

**FDA Food Safety Modernization Act: Regulations and Implementation,
March 21, 2016**

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FOOD AND DRUG ADMINISTRATION (FDA)

FOOD SAFETY MODERNIZATION ACT PUBLIC MEETING:

PREVENTION-ORIENTED IMPORT SYSTEM

REGULATIONS AND IMPLEMENTATION

Monday, March 21, 2016

FDA Center for Food Safety and Applied Nutrition

Wiley Auditorium

5100 Paint Branch Parkway

College Park, Maryland 20740

Capital Reporting Company

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P R O C E E D I N G S

WELCOME

MS. BARRETT: Good morning, everyone. I don't think the other mic is on yet. So we're going to wait till 8:35 actually to get started. We do have a number of people who are still going through security. But we will start right at 8:35. So I apologize for the delay, and we'll get started in just a few moments.

[Pause.]

MS. BARRETT: We are just about to get started. I do need the mic at the podium; thank you.

[Pause.]

MS. BARRETT: Okay, great. I think we're in good shape. I just need to get a little closer. Can everyone hear me? In the back? Are you good? Okay

Good morning!

[Chorus of "Good morning."]

MS. BARRETT: Happy spring, right?

[Laughter.]

MS. BARRETT: It's going to get better.
It's going to get warmer.

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Welcome, everyone, to today's FDA's Food Safety Modernization Act Public Meeting, and we're focused today on Prevent-Oriented Import Systems Regulations and Implementation. And my name is Kari Barrett, and I'll be moderating today's public meeting.

And again I always say this, but it's always so gratifying to see so many familiar faces. I know that I have worked with many of you over the years on FSMA issues and other issues. But what I do at FDA is really stakeholder engagement. So again, it's good to see many of you that we know and make some new relationships as well. That's in part what today's meeting is about, is to really forge those partnerships in the import arena.

So again, thanks for joining us. I also want to thank, in addition to everyone in the room, we have a very large webcast audience today. And I want to let those folks know how much we appreciate their time, too.

Now, before we jump into the program, I do have a number of housekeeping items that I'm going to

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quickly run through. So, first of all, all of you, hopefully, have been to the registration desk, you have a badge, and you have a folder. In the folder, you'll find the typical things. There's an agenda, there are biographies that we're not going to go into a lot of detail on that. We'll pretty much, as we introduce folks, we'll just give names and titles.

You'll also find copies of the PowerPoint which I hope you'll find helpful. And for the webcast audience, those PowerPoints should be posted online.

The other thing that I will draw your attention to is there's a one-pager on our FDA Technical Assistance Network, which we call TAN. And I think we'll give you some more specifics about that as we go through the day. But do know that that is an avenue for you to get technical assistance on FSMA implementation issues.

I also want to mention that for the media and press, we do have our press officers here today. So if you've not registered as media, if you could please do that, that would also be in the general lobby area.

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For those individuals who have signed up to give public comment this afternoon, first of all, thank you for doing that. We are very much looking forward to your remarks. We do ask that during the break or during lunch, that you check in with Juanita Yates, she will be around the registration area, just so she knows you're here and that your intention is still to give comment.

Also I want to mention, for lunch today, you are limited unless -- no, you're really limited.

[Laughter.]

MS. BARRETT: There's not much exception. Unfortunately, there's not a lot nearby this building. So we do suggest that you eat in the cafeteria. They are prepared for a larger crowd today. It will be your easiest and quickest option.

We also have a couple of meeting rooms as you kind of come into this back area along the hallway. So if you want to get lunch or you want to make a call or you want a place to sit outside the cafeteria, those rooms, which are 1A001 and 1A002, are available to you. And if you forget those numbers

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I've just given you, you can ask anyone at the registration desk. So do know that throughout the day, those rooms are available to you.

I also want to mention restrooms are also in the hallways. As you come upon the registration table, they're on the left-hand side as you walk towards the auditorium. I do want to ask that folks not bring food and drinks into the auditorium space. We would appreciate that.

I also want to remind everybody just to look for the nearest exit sign. It's always good to have that in mind, not that we anticipate anything, but again as a safety measure.

For sign-language interpretation, we did not get any requests, so we do not have that service available today. I always want to remind people to please silence your phones or put them on vibrate. Actually, silence is usually a better option, as vibrate is sometimes just as loud as ringing. But we do appreciate that. It is disruptive when phones go off. So if you could just take a minute to silence your phone, that would be great.

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And I do want to mention, too, that as in our previous FSMA public meetings, this meeting is being webcast. As I mentioned, it will be recorded. It will be posted. So it will be on our website as a reference.

We will also have a transcript of the meeting. That does usually take a couple of weeks before that's up and posted. Once that is posted, we'll send something through our FSMA listserv so people are aware.

And then just throughout the day, if you have any general questions, you need assistance in some way, please do ask the folks at the registration table. They'd be more than happy to assist you.

So with that, we'll sort of jump in right now to the program. And it really is my great pleasure to introduce our kick-off speaker, Mr. Michael Taylor. As many of you know, Mike has served as our Deputy Commissioner for Foods and Veterinary Medicine at FDA for a number of years. And Mike will be providing some opening remarks this morning. Mike?

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OPENING REMARKS

MR. TAYLOR: Thank you, Kari, and good morning, everybody. Just want to welcome all of you here. It's a great turnout in the room. But also, as Kari said, a very large turnout on the webcast and just indicative of the understandable interest in today's topic.

My job is just to really just take a few minutes to set up the discussion that you're going to have today. Unfortunately, I'm going to have to slip out of here after my talk. I've got an unexpected meeting downtown. But I will eagerly turn you over to the real experts and leaders in the import arena here at FDA who are going to be here all day for what I know will be a productive, productive discussion.

I think we're all aware of just how important the import element of FSMA is, given the nature of the world, the nature of the food system, and the challenge that it presents. I do believe personally that the import element for filling the FSMA vision with respect to imported foods is the biggest challenges, really, we have in implementing

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this law, not that preventive controls, domestically, isn't a challenge; not that produce safety isn't a challenge. I mean, this is a complex large-scale system change effort.

But I think for reasons that are obvious to people participating here, the large volume of imports, the challenge of fulfilling the FSMA vision, of not only having the right prevention standards in place, but being able to verify those standards are being met consistently every day. That verification challenge is just enormous, and that's really what this is all about. That's what we're largely going to be focusing our discussions on today.

I think we're all clear what a big shift this really is for imports. We have had historically, under the law as it existed pre-FSMA, an import oversight program that we believe was effective within the constraints of the program -- of the law, I should say.

But it was a program that really relied on FDA being at ports of entry, detecting problems. When we find potential problems, we can keep product out.

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But it's been historically on FDA to find those problems and turn product away or have the problem corrected.

The powerful idea in FSMA, as everyone here knows, is that now we have a system that relies on prevention, not only domestically, but with respect to imports, and really creates this fundamental obligation on the part of private-sector supply-chain managers to verify that prevention is happening at point of production offshore or wherever in the system that supply-chain hazards can be most effectively minimized.

That is a huge paradigm shift. It is one that I think we all embrace conceptually. The idea that foreign product needs to meet U.S. safety standards is not new, but creating a system of prevention standards and creating an expectation and a set of tools that permit us, collectively, to verify that those standards are being met, that is a very big, new idea.

Fulfilling that with respect to imports, in my head, is a really significant challenge in part

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because of the different starting point. When you compare the verification challenge we have with respect to domestically produced product, we have, in the case of facilities and preventive controls, of course, a longstanding inspection program, longstanding relationships, partnerships with states.

We have, in the law itself, an inspection frequency mandate that we will be meeting. We have a base of resources to carry out an inspection program that can meet that inspection frequency mandate.

Very different on the import side. This is a whole new set of tools. The whole idea of importer accountability is a fundamentally new idea. We have tens and tens of thousands, as you know, of farm facilities and farms we need to deal with. And we are in the process of building up the base of resources needed to do that. And that's going to be a continuing challenge going forward.

So, I just want to underscore the magnitude of the challenge, the importance of the challenge, because from a public health standpoint, it is crucial that we be able to verify that foreign product is

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meeting our new FSMA standards.

From a consumer confidence standpoint, it's crucial that we be able to verify that those standards are being met. And I think we all share, I think most of us, certainly, would embrace that idea that trade is meeting important consumer needs, but in order for trade to be successful to meet those needs, the food has to be safe. And what we all need to be focused on is how we facilitate trade in safe food.

And you cannot have robust trade in food, obviously, without confidence in safety. So that's really what this is all about. I'm preaching to the choir on that, I realize. But it's the challenge that we need to face together.

Today we're going to be hearing mostly about the three statutorily mandated new regulatory tools, or vehicles, that we've got, the Foreign Supply Verification Program requirement, of course, which is the foundational regulatory tool. It's the one that really creates that mindset shift that's necessary in FDA's approach to imports and, importantly, the industry's approach to imports. Because it really is

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what creates that importer accountability for verifying how the prevention is happening.

We're going to talk about the Voluntary Qualified Importer Program, which provides the incentives for high performance and gives some rewards for high performance in managing supply chains and, importantly from FDA's vantage point, is part of a toolkit that enables us to better target our resources so that we can focus our efforts in areas where we'll get the most food safety benefit.

And finally, we're going to talk about the Accredited Third Party rule that sets up the program that is necessary to support VQIP in terms of the basis for accrediting auditors, and also relates to the Mandatory Certification program.

So these are three nitty-gritty regulatory tools that I know that the community has a lot of interest in. How are they actually going to be played out? What's expected of folks? How do we interact to make those a success? And we do have today the folks who have been the architects of these rules and who will be leading implementation. And again, one of our

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major purposes today is to have a robust discussion about those tools.

The thing that I want to emphasize for just another couple of minutes, though, is that our approach to achieving the FSMA import vision requires looking beyond these three new regulatory tools and really trying to figure out, what is the holistic strategy that uses not only these tools, but other authorities and tools that we have at our disposal to achieve what we think is one of the central expectations, that are what we consider one of the central expectations that we have at FDA?

And that is that we are, in fact, providing a comparable level of oversight of imported food compared to domestic food, given the differences that clearly exist in where we're located, what our resources are, and what our tools are.

And so, the FSMA mandate and toolkit, of course, go beyond the tools we're going to be talking about today. We are directed to conduct significantly more foreign inspection. We're committed to increasing the foreign inspection numbers, even though

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I think if you're familiar with the way those number play out, we're very, very far short now of the 19,200 inspections, annual foreign food inspections that Congress envisioned. We're less than 2,000 now. We're working to increase that gradually. That's a very resource-dependent thing.

