few little adjustments there.

So let's see. Now if you are hearing the background noise that's your own computer; that's a great question. If you're hearing the background noise like the music playing it's not playing anymore; we already turned it off. That's your own computer; you can just log out, log back in, and you'll be fine. It is a little glitch that I see that people have on their own computers. So it's a great question. So yeah, you can do that.

Anyways. Other than that all right. Are you ready, Kari?

MS. BARRETT: I am ready and welcome back,

everyone. And Michael, thank you so much; I know everyone has heard your voice throughout the day but you do so much to make these events successful and I know it's a lot of moving pieces. So thank you and we are now at that point of our agenda -- excuse me -- where we're going to hear some external stakeholder perspectives on the proposed rule on traceability.

And to help moderate or to moderate this session we have Rebecca Buckner; she's our CFSAN senior science advisor to the center director. And Rebecca, I am just going to turn it over to you and slip out. So thank you.

DR. BUCKNER: Okay. Great. Thank you so much, Kari.

Good afternoon; I'm Rebecca Buckner and I'm from FDA and it's my pleasure to moderate this afternoon's panel discussion on perspectives on the traceability proposed rule.

We are fortunate to have with us this afternoon four very accomplished panel members and we appreciate them taking time to participate and share their knowledge.

Our panelists for this afternoon are De Ann Davis -- Dr. Davis serves as the senior vice president for science for Western Growers; she most recently served as food safety

director for Commercial Food Sanitation, a provider of strategic consulting services, expertise, and training that addresses food safety and sanitation challenges for food processing plants. Previously she was vice president of food safety and quality for both Church Brothers Farms and Earthbound Farm and earlier she was chief food safety officer for Kraft Foods, where she was engaged in the development of the regulatory framework for FSMA.

Next joining us is Sandra Eskin. Ms. Eskin is the project director for food safety at PEW Charitable Trusts, where she directs PEW's work on food and dietary supplement safety. These initiatives engage the federal government, industry leaders, and other stakeholders in efforts to reduce health risks from contaminated foods and supplement products. Before joining PEW she was a public policy consultant to consumer and public interest organizations, providing strategic and policy advice on issues including food safety, dietary supplement safety, and food and drug labeling and advertising.

Our third panelist this afternoon is Greg Ferrara; Mr. Ferrara is president and CEO of the National Grocers Association. In this role he is responsible for working closely with N.G.A.'s board of directors to develop and

implement a strategic vision which advances the association's efforts and public policy positions in support of the supermarket industry. He was previously N.G.A.'s executive vice president and chief lobbyist, responsible for representing the association and its members before members of Congress, federal agencies, and the executive branch on a wide variety of issues. He brings a wealth of experience in the grocery industry to his work with N.G.A., having previously managed his family's century-old supermarket in New Orleans.

Our final panelist this afternoon is Lisa Weddig; Ms. Weddig is vice president of regulatory and technical affairs for the National Fisheries Institute, which advocates for the seafood community. She joined N.F.I. in 2007 and serves as the primary liaison for regulatory issues, food safety development, and seafood fraud concerns for the association members. Prior to joining N.F.I., Ms. Weddig spent 18 years with the Food Products Association -- which is now the Consumer Brands Association -- where she held various positions in thermal processing, HACCP, food safety and educational support for association members.

As you can tell this panel has a wealth of food safety experience and that was just a snapshot. Again we thank

them for their time this afternoon and with that let's get started with our panel.

I'm going to start with an overarching question that I'm going to ask each of you to speak on and then we'll move on to follow-up questions that you all can just jump in on; if you don't jump in I'll call on you so, you know, it's in your best interest to speak first.

So here's the overarching question and maybe you all can answer this in the order that I introduced you -- which means we will start with De Ann.

I would ask each of you to briefly discuss your experience with traceability and your perspectives of why food traceability is important -- just an overview about your organization, yourself, and why traceability is important.

So De Ann, I will turn it over to you to start us.

DR. DAVIS: Sure. Hello everyone. So Western Growers was founded in 1926 and we represent local and regional family farming, growing fresh produce in California, Arizona, Colorado, and New Mexico. Our members also have operations in other states as well as other countries.

Western Growers members and their workers provide over half the nation's fruits and vegetables and tree nuts, including one-half of America's organic produce. So Western Growers also supports the scientific and technical activities of the Leafy Green Marketing Agreement in California and Arizona.

Our members work tirelessly every day to make sure that our consumers have access to safe and fresh produce year round.

To begin I just really want to thank the FDA for the opportunity to participate in this panel; these are great learning experiences but I also appreciate the opportunity to share the perspective of our members regarding this draft rule.

Our membership has made tremendous progresses in food safety and regulatory compliance since the introduction of FSMA; we also seek continuously improve our food safety program from field through distribution.

You see, traceability is an important part of these food safety programs. For such commodities -- such as leafy greens -- traceability at the level of the farming operations we've been challenged more often than we'd like to talk about; evaluated and progressed as a result of widespread

commodity advisories that resulted from foodborne illness outbreaks.

For other commodities we are still learning and evaluation what the challenges and implications are related to this proposed rule.

So my colleagues on this panel will be focused on the need to make sure that the fundamental's right and make sure that we built a system that works. We ask for clarity in the role and description of each participating entity -- including the designation of a farm -- as this will ultimately incur upon the first receiver definition.

Clarity in the definition of each activity within the supply chain -- such as receiving and/or transforming -- and most important keep clarity as to the definition and value of each of the KDEs and CTEs is critical.

For example we've been examining the request to include cooling information. Cooling activities are not singular and they happen throughout the supply chain so this creates complexities and costs in data collection and sharing and then that can in the end may be of limited value in improving the speed of an outbreak investigation.

We believe the most direct CTEs and KDEs will bring the highest value in building an effective and consistent system and we ask the agency to focus on what information is truly needed.

Our members are eager and willing to support improvements in the field-to-fork traceability for all fresh product; the last mile of traceability -- as we all know -- has been a consistent gap for leafy greens and other fresh produce commodities. We understand that improved traceability is critical to limit illness as well as supply chain disruptions when a food safety concern rises.

But importantly we're also eager and willing to make sure that all considerations and needs are addressed to assure that we have a traceability system that works in the end and adds value for all stakeholders. So that concludes that -- comments.

DR. BUCKNER: All right. Thank you. I think we'll go over to Sandy next.

MS. ESKIN: Hi everyone; and again thanks for inviting me to participate.

First, about my organization; the PEW Charitable

Trust is an independent nonpartisan research and policy organization and it was formed by the trusts of the sons and daughters of the founder of Sun Oil.

We have a longstanding focus on public health but specifically in terms of food safety -- the project that I direct -- began in March of 2009 and the timing couldn't have been better because there was momentum building through the enactment of the FDA Food Safety Modernization Act, which we were involved in both or all of not only the enactment but then the implementation and the funding.

We do other food safety work but again we began with FSMA and it is something that is still of high importance.

We knew it would take a while to implement; perhaps a longer while than anyone had expected. And obviously - - as has been noted many times today -- traceability is an important public health tool.

We know that FSMA and so much of food safety oversight and regulation has focused on prevention but in reality even with the strongest regulations people are people; things happen and we have outbreaks and problems and a quick response is critical.

So there are three reasons why traceability is important from the consumer advocacy perspective. One is quicker identification of food vehicles in an outbreak means fewer deaths and illnesses. Two, quicker identification of food vehicles in an outbreak means fewer deaths and illnesses -- you get the point.

It's absolutely critical and we know that certainly in recent outbreak investigations FDA has been stymied across a range of products; when traced back the investigation has just not been able to identify some food vehicle for the illnesses.

So we think it is great that the rule finally came out -- again longer than we had hoped and it did take some litigation. I think anyone that has looked at the rule -- and I don't have to say this to most people in the audience -- it's not the most artfully -- yeah. Actually let me start again.

The provision 204 -- Section 204 is not the most artfully-drafted legislative provision. I still wonder sometimes -- and I haven't gotten a straight answer; we were not involved in the actual legislative drafting but -- who wrote this? -- that said I think again FDA has done a very good job in trying

to set up a system that is workable.

I had listened all day long and will continue to listen -- the colleagues in the food industry; this has to work for them, this has to work for retail, it has to work for everyone.

That said I think that there's a few things I've heard to date and I for one am still reading through the very comprehensive regulation and will continue to do that but I think there is a concern that there needs to be uniform standardized terminology and terminology industry is familiar with. There may be variation but it would be really unfortunate if we have this rule and it's finalized and we wind up with essentially as a Tower of Traceability Babel. That's not going to help anyone so that's something.