But we want to increase foreign inspection, and we want to make them better targeted to achieve public health benefit and to contribute to the overall verification, a comparable level of verification goal that I mentioned.

Very critically, we are all in on carrying out the FSMA mandate expectation that we partner more fully, collaborate in new ways with our foreign government partners. And this is a huge area of focus for us, because we know that in the case of most of our significant trading partners, really in all of our significant trading partners, food safety is a recognized important issue. It's recognized to be essential to maintaining trade.

We have a wide array of relationships with the governments and our foreign trading partners, some

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of which are very robust food safety partnerships. And we want to build on those relationships, those partnerships, to take advantage of what they do to complement what we do, to complement what our U.S.-based importers do to contribute to that level of oversight that will meet the FSMA expectations.

And so, that will include everything from the kind of engagement we're having now to educate, inform foreign governments about what the new system looks like, to work with foreign industry groups in conjunction with foreign governments to build the base of understanding and confidence that would permit us to ultimately rely in various appropriate ways on the work that foreign governments are doing to verify that our standards are being met.

A great example of this and something that Domenic and I spent time on last week out in Arizona, meeting with Professional Produce Association of the Americas is the U.S.-Mexico Produce Safety Partnership, where we have a very robust engagement going on with the two agencies and the Mexican Government that are focused on food safety, SENASICA

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and COFEPRIS, tremendous engagement with the industry that is trading product across that 2,000-mile border between the United States and Mexico, huge volume of product, sensitive commodity from a food safety standpoint, fresh fruits and vegetables.

We know that we can't fully achieve what FSMA expects with respect to the safety and verification of that flow of product without working with the Mexican Government and the industry down there. So that's the kind of partnership with foreign governments and public-private partnership that is also, from our vantage point, necessarily a part of a holistic strategy.

Finally, I mention systems recognition. Camille Brewer is here, and along with others, has been a real leader in developing a tool for appraising the total food safety system with some of our trading partners who have advanced systems that have comparable capacity, comparable approaches, able to achieve food safety outcomes compared to our system.

How can we recognize those systems so that we can formalize regulatory cooperation, formalize

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neutral reliance, and enable us again to focus our resources on areas where there's more need for our engagement to be sure that standards are being met? We have a system of recognition agreement already with New Zealand. We're at advanced stages with Australia and Canada, and we're beginning work with the European Union [sic] to pursue systems recognition.

Again, it's a way to support regulatory cooperation, but also by virtue of us recognizing foreign system efforts, as you know if you've delved into the details of the Foreign Supply Verification Program requirement, we think this can contribute to regulatory streamlining, reducing burdens on importers as well.

So, our challenge is to look at this entire toolkit, to figure out, what's the holistic strategy that enables these tools to work together synergistically? If we're going to be doing foreign inspections, which we are, how do we have them reinforce foreign supplier verification? You know, how do we tie inspection, to some extent, to verifying that what we're seeing in the records of an importer

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is actually happening overseas?

There's a whole array of possibilities for seeing these tools work together to achieve the level of oversight and verification that we think Congress expected and that we think American consumers expect.

We are at a point where we would envision this summer being able to have another, some engagement, perhaps like this, perhaps in other settings, but engagement with the community on this holistic strategy. We want the benefit of your thinking. We want to be transparent about what we're doing. We want people to understand the effort that is being made here at FDA to achieve the comparable level of oversight for imports that I think we all aspire to.

So, that's my high-level setup and overview for today's meeting. I really again thank you all for your engagement. Thank you for being here. Some of you may have heard that I'm going to step down from my job come June 1. That's about the right time for me. It's been seven years, and it's been fantastic, and I enjoy this job every day. But I'm thrilled that this

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program is in such great hands with the people that you'll be talking with today.

Also, that Dr. Steve Ostroff will be taking over as Deputy Commissioner for Foods and Veterinary Medicine. For those of you who don't know Steve, you probably are familiar with him. He's been the acting Commissioner of FDA for most of the last year. He came into FDA about three years ago into our Foods Program as Chief Medical Officer at the Center for Food Safety and Applied Nutrition as a Senior Public Health Advisor to the program as a whole.

He quickly was snatched up by Peggy Hamburg to be the Chief Science Officer for the Agency, and then the Secretary made him the acting Commissioner. His availability now, with the confirmation of Rob Califf to be Commissioner, makes the timing really perfect here.

Steve is a true food safety expert, a true public health person at heart. He had over two decades at the Centers for Disease Control. He was the senior health role in the State of Pennsylvania when we recruited him here. And I think you'll find

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him to be a great partner to work with in the months and many years ahead.

You know, this is a continuous process, getting FSMA done. Every point is crucial. No point is the end of the road. And I just really wish Steve and all you well in the months and years ahead. So, I unfortunately have to slip out stage left. But thanks, all, for being here. Thank you.

[Applause.]

MS. BARRETT: Thanks so much, Mike.

Okay. We'll now move on to the "architects," I think you are called, of some of the regulations that we're going to cover today and voluntary program, I should mention. But we do have two of our leads who will speak next on FSMA, one on the Foreign Supplier Verification Program, or FSVP, which I always find a little challenging to say.

And then we also will be discussing the proposed FSMA Voluntary Qualified Importer Program, or also known as VQIP, and Brian Pendleton, who is our Senior Policy Advisor, the Office of Policy at FDA, will start on the Foreign Supplier Verification

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Program. And he will be followed by Domenic Veneziano, who is our Director, Division of Import Operations, in our Office of Regulatory Affairs at FDA. And Domenic will speak on the VQIP, as I mentioned.

So, Brian, we'll have you come up.

FSMA FOREIGN SUPPLIER VERIFICATION PROGRAM (FSVP)

FINAL RULE OVERVIEW

MR. PENDLETON: Thanks, Kari. Good morning, and thanks to everybody for the opportunity to talk with you today about FDA's final rule on Food Importers Supplier Verification Programs, or FSVP.

As Mike said, the FSVP Regulation will play an important role in the risk-based preventive-oriented approach to food safety that the Agency is establishing consistent with FSMA. And FSVP is truly significant because for the first time it requires importers to take specific steps to ensure that the food that they're bringing into the United States meets U.S. standards.

[Pause.]

MR. PENDLETON: Just a brief bit of

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background on the FSVP Regulation. In FSMA, Congress required food importers to perform risk-based foreign supplier verification activities and directed the Agency to adopt regulations on the content of FSVP's. We issued the proposed rule on FSVP in 2013, and the following year we issued a supplemental notice of proposed rulemaking that included several changes to the initial proposal that we made, in response to some of the more than 300 comments that we got.

And after considering the comments on the supplemental proposal, we issued the final rule in November of last year, also making several changes in response to some of the later comments.

[Pause, presenter addressed issues with the slides.]

MR. PENDLETON: Sorry. A little technical difficulties. Okay. Thank you.

I'll start with some of the key principles in the Regulation. As I said earlier, the final rule will, for the first time, require most food importers to take responsibility for ensuring the safety of the food that they import. There are requirements now for

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importers of juice and seafood under the HACCP Regulations. But for the first time, the regulation extends to most importers, the requirement to take certain steps to ensure that the food they import is safe.

Consistent with our other FSMA rules, we designed FSVP to be risk-based, because it takes into account differences among types of hazards, types of importers, as well as suppliers.

As I'll discuss in more detail later, the rule gives importers flexibility in meeting the requirements to accommodate modern global supply chains, principally by allowing importers to rely activities that are conducted by others.

And the rules very closely align with the supply-chain program provisions in the preventive controls regulations for human food and for animal food, to avoid imposing redundant requirements on importers that are also receiving facilities under those regulations and to ensure a level playing field for domestic and foreign suppliers.

I also want to emphasize that, except for

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the requirement that the FSVP importer ensure that it is identified as the importer at entry of the food into the United States, FSVP will not change entry procedures. The rule doesn't require verification of FSVP compliance at entry, and it doesn't require documentation of a supplier's compliance with the underlying food safety requirements that apply to the supplier. We'll be inspecting importers as part of our overall Food Safety Compliance Oversight Program.

As directed by the statute, the regulation requires importers to develop FSVP's to provide assurances that their foreign suppliers are using processes and procedures that provide at least the same level of public health protection as those that are required under the preventive controls or produce safety provisions of FSMA, as well as the regulations implementing those provisions.

This standard allows flexibility consistent with our trade obligations for an importer to obtain food from a foreign supplier that uses a different procedure than is specifically required under the Preventive Controls or Produce Safety Regulation, as

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long as it provides the same level of public health protection.

FSVP's also need to be designed to provide assurance that the foreign supplier's food isn't adulterated and isn't misbranded with respect to allergen labeling.

The FSVP Regulation applies to importers of food, of course. Under FSVP, the importer of food must be someone in the United States who takes responsibility for the safety of the food. The importer is the U.S. owner or consignee of the food at the time of entry into the United States. And the Regulation defines "U.S. owner or consignee" as "the person in the United States who at the time of entry either owns the food, has purchased it, or has agreed in writing to purchase it."

If there isn't a U.S. owner or consignee at the time of entry, the FSVP importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry. And the regulations specify that there must be a signed statement of consent from the person designated to be the U.S. agent or

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representative to serve as the FSVP importer, for that designation to be valid.

Note that the importer of a food for FSVP purposes could be, but isn't necessarily, the importer of record, for purposes of submitting entry documentation with U.S. Customs and Border Protection. That person, who might be a customs broker or filer, might not always be a person with financial interest in the food or have the knowledge and ability to conduct supplier verification.

The regulation includes several exemptions from the FSVP requirements. Importers of juice or seafood made in compliance with the HACCP Regulation are exempt, as I mentioned, because those importers are already subject to certain verification requirements under the HACCP Regulations.

And the final rule also clarifies that firms that are importing juice or seafood, raw materials, or other ingredients for use in making juice and seafood products under the HACCP Regulation are also exempt. The final rule also exempts food that's used for research or evaluation, food importer for personal

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consumption, alcoholic beverages and the ingredients used to make them.

Some further exemptions include food that transships through the United States to another country; food that is imported for processing here in the United States and then exported; as well as U.S. food returned, or food that is produced here, is exported, and then is brought back into the United States without being subject to further processing.

There is also an exemption for meat, poultry, and egg products that, at the time of importation, are subject to USDA Regulation.

As I mentioned, the final rule aligns FSVA with the Preventive Control Supply Chain Program provisions. In at least a couple of principal ways, we've aligned the provisions and terms, in many ways, so the provisions regarding analysis of hazards and supplier verification are aligned to the extent possible and appropriate.

The regulation also specifies circumstances under which an importer who is in compliance with preventive controls is deemed in compliance with most

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of the FSVP requirements. So an importer that is also a food facility is deemed in compliance with FSVP, except for the requirement to ensure that it is identified at entry as the importer of the food, when it is in compliance with certain preventive controls provisions.

And that includes when it has a supply-chain program for the raw material or other ingredients that it imports, when it implements preventive controls for the food that it imports, and when it's not required to implement a preventive control for food under a PC because its customer or a subsequent entity in U.S. distribution is addressing the hazards in the food. Also, when the importer has determined that a food can't be consumed without the application of an appropriate control such as with coffee or cocoa beans -- and I'll talk about the parallel provisions in FSVP later.

The regulation requires use of qualified individuals to perform FSVP tasks. The final rule provides flexibility by stating that a qualified individual is the person who has the appropriate

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education, training or experience, or a combination of those factors, needed to do whatever tasks they are doing under FSVP.

The definition also states that a qualified individual might be, but doesn't have to be, an employee of the importer, and a qualified individual could be a government employee, including a foreign government employee.

Rather than require that all FSVP records be maintained in English, as we had originally proposed, the regulation requires that a qualified individual be able to understand the language of any record that he or she is reviewing, and also gives FDA the authority to request translation of records.

Importers will be required to analyze the hazards in the foods that they import. Specifically, they need to look at biological, chemical, and physical hazards that are known or reasonably foreseeable to determine whether they require a control. Importers need to consider hazards that are controlled that occur naturally that may be unintentionally introduced or that may be

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intentionally introduced for economic gain.

But again, this is limited to hazards that are known or reasonably foreseeable. We don't have to go looking for hazards for which there isn't any evidence or known information about.

The final rule builds flexibility into these provisions by allowing an importer to rely not only on the hazard analysis that may have been conducted by the foreign supplier, but by a hazard analysis conducted by another entity, such as a consolidator of a raw agricultural commodity or, if it wants to, the hazard analysis done by an industry or a trade association, provided that the importer reviews and assesses that analysis.

If there are no hazards that require a control, the importer doesn't have to evaluate the food, and suppliers I'll talk about in a moment, and doesn't have to determine and conduct appropriate supplier verification activities. The final rule notes several types of food for which an importer might find that there are no hazards requiring control, such as crackers, dried pasta, cookies,

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candy, sugar, soft drinks, and some jams and jellies.

In alignment with the preventive-control supply-chain provisions, FSVP requires importers to consider certain characteristics of a potential foreign supplier and the risk posed by a food in both approving suppliers and determining appropriate supplier verification activities.

So, in addition to the hazard analysis for the food, the importer must consider the entity that will significantly minimize or prevent the hazards in the food or verify that hazard has been significantly minimized or prevented, such as by the supplier to a foreign supplier.

Look at the foreign supplier's food safety processes, procedures, and practices -- the importer needs to evaluate the FDA food safety regulations that would apply to the food and the foreign supplier and consider the supplier's compliance with them, including whether the supplier has been the subject of a warning letter or import alert.

And this is going to be information that is publicly available, including information that's

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available on the FDA website.

And the importer, in its evaluation of the supplier, needs to look at the supplier's food safety information, such as its history of meeting the customer's specifications, including as assessed through results from auditing and testing, as well as the supplier's responsiveness to correcting problems.

The rule requires importers to reevaluate the foreign supplier and the food, and the risk posed by the food -- that is, when they become aware of new information about these factors or at least every three years. And as with hazard analysis, the importer may rely on a food and supplier evaluation that's conducted by another entity.

In addition to supplier verification activities such as onsite auditing, the rule requires importers to conduct certain related activities. Importers must establish and follow procedures to ensure that they receive food from suppliers that they have approved. But the rule also gives importers the flexibility to use unapproved suppliers, if needed, on a temporary basis when they subject the food to

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verification such as by testing it or looking at lot records on the food.

Use of an approved supplier might be appropriate when, for example, there is environmental catastrophe in the region where a supplier is located or perhaps when there is an equipment breakdown of a sole supplier of a food. And importers must have written procedures for their determination and performance of appropriate supplier verification activities.

Based on the food and supplier evaluation that the importer conducts or when they review someone else's evaluation, importers would need to determine what verification activities to conduct and how frequently they should be conducted.

Possible activities include onsite auditing of foreign suppliers, sampling and testing, review of appropriate FDA food safety records, and other measures that the importer may have determined are appropriate to provide appropriate assurance that a hazard is being addressed.

The regulation makes annual onsite auditing

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the default approach when there is a hazard that can result in serious adverse health consequences or death to humans and animals.

But there is flexibility for an importer to perform some other activity and-or less frequent auditing if the importer can demonstrate that it provides adequate assurance of safety, such as when the supplier has a long record of being highly compliant. In other words, if you've had a longstanding relationship with a supplier and they've had a very good compliance record, that might be a case where you would not necessarily have to do annual onsite auditing, but you could do some auditing with use of some other verification measures.

As with the other requirements, the final rule gives importers the flexibility to rely on others to both determine and perform appropriate supplier verification activities, such as when an importer of a raw agricultural commodity relies on audits of farms that are conducted by a produce distributor.

But whether the importer conducts the activities itself or relies on others, the importer

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must review and assess the results of those verification activities. If the results don't provide adequate assurance that the hazards are being controlled, the importer must take appropriate corrective action, which I'll talk about in just a moment.

I want to make a few comments about one type of supplier verification activity, and that is onsite audits. They need to be conducted by a qualified auditor, and that's a person with the appropriate education, training, and experience to do such audits under FSVP. We're not establishing any specific accreditation that is required. You just need to have the appropriate expertise to do audits under FSVP.

And an audit that's performed for FSVP purposes needs to consider the appropriate FDA food safety regulations, or in cases where in a country that we have officially recognized their food safety system as being comparable to that of the United States or determined that it be equivalent, then in that case you could look at the laws and regulations of that country.

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In some cases, an importer can substitute the results of an inspection by FDA or the competent authority of a food, in a country that is officially recognized as comparable or determined to be equivalent, provided that that inspection occurs within one year of the time that the audit was due.

I also want to note that we recognize and we've heard several questions about existing food safety auditing schemes and how that might apply to FSVP, as well as the auditing under the preventive controls regulations.

And in general, some of those systems might be appropriate for use in meeting supplier verification requirements, as long as they evaluate adherence to the FDA food safety standards and they meet the other requirements for audits under FSVP, such as what must be included in the documentation of an audit.

However, some of the schemes might need to be modified or changed to make sure that they do meet those requirements that are set forth in the regulations. Unfortunately, we don't have the

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resources to evaluate all of the existing auditing schemes, but we do encourage audit scheme-owners, importers, suppliers, and others to analyze existing schemes for their consistency with the FSVP Regulation and share their findings with the Agency.

The final rule provides additional flexibility by not requiring food and supplier evaluation or verification of the supplier in certain circumstances when it's really not necessary or relevant. This includes when the importer determines that the food basically can't be consumed without application of an appropriate control, such as with coffee or cocoa beans.

Also, food and supplier evaluation and verification activities aren't needed when the importer's customer or some subsequent entity in U.S. distribution significantly minimizes or prevents, or otherwise addresses, the hazard in the food.

The requirements vary slightly depending on whether the customer is subject to the prevent controls regulations, but in general, the importer would need to disclose that the food hasn't been

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processed to control a particular hazard and annually obtain written assurance from the customer that it or some other entity subsequent is significantly minimizing or preventing the hazard or making the food in accordance with application of food safety requirements.

Finally, we built flexibility into the regulation by allowing importers to perhaps create and implement some other system that ensures control of hazards at a subsequent distribution step.

The regulation includes a few other requirements. If an importer learns that its foreign supplier isn't producing food consistent with U.S. safety standards, the importer must take appropriate corrective action. This might mean just working with the supplier to address the problem. And in some cases, it might mean temporarily discontinuing use of the supplier until the problem is resolved.

For each line of entry of food into the United States, the FSVP importer needs to ensure that its name, email address, and a unique facility identifier recognized as acceptable by FDA is provided

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electronically to Customs at entry. In the forthcoming FSVP draft guidance, we anticipate recognizing the Dun and Bradstreet data universal numbering system, or DUNS number, as acceptable.

And the rule also has certain recordkeeping requirements. It requires that FSVP records generally be kept for two years after they are either created or a few years after they are no longer in use. And it requires that records be made available promptly to an authorized FDA representative for inspection and copying. Offsite storage is permitted if the records can be provided onsite within 24 hours.

In addition, FDA may request that importers send records to FDA electronically or through some other prompt means. Importers can rely on records that are created for other purposes, such as to comply with other regulations, if the records contain the information that is required under FSVP and importers can supplement existing records with other information to meet FSVP requirements.

So I've just given an overview of basically the standard FSVP requirements. There are three types

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of modified requirements under FSVP that I want to talk about.

The first concerns dietary supplements. Most of the FSVP requirements would not apply to importers of dietary supplements and dietary supplement components, who set specifications for components or packaging under the Dietary Supplement Current Good Manufacturing Practice Regulation and verify that those specifications are met.

The same applies when that is done by the importer's customer. In that case, the importer needs to get assurance from the customer that it is complying with the Dietary Supplement CGMP provisions.

Other importers of dietary supplements will need to meet requirements that are similar to the standard requirements that I discussed, except that importers of these dietary supplements aren't required to conduct a hazard analysis, and verification is to provide assurance that the foreign supplier is using processes and procedures that provide at least the same level of protection as those that are required under the Dietary Supplement CGMP Regulation.

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The second type of modified requirements concerns very small importers and foods that are imported from certain small suppliers.

In the final rule, we changed the definition of "very small importer" to a line with a definition of "very small business" in the regulations on preventive controls for human food and preventive controls for animal food, so that an importer can have very small status for human food that it imports with a ceiling there of \$1 million in annual sales, or for animal food with a ceiling of \$2.5 million in average annual sales, or for both.

The small foreign suppliers that are covered under these modified provisions, in alignment, actually, with the corresponding provisions in the Preventive Control Supply Chain Program Regulations, are qualified facilities as they are defined under the preventive controls regulations.

Certain small farms that aren't covered farms under the Produce Safety Regulation -- and basically, those are farms that have less than \$25,000 in annual sales or that they qualify for the qualified

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exemption under the produce safety regulation, as well as producers of shell eggs with fewer than 3,000 laying hens.