And I think the thing that we are looking at and focused on and I think many of my colleagues who have spoken at prior public meetings say the same thing is exemption. FDA as is its authority -- you know, they were required for certain exemptions by the law but also made some decisions at least tentatively.

And the concern is we want an end-to-end system.

If there are major holes in the farm-to-form traceability continuum that's not good. We said the same thing when we have commented on the rule itself [sic] -- the other FSMA rule -- and perhaps in this instance it's important for FDA to evaluate all of the proposed exemptions and ask whether rather than exempting would it be better to develop, to help, to provide assistance to smaller entities so they can have size-appropriate, operation-appropriate traceability that works.

Again rather than exempt from the rules is there a way to help companies to set up a traceability system? And I think that's it for right now.

DR. BUCKNER: All right. Thank you very much and now we'll turn over to Greg.

MR. FERRERA: Hey. Good afternoon, everyone, and apologies that I'm the one whose computer is on super-zoom today so you get a close-up.

But thanks again for having me. The National Grocers Association is a nearly-40-year-old trade association. We represent the retail and wholesale grocers that comprise the independent sector of the supermarket industry.

For us an independent is simply an ownership

structure; so privately-owned, family-owned, or employee-owned companies make up our membership. We're in every state and all the way down to Puerto Rico as well. About half of our members are small businesses, typically on the retail side -- which I think's, you know, really important as well.

Our membership are all supermarkets so I think that's important to understand -- that range from, you know, a single store in rural Nebraska all the way to regional supermarket chains that operate multiple states and do billions of dollars in sales.

But overall the independent supermarket industry -- around 131 billion in annual sales and we employ around a million workers who we are so grateful to -- I want to just say -- for everything they've been doing during this pandemic; we call them our supermarket superheroes.

A little bit about, you know, kind of where our perspective -- obviously, you know, we are absolutely committed to ensuring that, you know, our -- to enjoy the safest food supply in the world and we're committed to promoting a food safety culture.

I tell people often that if consumers don't have

confidence in the food that we sell in our stores we won't be in business very long. So it's very, very important to us.

And I think we're also unique in our members are part of the communities in which they operate; they live there, their families live there, they eat there. And so food safety is obviously so important and essential to them.

I think if you really, really look today while we do certainly have challenges we do have a fairly effective system that works. Retailers every day are dealing with quite a few recalls that come through and we're addressing those.

We certainly as retail are kind of that -- either you call it the last line of defense or the first touch to the consumers. And so we are the ones that are charged with getting the product off the shelves; often we're able to actually stop that product in distribution centers before it even gets on a truck to the grocery stores when we know about it early enough.

And of course having more information and having uniformed information will certainly aid all of us and ultimately of course the goal is to reduce the amount of recalls that are coming through the system. If we can get, you know, better at what we're doing there.

I just think it's also very important that -- you know, we are certainly supportive of traceability and we're going to -- you know, we'll work with FDA and other stakeholders to ensure we've got a system that is smart, that's scalable, and it's affordable.

We want something that's going to work and it's going to work for all in the supply chain. And so we want to make sure that we really look at a full scope and scale of supply chain.

And finally let me just say thank you to FDA; we obviously are still in the middle of this pandemic. We're in the middle of the holiday season so our stores are very busy. But the agency has been -- really done an amazing job from day when we had a lot of strain on our food supply system. And you know, agencies like FDA really are some of the unsung heroes in this.

And so just wanted to say on behalf of our members in the industry thank you for what you have done and for what you've continued to do so that we have a safe and constant supply of food to be able to serve our communities with. Look forward to the questions.

DR. BUCKNER: Great. On behalf of FDA thank you

for that. And finally, we'll go to Lisa Weddig.

MS. WEDDIG: All right. Thank you, Rebecca and thank you for inviting N.F.I. to be part of this panel.

This proposed rule will impact pretty much 100 percent of N.F.I.'s membership so this is a very important rule for us and we certainly want to work with the agency to make sure that it provides the information that is needed to do rapid tracebacks in case of outbreaks.

So N.F.I. is the nation's largest commercial seafood trade association. 2020 marks our seventy-fifth year as an organization and today we represent seafood harvesters, vessel owners, processors, importers, distributors, retailers, and restaurants that help feed families in the United States and around the world. And our members support and promote sound science-based public policy.

So traceability obviously has been a part of our industry for many, many years and the various traceability programs that we have been involved with are key to certain -- to actually different purposes; some to promote -- to improve sustainability of stocks; to trace where products where harvested; and even for food safety purposes. So each

traceability system really serves unique purposes.

So the industry's experience with traceability goes back many years. You know, we have our traceability requirements for mollusks and shellfish that are outlined in the National Shellfish Sanitation Program and FDA regulations; through NOAA Fisheries trade monitoring programs such as the Antarctic Marine Living Resource Program, which traces the harvest of Chilean sea bass. We have the Tuna Tracking and Verification Program and the Highly-Migratory Species Trade Program. So these are all specific regulatory traceability programs for certain species.

And then recently we have NOAA's Seafood Import Monitoring Program -- or refer to it as SIMP -- which requires specific traceability information from harvest to point of import for 13 specific species or groups of species.

So traceability is an integral part of third-party voluntary programs as well, such as the Global Aquaculture Alliance best practices -- best aquaculture practices, sorry -- and Marine Stewardship Council and both of these are traceability's important to ensure proper chain of custody of certified products.

Now with all these various programs and regulations it's very challenging to comply with all of these programs because each require slightly different pieces of information. So that is one of the challenges that the seafood industry will face with this new regulation.

So as an industry association we've assisted our members by working with GS1 to develop guidelines for implementing GS1 traceability standards for the seafood supply chain. And then just last year or actually the beginning of 2020 we completed a pilot to assess the use of blockchain to facilitate traceability and document the chain of custody requirement system.

DR. BUCKNER: Sandy and Lisa -- Sandy got it -- can you turn your camera back on? I don't know what happened to them. Perfect. Thank you. Yeah.

MS. ESKIN: Okay.

DR. BUCKNER: We lost everybody -- for a second. Thank you.

MR. KAWCZYNSKI: But good news is look at Greg; he's not zoomed in anymore.

DR. BUCKNER: I know. I thought maybe Greg did

it. I was like "Greg figured out how to fix his camera and it had to turn all of us off" -- Lisa, were you done or did I interrupt you?

MS. WEDDIG: Oh no, no; I'm done.

DR. BUCKNER: Okay. All right. Thank you very much. All right.

Thank you all very much for your statements. There was a lot in there; I think you covered some of the things that we may cover in some of these upcoming questions that I'm going to ask you but I'm going to ask them anyway. But yeah; thank you.

We definitely know. We definitely hear you on that it needs to work for everyone; there's a lot in this rulemaking. Thank you, Sandy, for not saying that it was our composing that was inartful.

MS. ESKIN: Sorry.

DR. BUCKNER: Yeah. So we know there's a lot in there. We know there's a lot to discuss; that's why we look forward to opportunities like these four stakeholder engagements to hear from you all to get a sense of how we can improve things as we move towards the final rule.

So with that I'm going to start with some of the follow-up questions. First questions are around food safety. We heard a little bit about this in what you've just said but how can traceability improve food safety?

Obviously there's the whole outbreak thing -- following up on outbreak factor but there may be some efficiencies around recalls and things like that. So would love for you all to speak to that idea.

MR. FERRERA: Well I'm happy to jump in on this one. So yeah; obviously our goal is to stop, you know, product that's involved in a recall honestly before it gets to the store shelves. So the quicker that you have a traceback process that certainly aids all of us in the food supply chain.

I think it's also important to customers; customers are obviously very focused on, you know, knowing where their food comes from, transparency. And if we can communicate the most effectively to consumers and give them that confidence that's very important.

I think the important word, Rebecca, that you used is recalls because we have a very established process for recalls; it's one the industry knows, it's one our retailers are

familiar with all the way down to the store level that, you know, if a recall comes through there's a process. The manager on duty or the department manager knows what to do with the product; they know whether to destroy it or to send it back to the distribution network or whatever the process is.

And there's also protections in place in terms of the costs around that. One of the challenges certainly that, you know, everyone here is very aware of with dealing with the 2018 romaine issue -- and that -- with being a withdrawal -- that caused a lot of problems for our members; particularly our smaller business members and we kind of -- we moved out of that recall process.

So I think that's certainly important, you know, that we work within kind of that structure that we're familiar with. And again, you know, the more we can do in terms of uniformity, in terms of sharing data -- doing so in a way that's scalable and affordable and includes everyone in the supply chain I think will only help make us, you know, a safer food system and give customers ultimately more confidence.

DR. BUCKNER: -- I think De Ann --

MS. ESKIN: Go ahead please.

DR. DAVIS: So I was just going to build on Greg's comments -- particularly regarding romaine and broad advisories; those really do net into a kind of a lose -- from a commodities standpoint a lose-lose situation. Right? The economics don't work for anyone and the incredible amount of food waste that goes on as well as credibility for the industry that's impacted is very important.

So having the strong traceability system obviously does enable recalls to be more efficient and more effective but more importantly what we'd like to make sure that a strong traceability system achieves is identifying the offending product quickly so that it can be removed.

And so that's why I really want to emphasize that the most important part of a strong food safety program is going to be not only producing the safe food but also making sure that you're asking so much that it's a distraction away from the fundamentals that -- particularly for my members, our farmers -- don't get distracted from what they absolutely need to do every single day and are bringing forward that information that's critical for that rapid identification.

MS. ESKIN: I was going to actually tie it

together and I know that's done in the blueprint and it's been mentioned before but it bears repeating.

So the quicker you identify the food vehicle that's causing illness, the fewer illnesses, whatever -- that's critical obviously. And then, you know, again that the traceability allows you to do that.

But another piece of it in the whole sort of big puzzle of food safety is then looking at root cause analysis. Right? So you know what the product is but how did it get contaminated; why did it get contaminated? And that information is what's fed back into the prevention-based system and hopefully prevents a similar problem from happening again and often again and again.

So again in a broader perspective talking about food safety writ large; it is preventive. I said earlier it's not prevention but it is; it's a degree that it then effectuates root cause, which then feeds into the preventive loop so to speak.

DR. DAVIS: Yeah, I would completely agree with that comment. Thank you, Sandy.

MS. ESKIN: Sure.

MS. WEDDIG: Yeah; I do too. Actually I was going to comment that, you know, traceability does help with identifying the root cause of an -- outbreak. And you know, having a comprehensive rule like this does facilitate traceability and the fact that everyone in the supply chain then would have essentially comparable traceability systems within their operations.

So that definitely would help with the rapid traceback -- there was an outbreak.

DR. BUCKNER: Yeah; thank you, everybody. No; we agree. We think obviously the first -- the reason we have this rule is to effectuate rapid tracing and, you know, getting -- being able to respond to outbreaks quickly. But certainly also agree that the ability to -- because we can do that faster maybe be on the scene faster for where there was a problem and really be able to engage in better root cause analysis because we were just there faster in terms of what happened.

And finally -- I think Greg may have mentioned it -- the consumer confidence; avoiding the overly-broad recalls -- if we can do that with this, which is a very important aspect of this so -- and I think all of you spoke to all of those things.

So thank you for that.

Moving on to a piece of that; why is traceability important specifically from a consumer perspective? In other words from -- we're all very baked in food safety and outbreaks and everything but from a consumer's perspective why is traceability important?

MS. ESKIN: I think the other panelists have touched on them in very sort of specific terms. Right? Start with the broad type of withdrawal or recall that I think is really problematic to everyone and I think this avoids that and I think that it -- as I think Greg mentioned too -- traceability as a principle is important for every industry but certainly for the food industry.

Food is an essential thing that we all need; we also enjoy it. It has so many components. So if we have a better sense of being able to identify quickly a particular food product that's causing a problem I think that does help consumer confidence.

So you know, again I think -- the way that I'm thinking of it in terms not only obviously of outbreaks but we also talked about recalls or whatever process is used here. I

think it is -- even though I couldn't tell you off the top of my head when I'm sure I see a lot -- you know, what the traceability looks like I do know that it translates and will translate into a message that enables consumers to act if they have to.

MR. FERRERA: Sandy, I'd build upon what you said earlier about prevention and then this ultimately leads to prevention.

My worry is that we have so many recalls and -- you know, goes in spurts it seems like. But the consumers can become numb to it and then when there is a recall that's really important maybe they miss something.

And so to the extent that traceability can make us better at finding the root cause and preventing contamination or even mislabeling -- whatever it is -- I think ultimately that would be -- it's good for consumers so that --

MS. ESKIN: Yeah.

MR. FERRERA: -- you know, they know that when there is a recall -- "hey; we'd really do need to pay attention" because that's one of the things I think -- you know, I do worry about is that is -- as a consumer do you become numb if you just

see them over and over and over again and maybe --

MS. ESKIN: Sure.

MR. FERRERA: -- don't pay as close of attention as you should.

MS. ESKIN: Right; I think that's a very fair point and I know there are people in FDA and other agencies trying to make recall communications better -- more targeted.

But to your point too. You know, again I think people get confused if you have a recall where it gets called a rolling recall. Right? And it expands and it contracts and it's unclear what they actually should be doing. It is obviously a challenge.

So I think in conjunction with perhaps more-targeted recall information and comprehensive traceability -- as you noted -- we're going to have less situations where it's like "it's romaine; it's this; it's from where? It's from everywhere. No, it's not."

I understand the goal here and I don't want to undermine that. You don't want people to get sick. But if there's a way to really hone in on the product it's better for everybody.

MS. WEDDIG: Yeah and I think being able to rapidly trace back food to find the source of the problem will help with that -- that you can pinpoint products versus having a generic warning or a recall or these rolling recalls, which certainly don't help the consumers or the industry.

MS. ESKIN: Right.

DR. BUCKNER: Yep; we agree and are very hopeful that this rule when it's finalized will really help address these broad recalls that we know no one likes.

All right. Moving on to some more-specific questions about actually implementing tracing. I would ask you all what steps are you aware of that have already been taken by industry to implement tracing systems and how would the rule further enhance what folks are already doing out there?

DR. DAVIS: So we can start --

MS. ESKIN: Go ahead, De Ann.

DR. DAVIS: I was just going to start with the leafy green industry. I mean I think there's been a lot of examples about what they've done to enhance traceability but they started this process back in 2007 and they still had a lot to learn.

You know? So I just want to emphasize that.

Right? So we have some tried-and-true system within the fresh produce industry and it still has shortcomings and it's been in existence for, you know, over a decade. Right?

And then fresh produce in and of itself is incredibly complex and I think you heard Natalie rattle off stats that I often just go "I'm just not going to hear that because it's just so hard." But you don't understand how complex it is until you sit on the other side.

And every farming operation is different. Every business relationships and how they get product out of the ground and to the consumer varies. There's agents, there's brokers, there's all sorts of other intermediaries that aren't in other types of food types that are also covered by this rule.

So I think it's really important -- and I'll go back to my comment earlier -- that we think about what we really do know about commodity traceability based on the pilots that have been available because they're very limited in what we really don't know and how important it is to make sure that as we develop this rule and it comes to finalization that we really are focused on the fundamental needs and not necessarily

"they're nice to have."

And I'll go back again just to my example about cooling; because we have such complexity within the system I just want to make sure that we end up at the end of the day with a very successful system.

So we do know this; P.T.I. for example's been around for a decade -- still trying to get it implemented.

Right?

So I just think it's a long journey and we need to be very, very focused on the fundamentals to get it right.

MS. WEDDIG: Yeah, I think that --

MR. FERRERA: I would add the -- sorry; I would just add for what we, you know, do today in terms of, you know, the bioterrorism law. I mean we have to be able to trace, you know, one-up/one-back.

And it works. You know, I know it's maybe not as specific sometimes as folks would like but, you know, in the grand scheme of things pretty quickly we can be able to identify kind of where product came from -- particularly if we have a P.O. number at the distribution level.

What is also I think good about the one-up/one-

back is from a retailer's perspective we're able to look to our distributors -- who are often more -- have much more-sophisticated systems. They're getting a lot more information from, you know, where the product's coming from on the P.O., the bill of lading, and have the sophisticated warehouse distribution systems that know wherein the product came in, what slot it went to, when it moved from a reserve slot to a pick slot, what stores were selected during that time period, and we know where it went.

And so you know, we do have some systems that are kind of in place today and there's the things we should -- you should really look at as we continue through this process.

MS. WEDDIG: Yeah and I think, you know, the bioterrorism traceability recordkeeping requirements are in place and, you know, we've been talking with our members about this rule and, you know, the comment that we get is "well I can trace everything. You know? I know where I sent it and where I received it and I can get that information in, you know, two to four hours."

But it's putting the pieces together along the complex supply chain that I think is the challenge.

The one thing that we find with all the various traceability systems that the seafood industry deals with is each of these programs are put in place for different purposes. So having common KDEs and CTEs -- that aren't in place right now; I mean every system has different data requirements or data capturing requirements.