These are all entities that tend to be smaller and that, primarily because of their smaller size are subject to different provisions under either the produce safety or the preventive controls regulations, and we concluded that it was appropriate to have different requirements for importers of these foods under FSVP.

For the modified requirements to apply, the importer will need to annually document its very small importer status if that's the way that they are eligible for these requirements, or obtain assurance that its supplier meets the criteria as one of the small types of foreign suppliers.

Verification will require obtaining written assurance from the supplier. For very small importers, they will need to obtain assurance at least every two years that the supplier is producing food consistent with U.S. safety standards. If the supplier is a qualified facility, the importer will

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need to obtain assurance at least every two years that the supplier produces food in accordance with applicable food safety regulations.

And for the latter two categories of certain types of farms that aren't covered farms, as well as the small-shell-egg producers, the verification is that the supplier acknowledges that its food is subject to the Federal Food Drug and Cosmetic Act, with respect to the adulteration provisions in particular.

There are some requirements that only apply to importers of food from these small suppliers, not to very small importers. And these are requirements to evaluate the compliance history of the foreign supplier, to approve the supplier, the small supplier, based on that compliance history evaluation, and to ensure that you're receiving the food from the supplier that you have approved.

The last set of modified requirements concerns food from suppliers in countries with comparable or equivalent food safety systems. As Mike noted, the Agency has in recent years been developing

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a systems recognition initiative under which we conduct a comprehensive assessment of a country's food safety system to determine whether it provides a similar level of protection as that offered under the U.S. system and a similar level of oversight and monitoring.

To date, we have entered into a systems recognition arrangement with New Zealand, and we're conducting reviews of Canada and Australia, and we've also begun, as Mike noted, talking with the EU [sic]. We believe that systems recognition will enable the Agency to leverage the resources of other countries to make efforts to ensure the safety of imported food more risk-based and efficient.

Under the FSVP rule, food from countries with comparable or equivalent systems that is not intended for further manufacturing or processing, including packaged food products, as well as raw agricultural commodities that won't be commercially processed before consumption in the United States, would not be subject to most of the FSVP requirements if certain requirements are met. The importer would

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need to ensure that it is identified as the importer of the food at entry.

So, for these modified requirements to apply, the foreign supplier would have to be under the oversight of a comparable or equivalent food safety system. The food itself would need to be within the scope of the official recognition of comparability or the equivalence determination.

And the supplier would have to be in good compliance standing with the competent authority in the country with the comparable or equivalent food safety system, as appearing on a list that that authority creates or any other way that the competent authority chooses to designate suppliers as being in good compliance standing.

We recognize that importers will need additional time to familiarize themselves with the FSVP requirements. So we've built in time to comply with the regulation. The earliest that any importer will need to comply with FSVP is in May of next year. But it seems far away, but it will get here much sooner than you might imagine.

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If the importer's foreign supplier is subject to the preventive controls or the produce safety regulation, the importer of the food from that supplier won't be required to comply with FSVP until six months after its supplier is required to comply with the underlying food safety regulations.

So this might result in different FSVP compliance dates for importers, depending on the type of food that they import and the size of their suppliers.

We also realized that importers needed additional clarification on some of these requirements, and we expect to issue a draft guidance later this year. In addition, we're working with the Food Safety Preventive Controls Alliance to develop training materials for industry on the FSVP Regulation.

And we continue to host or participate in meetings and webinars like this to provide information on FSVP. We will be working closely with industry to help importers come into compliance with the rule.

Of course, you can get additional

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information on FSMA, as well as the other parts, the import parts of FSMA, including the Foreign Supplier Verification Program, at this site, www.fda.gov/fsma. And at the website, there is a subscription feature available where you can sign up to get information on FSMA when the Agency releases it.

And it's very important, at the website also, you can go to the place indicated as "Contact Us" and submit questions about the Foreign Supplier Verification Program Rule, as well as all the other regulations that we have issued to implement FSMA, and our Technical Assistance Network will answer your questions.

And we have received hundreds of them to date, and we welcome your questions and comments through that avenue, and I look forward to your questions later today. Thank you.

[Applause.]

MS. BARRETT: Thanks so much, Brian.

And I do want to direct people who are coming that there are a number of seats in the first couple of rows here, on your left, my right-hand side.

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So please just know that there are some seats up front; it's hard to tell as you come into the room.

Next, we have Domenic, who will speak about our VQIP Program.

PROPOSED FSMA VOLUNTARY QUALIFIED IMPORTER PROGRAM
(VQIP) OVERVIEW

MR. VENEZIANO: Thank you, Kari, and good morning to everyone. I'm happy to see a full crowd and a lot of people on the phone.

One of the things we will be talking about right now is the Voluntary Qualified Importer Program. We will be -- let me see if I can do a better job with this than Brian. I don't think so, though.

[Pause.]

MR. VENEZIANO: All right, Brian. What's the secret?

[Laughter.]

MR. VENEZIANO: There we go. Thank you. Ah, technology.

So, what is VQIP? VQIP is a user-fee-based program that is meant for the best of the best of expediting shipments into the United States. Its

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eligibility is limited to importers who demonstrate a high level of control over the safety and security of their supply chains.

Section 806(g) defines "importer" as "the person that brings food, or causes food to be brought, from a foreign country into the customs territory of the United States." It can include manufacturers, consignees, and importers of record for food for humans and animals. It may or may not be the FSVP importer.

The biggest difference between the FSVP importer and the VQIP importer is that the VQIP importer does not have to be within the United States. It can reside outside of the United States. This is important because importers of record oftentimes don't have to be in the United States either. So it kind of mirrors the Customs and Border Protection, Customs and Trade Partnership Against Terrorism Program as well.

The guidance or the eligibility associated with this -- the key to the program is the quality assurance program itself -- is the assurance of compliance with the supplier verification and other

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importer responsibilities under the applicable FSVP or HACCP regulations. The big key is making sure that you are in compliance with FSVP and building a relationship between the entire supply chain, from the manufacturer all the way through the FSVP importer or the HACCP importer in terms of regulations.

You have to have a current facility certification, including farms, issued under the FDA's Accredited Third-Party Certification Regulations for each foreign supplier of food in VQIP.

You have to have a three-year history of importing food into the United States. You can't have any ongoing FDA administrative or judicial action, including import alerts, injunctions, recalls, seizures, or other history of noncompliance with food safety regulations by the importer, other entities in the supply chain.

That includes the brokers and the filers who import or provide the information to Customs and Border Protection through the FDA in terms of that -- extremely important. And again, as I mentioned earlier, it's all about building that relationship

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between manufacturer all the way through the supply chain to the FSVP importer.

Some of the elements to the Quality Assurance Program -- corporate policy statement -- we want to make sure that the commitment starts from the very top. We want that corporate statement saying that any changes that have to be made or any commitments that are made through the policies and procedures that have been developed will have the full support of the entire company.

We want an organizational structure including individual responsibility. So we want to know who is responsible for every step along that requirement. And when we go do an VQIP inspection, we want to know who to talk to along that process.

Policies and procedures to ensure food safety from source to entry -- looking at temperature controls and storage controls. And it also includes logistics. How would the product get into the end use? Do you have controls in place to ensure that the temperature is going to be handled accordingly?

We want to make sure that compliance with

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supplier verification procedures in the verification procedures in the FSVP or HACCP rules, if applicable, is in maintenance of current facility certification under FDA's Accredited Third-Party Certification Program.

We want procedures related to communications of information about potential health hazards to FDA and others. We want to make sure that, as one of the best of the best, if there is an issue, you're notifying FDA and you're notifying other entities to ensure public health.

We don't want people just to go on and hope that FDA finds it; we want that open communication that, "Yeah, we're going to expedite all shipments into this program." We want to make sure that there's a communication in terms of any issues that may come about.

We want to make sure that this procedure is related to corrective actions to address food and foreign supplier noncompliance that pose a risk to public health. We want to make sure that food defense systems are in place to protect against intentional

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adulteration.

We want to make sure that there's experience and training requirements for employees responsible for implementing the Quality Assurance Program. Brian talked a little bit about the qualifications for doing an onsite audit. We would expect the same thing in terms of the Voluntary Qualified Importer Program. We want people that are experienced and trained in order to implement the procedures of the Quality Assurance Program.

We want written procedures for establishing and maintaining records related to the structure and implementation of that Quality Assurance Program.

So, what are the benefits of the program? This is where the heart of this goes to, the program itself. What are you going to get from that user fee? What are you going to get from this program? Overall, it's an expedited entry process. All right?

Now, as you know, we hold up a lot of shipments to take a look and to sample them and to make sure that they're in compliance. And as a result of that, you all hold that product usually at the

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border under the results come back.

This allows the expediting of those shipments without any stopping at the border itself.

We will do some examination in our sampling.

Generally, we're limited to "for cause." So if there is an outbreak, if there is a public health threat, we may stop shipments to determine what the cause is.

We may also do it based upon surveillance if we don't have enough samples to actually take a look at the product itself. We hope that that will be very rare an occasion. But if we do collect a sample, you're not going to lose your benefit. The other things that I talk about, moving forward, will still apply to you as a voluntary qualified importer, or at least under that program.

So, any samples or examinations that are done can be done at a location that you tell us. So instead of stopping something at the border and doing demands cost or storage cost in warehouses, you can allow that product to move to destination. You can tell us where you want us to look at it. And if it's in reason, we will go to that location.

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We will also expedite laboratory analysis for any samples that we do collect. So, if we do collect a sample or do an examination, and it has to go to a laboratory, we are working on a process with the laboratories to say, "This one takes priority over all others."

Again, outbreaks obviously are going to raise to the high level. But you would get that level, you would be first on the list in order to get the examination conducted or the analysis conducted.

I will also say, and it's not listed here, but we will work closely with Customs and Border Protection to allow you to export a product from the port of entry that you request. So that's a request that FDA can't -- we can't promise that. That's a request that has to go through Customs and Border Protection. But we will work with them, and we have their commitment of allowing that to happen.

We will also create a help desk for the Voluntary Qualified Importer Program. This help desk will allow you the capability of providing assistance with your application. It will also provide you with

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a contact person for any entries that do get held up, for whatever reason. Whether it's through Customs and Border Protection or whether it's through FDA or any other Federal Agency, we will reach out and we will determine why it's being held up and what the purpose of it is.