So that is a challenge that we've been working to try to come up with some common language with these different rules for decades now like De Ann said.

DR. BUCKNER: Yeah; I agree. I feel like I've been involved with traceability for a while now at FDA so it's certainly something FDA's been thinking about for a while -- I was in some public meetings back in 2006 or 2007 on this.

So it is complicated and it's -- you know, and when you do sort of start thinking about that next step down below one-up/one-back -- which is what we have done with this rulemaking in terms of granularity -- it is very complex.

And we know that and we definitely, you know, want to do what we can to put a system in place that works for everybody with our -- like overarching mantra now is "don't break the chain." Right? It's maintaining that chain of

information through there.

And so we're definitely cognizant of that and also as somebody noted there are other tracing systems out there in place for different purposes that use their own lexicon and we are aware of that too -- N.S.S.P., et cetera -- that we're looking at to see how we can harmonize what we're trying to achieve with what they already achieve.

And so definitely looking at all of that as we go forward and welcome your thoughts on alignments between those systems because none of us want to reinvent the wheel. So if there's things that work we definitely want to take advantage of those.

I think you all spoke to some of what my next question was going to be about successes and challenges; I would just ask you specifically are you all aware of any sort of innovative ideas out there that have been put in place with regard to tracing that's really sort of been successful?

At our last panel we heard about some -- I think it was vegetable folks in the Midwest who were kind of doing some interesting things with canned vegetables but anyway. Just wondering if you all heard of any innovative solutions out

there.

Okay. No canned vegetable examples here; that's fine.

MS. WEDDIG: All right. I know in the seafood industry there are quite a few partnerships with, you know, N.D.O.s who develops and demonstrates different traceability models but they're all kind of independent; it's not -- you know, the seafood industry is quite diverse as far as the products that are classified as seafood.

So whether it's farmed or wild captured; you know, artisanal fisheries or fishing vessels that go out to sea for weeks at a time. I mean it's -- each aspect of the industry is unique and presents challenges for having a one-size-fits-all-type of traceability system.

MS. ESKIN: Yeah, I agree with Lisa. And don't take my silence, Rebecca, as the fact that our members don't look for innovative solutions -- they do -- for them.

DR. BUCKNER: They do.

MS. ESKIN: But they're very -- yeah -- they're very singular efforts and I wouldn't say there's something that's broadly done today that would really answer your

questions.

I do think that the challenge -- you know, I just want to go back a little bit -- is technologies are great but they often are not always in -- they're always nearer to the business model at hand. So some of these traceability -- some of the KDEs that you're asking for at -- may be kept in one technology solution whereas the shipping and selling information may be kept in another technology solution.

So creating the bridge is going to be an investment and so those are the types of things I want to make sure that we pulled forward and think through because if we're going to truly create a technology-agnostic solution here it has to understand that.

And when you've got, you know, 2,100 different operations, you know, out there -- that's just people growing the food; forget all the other people who handle it -- you could see how that quickly gets complex.

DR. BUCKNER: Absolutely. No; and we know that, you know, the technology is going to have to adapt to kind of how this will work. Right? We need technology providers to come up with solutions that encompass all this information and I know

folks are definitely thinking about that -- certainly under the New Era effort. That is one of the groups is looking at technology solutions for -- that are as diverse as the food supply is because that's a very diverse system.

And so that will be something we're all going to have to work on together and innovate on together I think.

And that goes to one of -- sort of follow-up questions about people partnering and I would just ask are you all aware of groups getting together to partner? I think, Lisa, you'd mentioned the seafood industry; certainly we know P.T.I. with the produce industry coming together to partner on traceability.

Are there other examples that you're aware of groups getting together to partner to try to -- to work on traceability sort of in their areas?

MR. FERRERA: Well you know, I'll say that one of the more-recent kind of collective efforts that I'm very proud of was the I guess the -- you know, the romaine taskforce, which, you know, had government involved; it had leafy greens involved; retail and restaurants and everyone else in terms of kind of that -- the supply chain.

Now you did some really good work that was done there; a lot of good sharing that was done. And so you know, I think that there are opportunities to continue to bring industry and organizations and the full supply chain together to have those important conversations and to try to come up with, you know, ideas and solutions that can be workable.

DR. DAVIS: Yeah and Western Growers sponsors an innovation center and that certainly provides -- brings a home for places to -- for innovation developers, start-ups, other solution providers to meet up with growers and farmers.

So there are pathways forward; it's just -- and there's a lot of innovation conversation going on. And there's really some really good examples of -- to Greg's point -- of also existing partnerships that have happened.

MS. WEDDIG: Yeah and one thing I really -- you know, that the industry as a whole kind of needs to consider the facts that, you know, the end-user -- you know, Greg's members -- are dealing with all the different commodity groups.

So if we have, you know, partnerships such as deal with seafood and then leafy greens and other commodities at the end of the day it's all funneling into the same system at

the end of the line.

So you know, rather than having commodity discussions we almost need to have a whole food supply systems discussion if we're going to get the traceability to -- you know, systems to work together.

DR. BUCKNER: And I do think we believe that is the value of -- what we believe is at the core of our rule is the common data elements. So sort of the data elements will be the same across all the commodities and hopefully that is the common ground on which we will build the system, you know, that will work. I think that's our vision of this.

And so yeah; we're very hopeful that that is what will lay the groundwork for people to come together with innovative ideas since we have established what, you know, we feel is -- or at least proposed what we feel is the common framework of data elements realizing -- as I said before -- we do want to align where we can and with things that are already out there.

And so we're certainly looking to that but yeah; I would just ask -- I'm watching the time here -- are there other benefits you think of supply chain partners capturing

similar data? I mean in our minds that's what's going to make all this work but --

DR. DAVIS: So let me --

MS. WEDDIG: -- wondering if -- I definitely that having the standardized KDEs -- it defines what's achievable to have for traceability and it does allow, you know, the suppliers to say, you know "these are the KDEs that we are required to have. You know? You know? There's no need to expand upon that list to provide additional information." That's what gets challenging --

DR. DAVIS: Yeah; I think --

MS. WEDDIG: -- when each end-user asks for different KDEs from the suppliers.

DR. DAVIS: And then Rebecca, I would just go back to, you know, Frank's statements this morning. I mean there's obvious other benefits as well in terms of supply chain management. Right? And understanding where your product is and where it is not. And as well as -- particularly when you're dealing with very short shelf-life products like my members produce. Right? That are only really in a store for a few days and then in a consumer's home for a few days. Right? So we might

spend a majority of their shelf-life actually just getting to the store.

So those advantages I think will be realized as -
- because as businesses do they'll take it down to just that information and data.

DR. BUCKNER: And we agree and I think -- you know, I was going to ask but, you know, there are certainly costs associated with this rulemaking -- as you all have noted. There's going to be tech costs, et cetera.

Are you aware of other sort of returns on investment of implementing tracing systems that -- I mean you just mentioned inventory control, et cetera; supply chain management. Are you aware of sort of other non-public-health advantages of traceability systems?

Everybody's answering at once. All right.

MR. FERRERA: Yeah; Rebecca, I'm happy to jump in here.

So you know, I think are there benefits for having more information and knowing where product is in the supply chain? Yes.

I think the one thing that's -- you know, we have

to better understand is what are the costs of those benefits?
And not just costs in terms of, you know, man-hour costs but in terms of process as well.

And so I just think that's important to really -- you know, as we continue to talk to our members and digest the draft that we'll be, you know, obviously filing formal comments on is really looking at the current operations as they exist today and what is feasible and where do we expect to have areas that there could be challenges while also looking at where are there benefits that may be beyond than what we are seeing today?

So we're talking to our members now and we're kind of looking at that collectively but if you think about -- like today right now and dealing with the pandemic and, you know, what our members just went through in the last two weeks and the amount of volume flowing through those stores, you know, adding multiple different steps that potentially requires, you know, man-hours and labor is something that, you know, could presented challenges.

So we want to better understand for our members and get feedback and then be able to share that with you guys and work collaboratively, you know, to find a way forward.

DR. BUCKNER: Great. We welcome that. All right. I'm looking at the time and our hour has flown by -- totally flown by.

MS. ESKIN: You were right.

DR. DAVIS: I told you. So I would just ask each of you are there any sort of final thoughts you have; wrap-up statements? Don't feel compelled but offering you the opportunity.

MS. WEDDIG: So I'll jump in. I do want to comment about the global nature of the seafood chain. You know, 85 percent or more of what we consume in the United States is globally sourced.

MS. ESKIN: Wow.