We'll talk a little bit about some of the comments that came forward in terms of the help desk and what their ability is to do. And we'll talk a little bit about why and why not in terms of making releases themselves. And I'll get into that a little bit later.

One of the other things we wanted to do is publicly post those that are participating in the program. We've heard from all of you in terms of the industry that being part of this will help business. It will help to show who is doing things right and who may not be.

We also heard that there is a detriment to posting it, as well. So instead of making it one way or the other, we wanted to create flexibility to the importers to allow you to tell us, do you want it

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posted or do you not want it posted? And we will honor that request and put it on the website if that's what you would like.

Additional benefits -- talking a little bit about the application process, the elements. The draft guidance document itself will talk about the application process, what the elements are, what the timing is, how we will do our FDA reviews. It will talk about the revocation program process -- how to get kicked out of it and how to get reinstated.

There are differences between it. The final rule or the statute talks about having a process of revocation, not about suspension. So there's a big difference between what could constitute kind of a revocation with the ability to come right back into the program very quickly. There are other instances where the revocation could cause you to be excluded from the program permanently. We'll talk a little bit about that in terms of the guidance document itself.

Talk about FDA oversight, what we're going to do, the inspectional process as we go through. And it will discuss user fees as well.

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So, where are we in this process? A notice of availability was published in the Federal Register in June 5th of 2015. The draft guidance document is actually going through a final clearance process currently, making final changes to that document.

We are considering the burden to small importers. We're trying to figure out, can there be a way, is there a way in terms of user fees to reduce those fees for small importers, or should we just have it one-fee-for-all people that want to participate in the program?

Again, the comment period was open for 75 days. We are assessing that, and we'll talk a little bit about the top five that we've seen. And we anticipate that the final guidance document will be issued in the summer of 2016.

Some of the comments -- the requirement for a three-year history of imported food into the United States should be more flexible to accommodate the mergers and divergence between companies.

I think if there is a divergence, you can utilize that experience in the past. You just have to

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inform us that there has been a merger one way or the other, and we would account for that. So there's flexibility in terms of how that works. And you'd have to explain it to us, and then we would explain it, and then we would consider that capability.

We talked about DUNS numbers and the difficulties associated with getting those DUNS numbers. We addressed that in the final guidance in terms of the process to do that. And again, we would be available to help in the process of how to get a DUNS number and how to get it into our system.

Flexibility in terms of readiness in products throughout the year -- we addressed that as well. I think that was a good comment in terms of having people make changes throughout the year rather than waiting at the beginning of the year and the application process to make changes.

If we accept you into the program and we do that review of the application, it should be an easy transition to add somebody else, provided that certain requirements are met, like the certification process.

We talked about the help desk. The help

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desk, one of the comments was they should have the capability of making the admissibility itself and allowing things to come in. That's difficult for us to do because we don't know why something has been held up. So there has to be some kind of research.

The field is on the ground. The investigators are seeing things real-time. Customs and Border Protection and other agencies have different missions and different reasons for holding up shipments. So we don't want to be able to just release something without understanding the holdup.

It may end up like that. We can turn something around very quickly. We have the capability of releasing something. But we don't want to do it without actually getting input from the people for the agencies that are holding up products.

I could tell you that that happens currently on the other side. Customs and Border Protection will have under their C-TPAT program things that get released by them, but then FDA holds it up for safety issues. They contact us. We work closely with them and make sure that everyone is on the same page as to

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why shipments are being held up.

And then when possible, providing a may-proceed in advance of arrival. Under the new automated commercial environment, that problem is going to happen. So as soon as the shipments come in, we turn it around very quickly. But one of the things that we're concerned about is any substitutions in the future. So again, you being part of this program, the best of the best, we wouldn't expect to see that.

So under the program, you'll probably get that may-proceed very early and probably prior to arrival anyway. And I think overall, except for those occasional for-cause issues, you can anticipate things going through very smoothly and very quickly, moving forward.

And again, if something does get held up, you have a phone call. You have a phone number that you can reach out and find out why and what the turnaround time period might be. So you'll have that capability as well.

The timing of the program, informal fee estimates available early 2017. Again, one of the

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things we heard from industry is we need to have our budget in place. We need an understanding of what that fee is going to be so that we can create our budget and get it to our CEO's in order to plan for that and to submit the application.

So we wanted to put out an informal fee structure early on in 2017 so to give you an idea of what that cost might be. A formal fee will be published no later than August 1st, 2018. And then the anticipated first application would be January 1st, 2018.

That process, January 1st through May 31st of 2018, will be the time period when we will receive applications and do the review. And then during that time period, we will start the inspections following up to that. And then anticipation of the benefits will go in place after the user fees are paid in October 1st of 2018.

If we don't get to an inspection prior to October 1st of 2018, your benefits will still kick in and we will continue to do that inspection process, depending upon availability and resources of the

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staff.

That's all I have in terms of the Voluntary Qualified Importer Program. Again, Brian and I look forward to your questions to FSVP, as well as VQIP. Thank you very much.

[Applause.]

MS. BARRETT: Thank you, Brian and Domenic. I imagine we're going to have plenty to talk about later this morning. So what we're going to do, we're a little ahead of schedule, which is a good thing. We're going to go ahead and take our break, and we're going to get started again at 10:15. Okay? So we'll go ahead and break and come back at 10:15. Thanks.

BREAK

MS. BARRETT: Okay, folks, if you could take a seat. Folks, if you can go ahead and take your seats.

[Pause.]

MS. BARRETT: We will go ahead and get started, so please take a seat.

[General conversation from the room.]

MS. BARRETT: All right. Folks, if we can

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take a seat and begin to quiet down, and we'll begin our program again.

For folks in the room, I know it is a little warm; we have heard that. And they are working on adjusting that. Typically, it's freezing cold, but we do have a big crowd today. So we'll, hopefully, be able to have you at a comfortable temperature.

So we are going to take up where we left off. We're going to have a presentation for you next from Charlotte Christin, who is a senior policy advisor in the Office of Foods and Veterinary Medicine with FDA. She has been our lead on the FSMA Accredited Third-Party Certification Final Rule.

I know Domenic spoke a little bit about that, or at least referred to it in his presentation. Charlotte will tell you where it's relevant.

And then after Charlotte speaks, we'll go into our Q&A session, which will be open to questions on anything that we presented this morning. We would ask that you hold additional questions, perhaps further questions you might have on implementation, until this afternoon when we touch on those subjects

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in more depth.

But when we do get to our Q&A panel, we'll have Charlotte stay with us. We'll also have Brian and Domenic on the panel to answer questions. And we have Sharon Lindan Mayl, who is also a senior advisor for policy Office of Foods and Veterinary Medicine at FDA. And she'll also be part of the Q&A panel this morning, and she'll be speaking more on implementation this afternoon.

So with that, I'm going to turn the podium over to Charlotte.

FSMA ACCREDITED THIRD-PARTY CERTIFICATION FINAL RULE
OVERVIEW

MS. CHRISTIN: Good morning. And thank you for participating in today's imports meeting. I'm eager to discuss with you an exciting new program that FDA is establishing for foreign suppliers and importers of their product to use certification bodies and accreditation bodies that meet stringent FDA requirements.

On November 27th, 2015, FDA issued the final rule establishing the framework of a new program to

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accredit third-party certification bodies to conduct food safety audits and issue certifications of foreign food facilities and their foods.

The final rule reflects input we received from more than 150 commenters on the proposed rule, including comments from accreditation bodies, certification bodies, the food industry, governments, public health organizations, and advocacy groups, as well as individual consumers. We also received valuable input through dialog during the FSMA public meetings and outreach sessions.

Key points about the third-party rule. This is a voluntary program. Accreditation bodies, known as AB's, and third-party certification bodies, known as CB's, are not compelled to participate. Foreign facilities that want to be certified under the program must have an audit that meets these requirements.

The statute defines two types of food safety audits, consultative and regulatory audit, under the program and contains requirements relating to each. We received comments expressing concerns about the scope of consultative audits that would be subject to

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the program requirements.

Based on the comments, we revised the final rule to clarify that a consultative audit is one conducted in preparation for a regulatory audit for certification purposes. Other audits, such as onsite supplier verification audits under the preventive controls rule, as well as FSVP Regulations, are not covered by this rule, even when those audits are performed by a certification body that participates in the FDA program.

The audit criteria, or standards, under this rule are the applicable requirements of the Federal Food Drug and Cosmetic Act and FDA Regulations, which could include not only the applicable FSMA rules, but also any other applicable FDA Regulation, such as seafood or juice HACCP.

The statute requires facilities and foods to be determined in compliance with applicable FDA requirements to be certified under the program.

I would note that FDA is not requiring certification of every food imported into or offered for import into the U.S. The third-party program is

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targeted. Certifications issued under the program are used for two purposes: First, importers will use facilities certifications of their foreign suppliers in helping establish their eligibility to participate in the expedited entry program called the Voluntary Qualified Importer Program, or VQIP, that Domenic Veneziano discussed earlier this morning.

Once the importer has been accepted into VQIP, he or she will gain expedited review and entry of food covered by the facility certification.

Certifications also will be used in determining whether to admit certain imported food into the United States the FDA has determined, based on statutory criteria, poses a food safety risk and must have a certification or other assurance as a condition of admissibility.

This determination is based on a set of factors set out in Section 801(q) of the FD&C Act. Factors include consideration of the capability of the regulatory system of the exporting nation to ensure compliance with U.S. food safety standards.

I note that if a facility is high risk, such

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as for work planning purposes, its products are not automatically subject to import certification under Section 801(q). Only if FDA makes the specific determination I just mentioned will certification be required to satisfy condition of admissibility under Section 801(q).

This slide offers a visual depiction of the third-party program. FDA will recognize accreditation bodies based on certain criteria such as competency and impartiality. Recognized AB's will in turn accredit third-party CB's, who will perform food safety audits and issue certifications for foreign facilities and food for the two purposes previously identified.

It is important to note that FDA will have oversight at all levels of the third-party certification program. This includes the ability to withdraw accreditation from a third-party CB regardless of whether the accreditation was granted by FDA or by an FDA-recognized accreditation body. FDA does not need to wait for an accreditation body to act before taking action against a problematic

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certification body.

We are allowing both public and private accreditation bodies to apply for recognition under our program. At the time an accreditation body seeks recognition, it must demonstrate that it possesses adequate authority, such as the authority to suspend, withdraw, or reduce the scope of an accreditation.

They also must demonstrate competency and capacity. Generally speaking, this means having an adequate number of qualified assessors and adequate resources to sustain operation. They also must have written programs and procedures for conflicts of interest, quality assurance, and recordkeeping.