MS. WEDDIG: And you think about our suppliers overseas and, you know, they're not just selling products to the United States. So we have to think how this regulation will fit in with their operations as well where they're trying to meet requirements, you know, for the U.S., the E.U., China, wherever -- I mean Canada.

So we need to have a system that will work with them and a way for us to explain the new regulation to them. I

mean what -- some of our members have commented about, you know, how much effort it took to get their suppliers to comply with the Seafood Import Monitoring Program requirements. So now this'll be something on top of that.

So we have to really be aware of the impact of this on our trade partners as well.

DR. DAVIS: Yes and I think where I want to leave -- the final thought I want to leave everyone with is that, you know, the produce industry -- at least our members -- are extremely committed to improving food safety overall as well as to improving traceability of their products.

So we want to look at this broadly; not necessarily just those commodities that are represented within the food traceability list. And so in order to do that I will go back again to making sure that we have selected the right CTEs and the right KDEs for broad adoption and consistency across the supply chain.

And so that's really to us the most important part of this; some of the information that is asked for can be readily gotten upon inquiry but not necessarily always point to shipment information. So I just want to challenge us to speak

that route as we move forward.

MR. FERRERA: And I would just add that, you know, one, thank you for the opportunity; FDA knows us better than anyone. This is a very complex issue and, you know, the supply chain is very diverse -- from very sophisticated players to those who are not.

And so it's going to, you know, take a lot of work and a lot of collaboration and really understanding so that, you know, whatever is ultimately finalized is something that is implementable and it is workable and is affordable. That's be very important.

MS. ESKIN: And I know at the beginning of my remarks I was complaining about how long it took for FDA to put out this notice but perhaps the silver lining is it -- over the 10 years or almost 10 years since the law was enacted I think there have been developments in traceability across the food supply in certain commodities.

And I think the point that you made, Rebecca, multiple times is, you know, you don't want to build a whole new system; let's try to leverage what's there. And that's important.

And certainly I don't want to minimize the costs perhaps to some entities more than others in putting this system up and running but again a public health impact of outbreaks and just sporadic illnesses; that's -- we're trying to -- I'm now going to channel Frank Yiannas. Right? We're trying to bend that curve -- that arc of foodborne illness and this is a really important piece of it.

So I just want to -- one other thing real quickly. De Ann's made a really good point and I think that FDA is trying to put out a framework that works for the commodities that Section 204 tells them to identify but I think it's important and important at this stage to understand and address the broader issues that may impact commodities outside of what's on the food traceability list because you do want a system that can grow.

DR. BUCKNER: Absolutely. No; we agree with that and we think -- you know, we hope and wanted this to be part of the dialogue -- that the KDEs and the data elements that we have identified -- the tracking events -- are, you know, almost commodity agnostic so -- and would work for a broader array of commodities.

And so that is certainly the goal very much outlined in the New Era blueprint, et cetera. So yeah; no, we're very hopeful and that is the dialogue we want to have going forward is how do we put in the system that works well for everyone and is flexible but as we said, you know, doesn't break the chain.

So anyway. Finally, I would like thank all of our panelists for a great discussion. This is the third panel; they have all been amazing. Really great information out of all of them.

And I know hearing your experiences and perspectives about traceability and how this can be implemented will be really important as we move forward in this dialogue and our overall efforts around traceability.

Again we just really appreciate your -- today. I know you're all busy and so we thank you very much for taking the time to do this.

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

MS. BARRETT: Great. Thank you so much, Rebecca, and all your panelists; what a wonderful session. That was just

great to hear everybody's thoughts and perspectives and the dialogue. It felt good to see all of you and again having these conversations is so important.

So with that we are going up for one more break - - our last break of the day. So we will take that break and we'll reconvene at 5:50. So we have about a 16-minute break here and then we'll gather back for our public comment session. Thank you.

MR. KAWCZYNSKI: All right. And with that I'm going to take the -- okay.

Looks like we are coming back. Let's just double check; Kari, are you there?

MS. BARRETT: I am here.

MR. KAWCZYNSKI: All right. So Kari, let's see; it looks like we have everything all set up. Whenever you are ready to kick us off.

MS. BARRETT: All right. Well let's just go ahead and jump in; we are at time.

So as mentioned we are now at the point of our agenda where we're going to start our public comment session and this is an opportunity for us to hear from stakeholders who have

signed up in advance to offer public comment and to share their perspectives on the proposed rule.

And so I do want to welcome them; I think we have about 11 folks signed up for this afternoon to give comments. And I've heard you, Mike; it sounds like everybody is ready so that's fantastic.

What I will do is I will call each individual by name and then they have three minutes to present their remarks. Please as always be respectful of the time; for all those who are giving comment I know that Mike has kindly set up a timer for you and we just ask that if you could please pay attention to that. If you should go to a point where it turns red if you could just quickly conclude we'd appreciate that.

And with that I think we're ready to work through the roster of names. So we'll begin and I think we have Kelly Nuckolls up first with the National Sustainable Agricultural [sic] Coalition. So Kelly, are you on?

MS. NUCKOLLS: Yes.

MS. BARRETT: All right. You may begin.

MS. NUCKOLLS: Thank you. On behalf of the National Sustainable Agriculture Coalition I would thank FDA for

the opportunity to provide feedback on the proposed rule to create additional traceability recordkeeping requirements.

NSAC is an alliance of over 100 grassroots organizations nationwide that advocate for federal policy reform to advance sustainable agriculture and food systems.

Given the potential devastating impact of food safety regulations on sustainable agriculture and small- and mid-sized farms and food processors NSAC engaged heavily in a legislative process around the Food Safety Modernization Act; this led to the inclusion of a number of important provisions that formed the basis for the flexible scale and supply chain-appropriate language in FSMA Section 204.

NSAC members across the country also provide food safety trainings and technical assistance for farmers and food businesses including efforts to ensure product traceability is fully implemented throughout the supply chain.

We appreciate FDA's efforts to ensure flexibility and the scale and risk-appropriate approach in this proposed rule. We would like to thank FDA for including several important exemptions and partial exemptions to the proposed rulemaking -- both those required and not required by FSMA.

While we plan to submit more-detailed information on what we support and where sustainable small farms and food businesses have concerns we do want to highlight three recommendations today.

First, the proposed rule should not require businesses to keep traceability records and create a lot code for any exempt product; for example for farmed products that are exempt because of their products label the proposed rule as written might still require first receivers of the food to keep very detailed farm records of that product and create a lot code with farm's specific information regardless of any exemptions.

As a result businesses are likely to inadvertently require exempt farms to keep and send these records. This is not in line with the exemptions in FSMA Section 204 and is confusing for small farms that are exempt from the proposed rule based on any of the required or additional exemptions FDA included.

We request that FDA at the very least fully exempt products that are required to be exempt by law and maintain exemptions across the supply chain to ensure exempt businesses are truly exempt.

Second, NSAC members are also concerned about the requirements to provide FDA with an electronic spreadsheet of all required records if requested within 24 hours; while NSAC appreciates that required records can be in paper format otherwise we are concerned about the impact the spreadsheet requirement might have on small and rural businesses that do not have technology in place to quickly provide an electronic spreadsheet within 24 hours. We look forward to discussing alternate options or time periods with FDA.

And finally, our third recommendation echoes others who have asked for an extension to the comment period so farmers and small businesses can take the time they need to understand the impact of the proposed rule on their businesses. We request FDA extend the comment period by at least 60 days.

Thank you for your time and we look forward to submitting more-detailed comments.

MS. BARRETT: All right. Thank you so much for your comments.

We'll now go to our second commenter; Shaun Kennedy, Food System Institute. Shaun? Shaun, if you're there are you on mute?

MR. KAWCZYNSKI: Yep; we unmuted you, Shaun. Are you there?

MR. S. KENNEDY: I am here now; it was only -- the mute took a little time to take off so sorry about that.

MS. BARRETT: No worries.

MR. S. KENNEDY: So Shaun Kennedy, University of Minnesota and the Food System Institute. I would also like to first echo the commendations for a job very well done in a difficult time for FDA on the produce rule on traceability. I think it goes a great step forward in helping us in both protecting our supply chains and our consumers.

There are just a few points that in working with our network of farmers in the upper Midwest that would benefit from some reconsideration.

One of them is to define relationships a bit differently in that many small growers and producers don't keep detailed records but they have lineage as far as their relationship to their customer.

So as long as they can provide that lineage we don't need lot code information if they only sell or purvey their product to a certain location or a certain vendor.

So instead of the KDEs on a lot code basis provide the opportunity for KDEs on a relationship basis so we can simplify the initial traceback information to help stem any potential foodborne illness outbreak and also reduce the damage to the supply chain from any unusually large recall because we don't have enough information.