The AB also must demonstrate that it can meet the FDA program requirements if recognized. Based on comments we received on the proposed rule, we modified our approach regarding the use of voluntary international consensus standards of the International Organization for Standardization, or ISO. The final rule expressly allows an AB to use documentation of its conformance with ISO 17011 in establishing its eligibility for recognition.

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We recognize that some requirements of 17011, such as those relating to confidentiality, may differ from our program requirements. Therefore, in the final rule, we indicate that an AB may need to provide us some additional information to demonstrate that it needs all the criteria for recognition.

A recognized AB has certain responsibilities under the program, including using the certification body eligibility requirements of the third-party final rule when assessing CB's for accreditation under our program. They also must monitor the performance of CB's once accredited, such as through onsite assessment and records review, and submitting the reports of such activities to FDA.

They also must establish and maintain certain conflict of interest safeguards. They must perform qualify assurance activities, such as internal audits, and take timely and effective corrective action to address any identified deficiencies.

They must notify FDA when granting or denying accreditation, and they must provide FDA access to records pertinent to its program activities.

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I note that FSMA allows FDA to directly accredit certification bodies in limited circumstances that are described in the statute. After we have operated the program for two years, if we have not identified and recognized an accreditation body to meet the program requirements, then we may directly accredit auditors.

With direct accreditation, FDA will assume all the responsibilities of an accreditation body under the program. We believe this would be very resource intensive, and as the statute provides, should be used only in limited circumstances. Therefore, we do not expect to use direct accreditation frequently.

Foreign governments or agencies, or any other third party, may seek accreditation under our program. The statute contains a slightly different standard for assessing foreign government auditors than it does for other third parties. Foreign governments and agencies are assessed based on their food safety standards, systems, and programs.

Other third parties are assessed based on

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their internal systems and standards, as well as the training and qualifications of their auditors to ensure that facilities and foods meet the requirements of the FD&C Act.

Based on comments, we modified our approach regarding the use of relevant ISO standards, specifying in the final rule that a CB may use documentation of its conformance with ISO 17021 or ISO 17065 in establishing its qualifications for accreditation.

We recognize that some ISO requirements for certification bodies, such as those relating to confidentiality, may differ from our program requirements. Therefore, we indicate in the final rule that some additional information may be necessary to demonstrate that the criteria for accreditation have been satisfied.

At the time a certification body seeks accreditation, it must demonstrate that it possesses adequate authority, such as the authority to grant, suspend or withdraw certification. It must demonstrate competency and capacity. Generally

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speaking, that means having an adequate number of qualified audit agents and adequate resources to sustain operations.

A CB also must have written procedures and programs for conflicts of interest, quality assurance, and recordkeeping. The CB also must demonstrate its capability to meet our program requirements if accredited.

We received many comments on the audit protocols, notification, reporting, and records requirements we proposed. Based on the comments, we made several changes to these provisions. For example, we removed the requirement to maintain records in English. Now CB's will be able to maintain required records in another language, as long as they provide an English translation within a reasonable time if requested by FDA.

We were unable to accommodate some of the other changes that were suggested, such as dropping the requirement to notify FDA upon discovering a condition that could cause or contribute to a serious risk to public health. The notification requirement

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appears in the statute; therefore, we maintained it in the final rule.

However, we received several comments on the preamble question of whether to require notification based on FDA's Class 1 and Class 2 recall standards. The comments overwhelmingly opposed this idea, and we did not incorporate it into the final rule; rather, we maintained the standard that appears in the statute.

We made some adjustments to the data elements we proposed to be included in audit reports, such as removing the requirement to record information on recent recall. However, we maintained the requirement relating to submission of regulatory audit reports and maintenance of consultative audit reports because those are statutory requirements.

As Domenic previously mentioned, one of the uses of a certification issued under the third-party program is by an importer seeking to establish eligibility to participate in VQIP. In June 2015, we issued draft guidance on program eligibility and requirements. We are considering comments received on the VQIP draft guidance before moving to finalize it.

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In addition to the foundational third-party rule that we issued in November, FSMA requires us to issue model accreditation standards that describe the qualifications for accreditation under the program, such as the education and experience of auditors.

Our model accreditation standards draft guidance references relevant provisions from ISO 17021 and ISO 17065, which are widely used ISO accreditation standards for food safety auditing and other conformity assessment purposes.

We received several comments on the draft guidance, and we are currently reviewing those comments. And when completed, we'll move to finalize that guidance.

The other third-party documents that FSMA requires us to issue is a rule establishing user fees for the third-party certification program. The user-fee rule proposes to assess fees to AB's who apply for recognition and CB's who apply for direct accreditation. The proposed rule also would assess annual fees to recognized AB's and accredited CB's to reimburse the Agency for the costs associated with

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program oversight and monitoring.

We received several comments on the proposed user-fee rule and are considering them before finalizing the rule.

I would note that once the structure for assessing the third-party user-fee rule is in effect, we will launch the third-party program. At that time, AB's may begin to apply for FDA recognition. In the meantime, we continue to work on the third-party IT portal and on establishing the program information, operational plans, and procedures to be ready for program launch.

And, as you've seen before, for more information, you may consult the FDA website. And there's a subscription feature available. You also may subject a question to the FSMA TAN. Thank you for your attention.

[Applause.]

Q&A

MS. BARRETT: All right. So we're now at a point where we're going to turn to the audience, both in the room and on the webcast, for some questions.

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As mentioned, we would like to focus this session really on the specific regulations and programs that have been referenced.

We do have two microphones in the room. So what I would ask for people in the room, if you want to come to one or the other to ask a question, if you just go ahead and walk up.

If you see that there are already two or three people at the microphone, you might want to wait a moment or two. We don't want to have a long line of people standing. So we'll see if that works, if we can kind of work our way around the room with the questions.

Occasionally, too, I will turn to Kevin to see who is asking some questions on the webcast. For everyone asking a question, we do need your name and affiliation, and if you could say that slowly and clearly for the transcriber, I know that that would be greatly appreciated.

The other thing that makes this helpful is if you ask a question, if you can, if it's specific to a program for a supplier verification or VQIP or

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third-party, if you want to mention that up front or direct it to a certain panelist, that just helps us kind of quickly identify who may start the response. And others may join in.

I'm trying to see if there's anything else I should mention before we get started. I think we're in good shape. So again, I'll start on this side of the room and then work to the other, and we'll check the webcast. So please go ahead.

MS. WASSERMAN: Jessica Wasserman, Wasserman and Associates. And this is a question that goes to certification and the third-party accreditation.

So I understand that certification is required only in very limited circumstances, which are VQIP, and if the Commissioner deems that there is an emergency, or however you want to characterize it, and requires certification.

MS. BARRETT: I'm not sure if you're on -- maybe we should just --

[Pause.]

MS. BARRETT: If the green light is on -- is it on?

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MS. WASSERMAN: Yes.

MS. BARRETT: Okay.

MS. WASSERMAN: Okay.

MS. BARRETT: You might just need to speak more closely to it.

MS. WASSERMAN: Should I start over?

MS. BARRETT: No, we're good. Thank you.

MS. WASSERMAN: Okay. So, Jessica Wasserman, Wasserman and Associates. And my question goes to certification and accreditation.

And I understand that certification is required in the two limited circumstances of VQIP and if the Commissioner should deem that it's necessary to require certification in certain emergency-type situations.

But what I don't understand is -- so, is third-party accreditation then contemplated to be useful only in those two situations? Or is it a much broader effort, where third-party certification would become a competitor with or a substitution for GSSI and all of that? Or is the third-party certification also a very limited program really focused on those

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two situations?

MS. BARRETT: And for our panelists, when you respond, if you'll say your name, too, again for the transcriber.

MS. CHRISTIN: Certainly. Charlotte Christin. Thank you for the question, Jessica.

I would begin by saying that the third-party certification program, as you indicated, is quite limited. The Agency is exploring other opportunities for using third-party audits. And certainly, and when I'm finished, I'll turn to Brian to explain a bit about the Foreign Supplier Verification Program.

I think with respect, generally, to third-party audits, the Agency recognizes that industry has devoted a lot of money and attention to building a credible third-party audit program. The Agency needs to think about how and where those types of audits might be useful. But we certainly again do recognize that industry has invested a lot of energy into those types of activities, and to the extent that we can leverage those, it certainly could be to our benefit.

By no means do I think of us as a competitor

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to the Global Food Safety Initiative. You know, again, we're seeking to leverage the best efforts and best practices of third-party audits. So there's an opportunity as opposed to competing.

MS. WASSERMAN: Can I follow up, though? Because I just remain confused, and maybe it is just me. And I apologize for wasting your time if that's the case.

But would the typical importer, say, that needed to have -- they determined that they were in a SAHCODHA situation and so they had to do an annual audit. Would they turn to the accredited FDA program or not in that instance?

MS. CHRISTIN: So, with respect to 801(q), which is the section that I believe you're referencing -- oh, sorry, Charlotte Christin again -- so in that circumstance, the food must be determined to be in compliance with the FD&C Act. And so, as you know, the Global Food Safety Initiative and other private initiatives are based on private standards.

I leave it to the scheme owners to talk about the types of standards they have, but certainly

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those are based in codex. But those are not the requirements of the Federal Food, Drug and Cosmetic Act. I think there are opportunities for scheme owners, and certainly we've had a lot of positive feedback from scheme owners who are interested in how they might perform in that function.

But again, an audit done under this program must assess compliance with public standards -- the FDA Regulations and the Food, Drug and Cosmetic Act.

MS. WASSERMAN: Gosh, I'm sorry. I just have to ask once more, because I'm not really focusing on the GSSI issues so much; I shouldn't have mentioned that so clearly.

But, so not in these two certification situations, but just general audit that you need as an importer to meet your SAHCODHA requirement, where must you go to get that? I mean, can you do to who you have always audited with? Or do you need to -- can you modify that audit and show that it meets the standard? Or do you have to go to this accredited-by-FDA auditor?

MR. PENDLETON: Yeah, this is Brian

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Pendleton. That's a good question. No, the FSVP Regulation doesn't even specify that you have to use an auditor that's accredited in any particular way. You have to use a qualified auditor, and again that's defined as someone who has the appropriate education, training, and experience, or a combination of those, to do an audit that's consistent with the FSVP Regulation. You could use an auditor that's accredited under the FDA system. You wouldn't necessarily have to.