And in line with the prior commenter while it may seem obvious to most of us that an Excel spreadsheet is easy it's not that easy if you don't actually ever use your computer so a paper record should be acceptable as long as the relationships are defined.

I also agree that we should extend the comment period to allow specifically for small producers and processors to give their input into how they can comply with this in the best means forward so that we can reduce the public health impact of potential small-scale produce outbreaks.

Thank you very much and good luck, FDA.

MS. BARRETT: Great. Thank you so much for your comments. Thank you for joining us.

We'll go to our next commenter; Wyllys Terry, Shellfish Solutions.

MR. TERRY: Great. Thanks for having me. Can you guys hear me all right?

MS. BARRETT: Yes, we can; thank you.

MR. TERRY: All right. Hey; we're a technology company based in the northeast of the U.S. We work with about 100 different shellfish growers and dealers all over the -- you know, pretty much in every coast.

Most of them are pretty small and really as far as I can tell have been focused on this rule. So I'm asking a little bit based on what I know about their business and what I know about our business because I actually this is sort of an exciting time from a technology perspective but a scary time from a small provider perspective, a small grower perspective.

So my questions are really threefold, one of which is how does this align with the National Shellfish Sanitation Program model ordinances, which most states have adopted, and have you done any analysis about how these proposed rules align with or conflict with the model ordinances?

Number two; in our industry a product very often goes through five-plus steps from harvest to consumption and most folks live by a rule of one-up/one-down -- "I know who I

sold it to and I know where I bought it from but I don't see the whole chain."

And this rule sort of implies a full transparency that could be really threatening to many of these small dealers who are in the middle. And so I'm wondering what's your envisioning in terms of visibility? And only regulators can have the visibility or should everybody have the visibility?

And then the third is this could potentially be a really big cost for the over-2,600 dealers on the Interstate Shellfish Shippers list and I'm wondering if there's any federal or state programs intended or, you know, planned to support the -- course of adoption -- whether it's training or buying new hardware, et cetera.

And then, you know, as some people have spoken many of these folks have very limited computers; really often don't even have a printer; have some mobile phones that are out of date, et cetera. So I would imagine some of these folks are going to have some real technology challenges overcoming this.

So those are my questions. Thank you very much for doing this.

MS. BARRETT: Great. Thank you so much for

joining us and I know the hope is that you'll submit those questions to the docket and hopefully share your thinking on what those answers should be and ideas that you have. So thank you again for comments today.

We'll go to our next commenter; Angela Fernandez with GS1. You may start.

MS. FERNANDEZ: Good afternoon, Kari. Thank you. Can you hear me?

MS. BARRETT: I can. Thank you.

MS. FERNANDEZ: All right. I would like to thank the FDA for providing GS1 US the opportunity to speak today.

GS1 US is part of one of the largest identification and standards organizations in the world; we enable the digital and physical flow of foods and other items to consumers, earning GS1 the moniker "the global language of business."

If this is your first time to hear about our organization be assured that you know and are familiar with GS1 standards. The UPC barcode -- our first standard -- is scanned more than six billion times daily. GS1 standards are consistent with White House OMB Circular A-119, which encourages U.S.

government agencies like FDA to voluntary consensus-based standards and rulemakings like the one we're discussing today.

So in essence FDA is capable of leveraging the use of GS1 standards to meet its statutory requirements under FSMA Section 204.

I'm here to share that enabling end-to-end food traceability and establishing common requirements -- a common language if you will -- for sharing supply chain information is possible today by leveraging GS1 standards and are being deployed given the programs industry has defined.

Like English, creating common language for rapid and effective food traceability and recall requires the use of precise and consistent terminology as well as the use of proper data structure. That terminology -- the structure, that common language -- is all entailed in GS1 standards.

Our organization has invested 47 years developing and refining our global industry standards not only with industry but also the FDA. One example's FDA's use of the UPC when issuing recalls; if the FDA is already leveraging the standard expedite food recalls why not extend the use of the standard for the proposed rule?

We would like to caution FDA that the agency's use of certain terms in its proposal -- such as "common language," "interoperability," "product I.D.," "data structure," and "traceability" -- appear not offer the same specificity that's employed by businesses using standards in the marketplace today.

For example there's no reference to the use of consistent global unique identifiers. Also, there's been very little emphasis on the required data structure, which is critical -- as stated earlier -- for defining or identifying those linkages; this could result in significant confusion both for businesses using GS1 standards and those who will be regulated by the FDA in the final rule.

GS1 US kindly requests that the FDA acknowledge the widespread use of GS1 standards in the marketplace today and recognize their use as a practical and acceptable compliance tool.

Please note we're not asking for GS1 to be the only standard used but to be recognized as an acceptable marketplace alternative consistent with the statute itself so that we don't have a different solution for industry versus

government compliance.

So in closing food traceability requires a common language and that language is GSI. As always we stand ready to support and work with the FDA. Thank you very much.

MS. BARRETT: Great. Thank you for your comments this afternoon.

I'll now go to our next commenter, which is Paige Smoyer from the National Confectioners Association.

MS. SMOYER: Good afternoon. My name is Paige Smoyer, manager of food safety and scientific affairs at the National Confectioners Association -- or N.C.A.

N.C.A. and our members are committed to a safe, secure, and transparent food system for all foods, including chocolate and confectionary products. We appreciate the work FDA has done to implement FSMA, including the release of this proposed rule. N.C.A. supports the agency's overall efforts to improve public health by working towards a more-traceable food system.

The three major themes we would like to highlight today are time, flexibility, and greater transparency.

First we believe that the complexity of this rule

and of the entire food supply chain as well as the substantive amount of data collection and recordkeeping that will be required of industry demands more time for ensuring proper implementation past the typical two-year compliance period.

This is necessary for the agency to provide additional guidance and for industry to implement such guidance. It is also necessary considering the wide range of stakeholders throughout the supply chain that will be covered by the rule, including foreign entities. We also foresee companies needing more than one year to address any potential new foods added to the food traceability list.

Second, although we're still assessing the potential impact of the proposed requirement to provide FDA with an electronic sortable spreadsheet within 24 hours of request we do have initial concerns with this proposal.

We anticipate this could necessitate maintaining records in electronic form, which would affect both large and small companies. We are also concerned that because requirements are proposed for every level of the supply chain and because of the amount and level of detail of the information that would need to be maintained compliance with the rule would compel

companies to maintain records for all foods they handle -- not just those on the traceability list -- rather than have separate systems for different foods.

This would add additional complexity, time, costs, and effort for compliance and far exceeds the agency's best estimates in the regulator impact analysis.

Last, the N.C.A. believes in the need for greater transparency with respect to the food traceability list; although FDA outlined a process for making changes to the list it has not outlined a process for stakeholders to request changes to the list or to comment on the tentative list. We urge the FDA to share the frequency with which it intends to update the list as well as criteria it will consider.

Finally, there are many outstanding questions with regards to what foods fall under certain categories on the list. Additional details regarding the current foods on the list and what it means for food on the list to be an ingredient in another food would be helpful.

The proposed rule and its requirements are quite detailed and complex; as such N.C.A. and the broader food and beverage industry urge the agency to extend the current comment

deadline. We have already submitted such a request with supporting rationale to the agency through the docket. We look forward to continuing to participate and engage with FDA on its traceability initiative and the finalization of this proposed rule.

N.C.A. thanks you for this opportunity to present our views and will submit more-detailed written comments to the docket. Thank you.

MS. BARRETT: All right. Thank you so much.

We'll now go to our next commenter; Elie Cohen, Connecting Food.

MR. COHEN: Hello, Kari; hello, all. I'm honored to be here today to share my comments. My name is Elie Cohen; I represent Connecting Foods, a European leader in food transparency blockchain.

From our European perspective we applaud the FDA for taking these steps to better protect American public health by strengthening the food safety system.

2020's particular context has brought the food supply chain's challenges to the forefront and this situation has not been helped by the fact that food chains are not always

generalized and by the fact that data does not always exist in a standardized manner, creating a severe handicap when it comes to increasing foods' traceability.

We note that the four new mandate areas apply to prevention, inspection, response, and import. Taking the science-based approach to these mandates will help put into place preventative controls across food supply chain. We believe that new technology will be key in all four areas but beginning with prevention.

As travel restrictions are still in place in many areas remote auditing will play a key piece in the near future; other similar technologies are being developed, such as live audit -- which allows for real-time digital auditing of supply chain information.

We are all well aware of the large and frequent product recalls -- particularly when it comes to leafy greens -- and in the future data will be able to be leveraged to help ensure compliance; for example with the FDA's new mandatory standards for fresh produce.

Digital supply chain auditing technologies can also play an important role in the inspection and compliance

initiatives where the number of inspections will be increasing under F.S.M. Act there is still currently no way to ensure that what is seen during an inspection is actually consistent during the rest of the year.

This is where supply chain data can be used in combination with live audit to ensure compliance. Digitization of audits and certification documentation one side combined with centralizing of data will also help ensure food producers and manufacturers meet their new quality and recordkeeping standards.

The FDA is active in enhancing its ability to track and trace both domestic and imported food; many pilot projects have been carried out -- more will occur in the future. We believe it will be important for the FDA to partner with international firms -- such as Connecting Food -- in order to share and learn from global best practices for food safety.

Lastly, it has been challenging for importers to truly prove product origin; we believe that blockchain technology can force importer accountability while also helping the FDA review -- certification -- particularly for high-risk food and in an automated and efficient manner.

Ultimately new technology can be leveraged to communicate with consumers whether or not a particular batch of product is safe when the recall has occurred.

Thank you, FDA, for allowing Connecting Food to comment.

MS. BARRETT: Thank you for joining us this afternoon for your comments.

We'll now go to our next commenter; Patrick Smith for the Soil.

MR. SMITH: Good afternoon. I am a supply chain management information technology expert, having designed, developed, and managed systems for the natural food industry for 27 years. I am currently a USDA enumerator and soil health advocate.

The earth is in crisis on land, sea, and air -- and animal life, if not choking, is surrounded by poison. Most solutions are daunting, amorphous, and expensive.

These environmental issues heighten the possibilities of black swans and unpredictable foodborne calamities. The less prepared our health entities are the more likely these calamities will result in fixes, wipe out

advancements and healthy innovation.

Current consumer voices with a means of influencing producers and growers is nearly non-existent. As an investor -- I am overwhelmed by agriculture certifications, big ag, government influence, and a plethora of specialists with vicious know-how.

For the producers these same pernicious uncertainties plus our climate crisis add risking us.

We're here today because the valuable hand of the government is poised to give instructions for building information highways to protect the consumer from foodborne illness and manage food safety but can it also free the farmers and ranchers to be the heroes that we need now?

To do so all actors will need the same data maps and data structures and data definition that then will allow for building a means to connect all --

In terms of producer and consumer data today's proposed rules do not go far enough. Sensible standardizations do not give producers the support they need to be --

These three suggestions will make difference. For the producers bend the proposed KDEs, food windows that can

allow them to promote their work and their products. For example farm profiles, specialties, built -- built, practice histories, and field improvement plan.

For consumers add CTEs and KDEs from the purchasing data -- collaboration and group association options, and data security rules.

In addition to complete field-to-table tracking this suggestion will empower the consumers to work together, invest together, share data, communicate with producers, and show their support for the critical agricultural changes --

Finally, for the information technology -- the FDA needs to design, publish, and maintain data flow diagrams, relational schemas, and define data rules for all food safety KDEs --

In fulfillment of the New Era of Smarter Food Safety's broader goals, these suggestions provide a standardized means -- interoperability, harmony of data content, elegance in information -- sharing, and an infrastructure for us all to work together -- solve today and tomorrow's environmental and food safety --

MS. BARRETT: Thank you. Thank you for joining us

today and for your comments.

We'll now go to our next commenter, which is Beth Lowell from Oceana. Beth?

MR. KAWCZYNSKI: Let's give it a second; hers is taking a second to unmute.

MS. BARRETT: Okay.

MR. KAWCZYNSKI: Huh. Try this one more time. All right, Beth; are you there? Let's see. I don't know why but -- there we go. Now she's unmuted.

All right, Beth; are you there?

MS. LOWELL: Okay. Great. Hi; my name is Beth Lowell. I am the deputy vice president for U.S. campaigns at Oceana, an international ocean conservation organization. I appreciate the opportunity to provide comments on the proposed traceability rule.

Oceana supports full chain traceability to help ensure that products -- particularly seafood -- are safe, legally caught, and honestly labeled. Oceana will be providing additional written comments for this rule and strongly suggest that the FDA extend the comment period, as other have as well.

We have been working on seafood fraud since 2011;

specifically on species substitution. In our work we did a series of studies looking at seafood purchased at restaurants, small markets, and large supermarkets -- specifically we bought seafood, recorded how it was labeled, sent it to a lab for DNA analysis to determine the species, and considered a sample to be mislabeled if it did not follow the FDA seafood list rule. In our studies we found about a third of the seafood we sampled to be mislabeled.

We also conducted a global review of seafood fraud studies by governments, journalists, N.G.O.s, and others from around the world. In over 200 studies on average 1 in 5 samples were mislabeled.

Seafood mislabeling can disguise the species and true origins of products, which can have both conservation and health impacts. The seafood supply chain is complex and opaque in a way to help address both seafood fraud and ensure the seafood is legally sourced through full chain traceability, ensuring product integrity through the supply chain.

As you likely recall in 2014 an interagency government task force was established on combating illegal fishing and seafood fraud; the task force developed a series of

recommendations, including seafood traceability.

In 2016 NOAA issued a final rule establishing the Seafood Import Monitoring Program -- or SIMP -- which required documentation and traceability for some seafood imports considered a high risk of illegal, unreported, and unregulated fishing, and seafood fraud.

Traceability was only required to the first entry of U.S. commerce as NOAA did not have the authority to require traceability across the whole supply chain within the U.S.

Additionally, the Maritime SAFE Act -- which was passed as part of the National Defense Authorization Act in 2019 -- also created a working group on IUU fishing and seafood fraud to help align federal actions.

I mention these interagency efforts in SIMP to urge FDA to not develop these rules in a vacuum; SIMP requires key data elements and critical tracking events for seafood. The FDA should work with NOAA and harmonize the KDEs and CTEs across these regulatory requirements. It's important to not develop duplicative processes as it's the same products that are subject to these requirements.

The FDA traceability rule should also apply to

all seafood -- the catfish exclusion due to its being under USDA authority is another place with a silo'd agency approach doesn't work.

And finally, to be truly effective we believe that the recordkeeping requirements must be electronic.

Again Oceana welcomes this traceability rule and urges FDA to take a whole-of-government approach to ensure that all seafood sold in the U.S. is safe, legally caught, and honestly labeled. Thank you.

MS. BARRETT: Thank you very much. We appreciate your comments and joining us this afternoon.

Our next commenter is Bob Wolpert, Golden State Foods.

MR. WOLPERT: Golden State Foods?

MS. BARRETT: Yes; is that you, Bob?

MR. WOLPERT: Yes, I'm here now. Thank you.

Today I'd like to speak in support of the proposed rule. G.S.F. -- Golden State Foods -- is a 75-year-old private company in food processing and distribution primarily supporting the quick-serve restaurant industry.

About three years ago we invested in digital

transformation, which includes blockchain, I.O.T., and AI; and we partnered with IBM using the Food Trust platform.

In that process I became chair of the Food Trust Advisory Council so today I'd be speaking from the G.S.F. perspective and also the Food Trust ecosystem perspective that includes many others in the food retail and Q.S.R. space.

I'd like to point out one theme and two supporting points. I think my theme is that the time is now; there's a good opportunity for the intersection of public interest, business core process improvement, and affordable technology that will be well served by the FDA proposed rule.

Supporting point number one would be that sharing of cost in technology is much more possible and prevalent today in cloud and blockchain solutions and with cost down and technologies up -- including mobile access and blockchain ecosystems -- the FDA does not need to be afraid of creating a costly, undue burden.

These FDA standards along with alignment with leading standards organizations like GS1 will help with interoperability -- both blockchain and non-blockchain. So it's all in a good direction.

Point number two is return on investment; absent regulation investing in traceability is like investing in an insurance policy to cover a potential disaster. It's very hard to estimate an R.O.I. for traceability alone; other uses of the data can generate R.O.I.

Quality and freshness data and I.O.T. temperature data can lead to higher quality and less waste; sustainability data can lead to brand trust and customer loyalty; supply chains can be more efficient with end-to-end visibility; and we can meet consumers' desire to know details about the food they purchase.

All of this will come from a digital record of the physical movement of food items and ingredients and creating this digital record is hard work and slow because it crosses many company boundaries.

Rigorous processes to create and capture digital data and generate all the benefits and R.O.I. I've mentioned will come from a series of dominos falling; the FDA can give a strong push to one of those first dominos. This will help accelerate digital transformation in the food industry.