I spoke to the issue of getting a lot of questions from importers, from suppliers, and others about, can they use existing auditing schemes? And it's possible that that may be appropriate, although some schemes might have to be modified to make sure that they address the supplier's compliance with any applicable FDA Regulations, food safety regulations, as that is one of the requirements of FSVP.

There are certain requirements about the results of audits that you need to have to use for FSVP purposes. But that could be -- so, an importer could rely on the auditor that's accredited under FDA

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system or other auditors that are qualified because they have received training under many of the existing programs.

But I think that whether it's using one of the existing schemes or an auditor that's accredited under the FDA system, I think that we hope that more suppliers and importers will use one of those so that we can minimize the burden on suppliers from having to have multiple audits that are requested of them from different multiple customers.

But we're not trying to favor the FDA versus the other auditing schemes; no.

MS. WASSERMAN: Thank you.

MR. VENEZIANO: Let me just add one aspect to that, as well. The flexibility of FSVP, the way the final rule was written just requires you to assess the work of others. So you have that capability of using whatever you want, as long as you do an assessment to ensure that it meets the needs under FSVP.

MS. WASSERMAN: Thanks.

MS. BARRETT: Okay. I'm going to go to this

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side of the room.

MS. LARRIMER: Good morning. Natalia Larrimer with ANSI-ASQ National Accreditation Board. And my question is regarding the third-party accreditation rule. I have two questions, if you don't mind.

You mentioned that 17021 could be used as one of the standards to demonstrate a necessary supplement. As you may know, currently the industry is undergoing a transition period to 17021-1, which is, I guess, the next version of that standard.

I was just wondering if there's going to be any flexibility given to the certification bodies when they're demonstrating compliance to FSMA Regulation if they could use the newer version of the standard, because we will be accrediting them to that new standard in the next two years.

MS. CHRISTIN: Charlotte Christin. We certainly do recognize that ISO standards are frequently updated, or at least at some frequency. And so, again, a CB may use documentation of its conformance with an ISO standard 17021 or 17065. So

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certainly, as those are updated, again a CB could use demonstration of its conformance with that and then supplement it as necessary.

So a CB wouldn't be foreclosed from using documentation of conformance with an updated version of the standard.

MS. LARRIMER: Okay. Perfect. Thank you.

MS. CHRISTIN: Um-hm.

MS. LARRIMER: And my second question, just with respect to, I guess, the anticipated issuing of the model of accreditation standards, the guidance, when do you anticipate that they will be released?

MS. CHRISTIN: Charlotte Christin.

[Laughter.]

MS. CHRISTIN: We are working diligently to get it out. We can't start the program until we get the model accreditation standards final guidance and user-fee rule issued. So we know we have an eager audience, and we certainly are eager to have the program up and running. So we are working very hard to get those two documents issued.

MS. LARRIMER: Okay. Do you anticipate it

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within this year? Or you don't know yet? It's always dangerous ground for us, too.

[Laughter.]

MS. CHRISTIN: It is dangerous, so. Thank you for your interest, though.

[Laughter.]

MS. BARRETT: I'm going to come back to this side of the room. And then I'll take your question, and then we'll go to the web to get a couple. So please go ahead.

MS. BOSTOCK FELIX: Good morning. My name is Niki Bostock Felix, and I'm with Grain Millers. And I have a question as it relates to the Foreign Supplier Verification Program. My question is really around a foreign facility or foreign supplier that has the same corporate headquarters here in the U.S.

So, for example, we have manufacturing facilities here in the U.S., and we also have some manufacturing facilities within Canada that are subject to the same companywide standards of the U.S. that we have for our facilities here from a food safety and hazard-control perspective. And it has the

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same supply-chain management overview.

So my question is, do the facilities in Canada require the same oversight from a Foreign Supplier Verification Program as, for example, some of the facilities that we import from in other foreign countries?

MR. PENDLETON: It's Brian Pendleton.

Thanks for your question.

There isn't an exemption for food that is imported from suppliers that are part of the same corporate structure as the importer. But the importer definitely can take that into account as they're conducting their various activities under FSVP, whether it would be, for example, when you evaluate your foreign supplier.

In that case you're probably going to have a lot more information about them than maybe some other entities. Maybe not necessarily, but you might, and that could factor into your decision as to certainly whether to approve the supplier if you think you're going to do that.

But more importantly, to determine what type

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of supplier verification activities you need to conduct and the frequency with which you need to conduct that. So you can imagine a situation where if you have suppliers that are part of the same corporate structure and they're subject to the same internal supply-chain requirements, that you might expect that you might not need to do the same sort of verification activities as you might if you don't have that sort of relationship with the supplier.

MS. BOSTOCK FELIX: And then just a quick follow-up to that. You had mentioned that the Agency is conducting a review for comparable systems. When that review is concluded, would that potentially change that, my first question, or any of the activities involved in the first question? Or is that independent?

MR. PENDLETON: For those countries with food safety systems that we have officially recognized as comparable or determined to be equivalent, then if you're using a supplier from that country and the supplier is in good compliance standing, there are some other requirements, then in that case you would

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not be subject to most of the FSVP requirements.

So you wouldn't need to be doing hazard analysis. You wouldn't be doing supplier verification activities. So that would significantly change that, assuming that the food that you're wanting to import from that supplier is covered under, in the case of comparability, the systems recognition arrangement that we might have with that country.

Or if there's an equivalence determination that's covered under this for that food that's covered under that determination, then it wouldn't be subject to most of the FSVP requirements. So, yes, that could significantly change the impact of FSVP on the importer of a food from such a supplier.

MS. BOSTOCK FELIX: Thank you.

MS. BARRETT: Okay. We'll go to the other side now.

MR. LIEBERMAN: Hi. Erik Lieberman with U.S. Food Imports LLC. This is a question relating to the FSVP rule and its applicability to food contact substances.

FDA in the final rule cites a case, U.S.

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versus Articles of Food 688 Cases of Pottery (Cathy Rose), which references that ceramic pottery that leaches lead is adulterated food.

So my question is, what is the scope of applicability of the FSVP rule to food contact substances? Will importers of pots and pans be required to conduct verification? Will importers of knives and utensils, cutting boards, countertops? Even food manufacturing equipment -- would all of these items be within the scope of the FSVP requirements?

And then, secondly, the regulation requires evaluation of a foreign supplier's performance and the risk posed by the type of food imported. What would be the type of food contact substance? So, when you're conducting the verification, you conduct it for one type of food. What's one type of food contact substance?

And then, finally, under -- well, two more. Does VQIP apply to food contact substances? Could a food contact food substance importer be a VQIP participant? And then, in terms of systems

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recognition of a foreign food safety system, could a foreign food safety be recognized just for purposes of food contact substances?

For example, could FDA just recognize a country that exports a lot of pots and pans to the United States for just that, for the production of food contact substances, rather than food, traditional food that's consumed by humans or animals? Thank you.

MR. VENEZIANO: If you don't mind, let me take that. This is Domenic Veneziano.

The question answer for the Voluntary Qualified Importer Program is that it is exempt from the Voluntary Qualified Importer Program. So we defined "food" under VQIP to exclude contact surfaces, and utilized the definition of "food" under the Bio-Terrorism Act under the final rule requirements.

MR. PENDLETON: This is Brian Pendleton. So, yes, food contact substances, to the extent that they fall within the definition of "food" under the act, they are subject to the FSVP Regulation, where we have received a lot of inquiries about exactly how FSVP will apply to food contact substances as they are

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imported. And so, we are working through some of those questions.

I'm not an expert on whether pots and pans are covered under the scope of those materials. Perhaps somebody else on the panel can address that. But as it currently stands, the importers of food contact substances will have to look at whether there are hazards.

If there are hazards in those substances -- there may not be, but if there are, whether there are any hazards that are known recent and foreseeable and require a control. And in that case, they would need to conduct some type of supplier verification activity.

In terms of a type of food contact substance, I mean, we have the reference to the type of hazard analysis that could be used that gives more leeway so that you could broaden the scope of a hazard analysis to apply to more than one product. So I'm also not an expert on what typical types of food contact substances there are. Perhaps somebody else on the panel, or maybe Jenny, could talk about it.

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And then with the respect to the inclusion of food contact substances in systems recognitions arrangements, we only have one right now with New Zealand, and I can't speak to whether they're included. Maybe Sharon can.

MS. LINDAN MAYL: I just want to add two points to what Brian is saying. In terms of identifying hazards, remember there's standards about being reasonably foreseeable. So when you think about hazards in food contact substances, that's something to think about, about the history of whatever it is that you're bringing in and whether there has been a history of that. And I just wanted to add that to what Brian was saying.

With respect to systems recognition, right now the systems recognition is sort of the whole -- the whole system is what we're looking at with respect to systems recognition. So, you know, we're looking at all of the standards and not isolating one.

You know, I think in the future we can think about whether it's a possibility to think about narrowing it and having maybe not systems recognition,

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but particular agreements on certain things. But right now the systems recognition program is not isolated to particular standards.

MR. VENEZIANO: This is Domenic Veneziano. Pertaining to pots, pans, knives, anything, it doesn't matter what it is. As long as it meets the definition of a "contact surface," it still falls under FSVP. We'll say that we are looking into what those hazards are, working with the experts to determine how it can play a role in FSVP, and in determining whether there can be a way around it or whether there can't be a way around it.

Right now it falls under FSVP, and the requirements would still be met. And as Sharon said, you have to identify the hazards associated with those and then deal with them as we see fit. But everything, whether it's pots, pans, knives, all fall under that definition.

MR. LIEBERMAN: Thank you.

MS. BARRETT: Okay. We're going to turn to Kevin to see if we have some questions from the webcast audience. And, Kevin, if you have one or two,

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we'll go ahead and take those, please.

MR. ROBINSON: Thank you. The first question is from Wilson Lau from nuherbs Co.

"Under FSVP regarding dietary supplements, would a dietary ingredient such as Vitamin C be considered an imported dietary supplement component?"

MR. PENDLETON: This is Brian Pendleton. Dietary ingredients, to the extent that they are a component of a dietary supplement, they would be covered under the particular provisions so that we have, that I mentioned, with respect to the importation of dietary supplements and dietary supplement components for which the importer or its customer has to establish certain specifications.

So there are certain provisions in the dietary supplements CGMP provisions that apply to provisions with respect to components and to packaging. So if the ingredient is a dietary supplement component and it falls within those provisions under which the importer or its customer would set some specifications for that, then in that case, most of the FSVP requirements would not apply.

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The importer would need to ensure that it is recognized as the FSVP importer at the entry of the item to the United States.