I'd like to just finalize -- conclude with an

observation that this does matter beyond traceability. It matters because R.O.I. will foster adoption; and secondly, good traceability data will more likely be accurate and maintained as a core business process if it has multiple real-time uses beyond traceability.

So for these reasons I reiterate that now is the time for enacted this proposed rule. Thank you.

MS. BARRETT: Great. Thank you so much for joining us and thank you for your comments.

We'll now go to our next commenter, which is Ron Tanner; the Specialty Food Association.

MR. TANNER: Great. Thank you very much and thank you, Kari, and the FDA for hosting us in these great presentation.

My name's Ron Tanner and I serve as the vice president for education content and advocacy for the Specialty Food Association.

As the trade association for the specialty food industry, S.F.A. supports the overall goal of improved food traceability. We appreciate the opportunity to provide verbal comments on the proposed rule and will submit comprehensive

comments to the docket.

We also -- as many others -- strongly support FDA extending the comment period by at least 60 days.

S.F.A.'s 3,900 members include manufacturers, distributors, importers, and retailers of foods included on the proposed rule's food traceability list.

As more than 80 percent of our members are small and very small businesses, S.F.A. is particularly concerned as to how they will be impacted. Today we will focus on some initial comments and questions.

First we echo the concern expressed by other associations that the general categories of foods for inclusion on the FTL are not clearly defined; specifically S.F.A. requests FDA to clarify the definition of soft cheeses, fresh herbs, and tropical tree fruits and how the latter two would be impacted by drying.

Second, the S.F.A. questions how receiving manufacturers and distributors will be able to know whether a product qualifies for exemptions or partial exemptions without any labeling requirements by originating or preceding entities.

For example how will a process cause manufacturer

receiving fresh tomatoes know whether the product qualifies for the total commercial processing exemption versus the partial exemption for a kill step?

Third, S.F.A. encourages the agency to focus on the collection of key data elements that are most relevant for ensuring effective traceback. We'd recommend limiting KDE collection to date and location of a critical tracking event and eliminating time requirements. Time requirements will be especially difficult to define, track, and implement in many contacts and without yielding a comparable return for improved traceback.

Fourth, S.F.A. strongly supports an extended end-phase timeline for compliance with this rule based upon business size and entity type. Sophistications of traceability systems vary widely within the industry and small and very small businesses will need more time to adapt and develop systems to meet the requirements of the rule.

S.F.A. opposes sections of the rule which could be a competitive advantage for large food corporations.

Fifth, S.F.A. is concerned about the lack of education and training regarding this rule. The food

traceability rule introduced a new lexicon of terminology; however unlike previous FSMA rules there is no individual education requirements or programs. Without a corresponding education structure it will be more difficult to establish common understanding to facilitate translating regulation to implementation.

The Specialty Food Association looks forward to further clarification from the FDA on each of these issues and continuing to work with the agency on its development of this rule. Thank you.

MS. BARRETT: Great. Thank you so much for joining us and for your comments; I know you're on the East Coast and it's getting later so thank you very much.

And we'll go to our next commenter, which is Jennifer McEntire from United Fresh Produce Association.

Jennifer?

DR. MCENTIRE: Hi. Thank you for the opportunity to comment.

United Fresh is the national association for the fresh produce supply chain -- from growers through the restaurants and grocery stores.

And over a decade ago the produce industry launched the Produce Traceability Initiative using the GS1 system of standards to identify and track products at the lot level as is being proposed in this rule.

We weren't surprised that many fresh produce items appear on the food traceability list; and in general we don't dispute their inclusion. However the wording of some categories is vague and we're going to need much more detail from FDA -- perhaps in the form of guidance -- to understand where to draw the line on which foods are on or off the list.

For example are leafy greens defined as the commodities covered by the Leafy Greens Marketing Agreement or is the FDA list broader?

For some firms this might be a moot point because it will be very difficult to have two sets of procedures -- one set for foods on the food traceability list and a different set for foods that are not on the food traceability list.

We believe that the implementation of this rule will be facilitated by limiting the data that needs to be shared between trading partners. As written we currently find parts of the rule confusing when it comes to which data does need to be

shared with trading partners versus retained internally for submission to FDA upon request.

While some requirements being proposed seem onerous and even redundant -- such as requiring both the location I.D. and location description -- we also see some serious gaps.

For example the rule defines a person as a corporation and states that CTEs such as receiving involving customers; this could be interpreted to mean that the rule wouldn't cover shipments within one corporation if they were between different manufacturing locations, different distribution centers, or from a D.C. to a store within the same company.

We also have concerns that the first receiver is defined as the first non-farm entity that both owns and takes possession of a product. Setting aside the serious issue of not having a clear workable farm definition the first receiver definition could be interpreted to exclude product handled by brokers, product sold on consignment, et cetera.

Finally, we appreciate that FDA would be willing to skip steps to gather traceback information and be able to go

right to the source -- the creator or transformer -- using the lot number at the retail establishments. We urge FDA to expand upon this concept and consider that not all points in the supply chain are equal.

Given that subpart J will remain in effect we believe there's an opportunity to allow greater flexibility to the industry to determine how to get lot code information to that point of sale, point of service.

We commend the agency for using its authority to push the industry to improve; voluntary initiatives that have had limited success in getting all critical players to capture critical traceability data. And the tools and technology are there but we do need a regulation.

We also need to recognize that the outbreak investigations are about more than just recordkeeping and this rule won't solve issues related to epidemiology, length of time to identify a potential food vector; nor will it address some of the physical processes like comingling that challenge identifying product origin.

That said the implementation of this rule would facilitate traceback investigations and we stand ready to

support the refinement of the rule and its ultimate implementation. So thank you very much.

MS. BARRETT: All right. Thank you so much for your comments and again for joining us later in the day.

I want to thank all of our commenters this afternoon; it is such an important part of our process to have you again share these perspectives. And I know our subject matter experts and staff greatly appreciate your time and your thoughtfulness and preparing.

So at this time we are coming to the close of our agenda and really again the third of three meetings. And to close today we have our CFSAN center director Dr. Susan Mayne, who's been actively engaged in this rulemaking process and we look forward to her concluding remarks. Dr. Mayne.

DR. MAYNE: Great. Thank you, Kari; can you hear me?

MS. BARRETT: -- can.

DR. MAYNE: Great. So good afternoon, everyone -- or good evening depending upon what time zone you're in. I know all of you have been with us virtually for many hours today and so I'm going to keep my remarks brief.

First, I want to thank everyone who has participated in our three public meetings in support of this rulemaking. From our staff here at FDA to our state partners to industry and other food stakeholders so many people have been putting in so much energy to ensure the success of this rulemaking.

And you've all been doing so while also dealing with the challenges created by the COVID-19 pandemic.

So I think I can speak for all us here at FDA when I say thank you for taking the time to review this important proposed rule; for joining these public meetings to discuss requirements; and for submitting comments and feedbacks which will help us as we draft the final rule.

Second, I want to thank all of the panelists that we had here today as well. You have all given us a lot to consider and I hope the discussion has been helpful to all of you listening to think about the requirements we've laid out in this proposal and how they may affect your interests.

We recognize that we've introduced some new concepts in this proposed rule 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 what other materials might be helpful.

Our goal is for this rule to be flexible and workable across many different supply chains and in order to achieve that goal it is important that when you are submitting comments you provide thorough examples of your business models and how these proposed requirements would apply throughout your supply chain.

This kind of information will inform the final rule and ensure that it's workable across the food industry.

I've been fortunate to lead the Center for Food Safety and Applied Nutrition for six years. During this time we have done incredible things to improve food safety -- not the least of which has been the implantation of the seven foundational FSMA rules.

But even so one critical element has been

missing; comprehensive harmonized food traceability. The lack of enhanced, thorough, and standardized food traceability systems has proven time and again to be a tremendous barrier in our ability to rapidly respond to outbreaks.

The traceability systems we have in place today far too often leave us scrambling for information during the critical hours, days, and weeks after we learn about an outbreak from our state and local partners in 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 trust 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 this proposed rule.

While limited to certain foods the proposal 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've strived to make the proposed requirements compatible with those standards.

We also looked at data and information learned through our experiences handling outbreak and recall situation 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 will take in the final rule.

I really look forward to continuing these discussions with all of you as we move this rule forward.

So thank you again; thanks for staying with us throughout the day; and hope everybody has a good evening.

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

Mayne. And there is nothing to add; that is such a great close to our day and again to our series of public meetings that we've held on this topic.

So I just echo; I hope everyone has a wonderful evening and we will conclude today's public meeting. Thank you.

DR. MAYNE: Thank you.

(Whereupon, the meeting concluded at 6:32 p.m..)

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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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