If for some reason a food, a dietary supplement ingredient does not fall within that, then it would be subject to the provisions that we have for other dietary supplements.

MS. BARRETT: Okay. Kevin, do we have another question?

MR. ROBINSON: We do. This question is from Dan Kastor from McCormick & Co.

"If a BTA Regulation number is already issued for the facility exporting to the U.S., do we also have to obtain and document a DUNS number?"

MR. VENEZIANO: This is Domenic Veneziano. So, the question had to do with if a prior notice number is already submitted, do you have to also provide a DUNS number? I'm not sure if it's related to FSVP requirements or VQIP requirements. But the answer is going to be yes either way in terms of that.

The prior notice requirements under the Bio-Terrorism Act is totally separate from the FSVP

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requirements or the Voluntary Qualified Importer Program. So either way, you would still have to submit it as part of the process.

MS. BARRETT: Okay. Thank you. We're going to go back to the room for some questions. And then we'll follow up again with the webcast.

So if you'd like to go ahead and ask your question?

MR. FeDUKE: Good morning. My mic is a bit low. But good morning, everyone. Can you hear me in the back? Good morning. My name is Mark FeDuke, VLM Foods. And my question is regarding FSVP inspection and enforcement, which probably falls into a broader bucket of compliance promotion.

One of the elements that we see as an importer is the incredibly important need for compliance promotion. Many of us are FSMA apostles doing our work in trying to spread the good word. But not everyone is in that same camp.

And so, when we go overseas, occasionally we run across foreign manufacturers who are confused. And of course, water goes down the path of the least

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resistance, and so some of us may have some unintended negative consequences for being FSMA apostles.

So having made that commentary, my question is this. I noticed in Mr. Pendleton's presentation this morning, page 23 referred to a comment about, "If foreign suppliers are subject to the PC rule." Could we get some clarity on how enforcement of that may work?

When we discussed that with our trading partners overseas, their question is, how will that inspection work? How will that enforcement work? And if they're found wanting, let's say by having a food safety plan, but an error in their supplier verification component, does that see the registration being suspended, possibly yanked?

That degree of clarity on enforcement will greatly help our compliance promotion initiatives.
Thank you.

MR. PENDLETON: This is Brian Pendleton.
Thanks for the question.

Some foreign suppliers are going to be subject to the regulation on preventive controls for

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human food or the preventive controls for animal food. Or some of them are going to be subject to the Produce Safety Regulation. And they will be subject to potential inspection for compliance with those.

As I talked about some of the challenges we have to inspect foreign suppliers for compliance with those programs, we will be doing that.

But in the context of this morning when I was talking about the compliance state, so that's where if you are an importer of food from a supplier that is subject to either the preventive controls or Produce Safety Regulation, that's going to affect when you need to come into compliance with FSVP, and generally it's six months after that your supplier needs to come into compliance with it.

But I'm not sure if you're asking how they ascertain whether they are in compliance, but --

MR. FeDUKE: Well, maybe it's -- I should perhaps apologize that maybe it's more of a comment than a question. But moving forward, given the incredible work that you folks have done in stakeholder engagement, clarity on enforcement aspects

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will greatly assist trade promotion. Because quite often, when we speak with folks overseas, they see the 130-page provisional rule, the 856 Final Rule, and it gets a little complicated for them. So we're doing our part, but that would just be helpful.

MR. VENEZIANO: So, Mark, this is Domenic Veneziano. I think the question overall is more of an implementation and power going about to implement the rule itself, which is going to be covered this afternoon.

But in terms of whether you're going to suspend or whether you're going to do it, I think it's predicated upon the violations that we find and the course of action taken as a result of those violations.

So, you know, it's hard to give an answer right now, but I think it can be brought up later on. I think it's going to be during the inspection, what we find and what the enforcement aspects, or what's warranted based upon what we find during the inspection. So it's hard to give an answer whether we're going to suspend or whether we're going to give

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a warning letter or whether it's going to be an import alert overall. It's going to be a combination of all, and we can probably talk about it more this afternoon.

MR. FeDUKE: Thank you.

MR. VENEZIANO: You're welcome.

MR. PENDLETON: Brian Pendleton. Just to add, so FSVP, of course, applies to the importer, not to the foreign supplier. But it's possible that we might, in terms of, let's say when we're doing inspections of importers in the United States and looking at their records, we might find some reason to believe that some of their suppliers are suppliers not in compliance.

In that case, we also might use that information to look into the foreign supplier, if there's a reason to believe that they are not in compliance with a regulation that they're subject to.

MR. FeDUKE: Thank you.

MS. BARRETT: And this is Kari. I just wanted to add, this afternoon we will talk about implementation more. But you'll hear during that presentation a real emphasis on education before we

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really get into enforcement. So, you know, we all recognize these are very complex rules and really, our initial focus will be on educating people and giving them the guidance and the information that they need. So, a lot more to come on that, as well.

I'm going to go to the other side of the room.

MR. WATSON: Hello, panel. My name is Nick Watson. I represent Nopal Export and Chia Growers from Mexico. We're leading exporters to the United States, as well as to other parts of the world.

My questions really are quite simple, quick. So you'll be happy about that. But this is directed pretty much to Captain Domenic, and probably to Todd as well later. But I just wanted to ask you. We've noticed in Mexico that investigating FSMA, taking a look at the documents that are available on your website, we've noticed that some of the documents are in Spanish.

And we'd like -- my first question, quite simple, do you -- does FDA intend to, being that, you know, Mexico is a very large exporter of food and

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beverages to the United States, do you feel that it's necessary, so you have plans to have your documents, actually the regulations and implementation in Spanish?

MS. LINDAN MAYL: So again, this gets a little bit to the implementation of the regulations, and we're going to cover this a lot more this afternoon.

But obviously, the import rules affect a lot of foreign suppliers from a lot of countries. We have made great efforts to try to translate some of the key documents, certainly. The entire rules would be a little bit more of a challenge. They're hard enough to get through sometimes in English. So when we start translating them, it gets difficult.

But we'll talk a little bit more about the international outreach this afternoon. But it is something that is very important to us with respect to the import rules, but also with respect to the produce rule and the preventive controls rules in terms of reaching out to foreign suppliers to ensure that they have the information I need. So I would just say

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let's hold off a little bit, and we'll talk more about that this afternoon.

MR. WATSON: Okay. Thank you.

And then the second question is, we've recently -- one of our entities is a juice facility. And we've recently been certified by COFEPRIS. And that would be the NOM 251, which is quite similar to the CFR 221.

My question is, in regards to that, is there any -- Captain Domenic, you had mentioned that you were in talks with COFEPRIS to try and get them up to speed. What do we do now that we've been certified? We've been inspected. It took six months for us to get the actual document, seven months actually. But what is the FDA doing in order to get COFEPRIS up to speed with FSMA?

MR. VENEZIANO: I can tell you that we work closely -- this is Domenic Veneziano.

We've been working closely with COFEPRIS and SENASICA on the rules. We were with them last week going over them with the Fresh Produce Association and talking about the rules themselves. So

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they've been engaged very early on.

I would say that -- and during that presentation, I actually asked the individuals, "How many have read it?" I can tell you that COFEPRIS and SENASICA understand all of the rules related to FSMA, in terms of how it applies to them. So I think they're already engaged and they understand fully what the requirements are.

I think they're going to be interested in the near future with systems recognition, and we can play a part on that. In terms of the certification, there are things that can be utilized moving forward. So Brian talked about the Foreign Supplier Verification Program and the fact that you can assess other works of certification.

So, you know, if there was a certification that was done by SENASICA, it's very possible that that would meet the needs under the Foreign Supplier Verification Program, as long as you assess it and it identifies all the hazards associated with that work.

So there are things that are being there. We're working very closely with not only SENASICA and

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COFEPRIS, but I think the international community as a whole in terms of all the outreach, all the guidance documents, and all the work that we've been doing moving forward.

And we will continue, I think it was mentioned in Brian's presentation, to continue to do outreach, continue to do guidance documents, and put them in the web, and to make it available in different languages as well. So a number of things that we're doing not only with Mexico, but with other countries.

MR. WATSON: Will you keep meeting with COFREPRIS regularly?

MR. VENEZIANO: Absolutely. We have a working group that work with them regularly. And we'll continue to provide guidance not only to them, but to other countries.

MR. WATSON: My last point is a comment I'd like to make to you since you seem to be quite familiar with that process.

I'd like to tell you that the inspectors that we've found were very thorough, very capable, very professional. And they took us through a

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rigorous GMP HACCP at our chia facility. And it was very good. But the bureaucracy there, I think needs a little bit more attention.

That's all I ask is that, they're not familiar with the FDA way of doing things. And you smile, so I'm sure that you're aware of that. But --

[Laughter.]

MR. WATSON: Even (inaudible) -- even when it comes to our organic certification it's the same thing. I mean, they just take a year or two years to determine what to do.

So I know that the FDA cannot -- it's not their jurisdiction. But I really hope that you improve their bureaucracy in this because they're way far behind what you want to implement in Mexico in terms of bureaucracy.

MR. VENEZIANO: Thank you for your feedback.

MS. LINDAN MAYL: I just want to add something with respect to --

MS. BARRETT: Sharon Mayl.

MS. LINDAN MAYL: Oh, I'm sorry. I keep forgetting to do that. This is Sharon Mayl.

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I just want to add something with respect to the work of foreign governments. And I want to do it outside the context of the systems recognition agreements that we have, because those have separate requirements under FSVP.

But I just want to clarify that when a verification activity is required and an audit is chosen, with respect to that being the correct verification activity, the rule does allow for foreign governments to do that audit. But I just want to clarify that that, allowing a foreign government to do that audit, they still must meet the two requirements in the rule.

And the first is the one that Brian referred to earlier, the fact that they be a qualified auditor, have the necessary education, training, experience to do that audit.

But the second is that the audit must be done to U.S. safety standards or standards that offer the same level of protection of them. So that has been sort of a misconception from our foreign trading partners. So any verification work that gets done

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outside of the systems recognition agreement must consider U.S. safety standards, so produce and preventive controls, and that the supplier is using processes and procedures that offer the same level of protection as those rules.

So verification to some other standard, whether it be a foreign standard or whether it be a private audit standard still must be benchmarked against our U.S. safety standards. And I just want to be very clear about that.

And again, outside the systems recognition process, which has its separate requirements. But other work by foreign governments with respect to verification activities.

MR. WATSON: That's a very good point. It just brings up a quick question on this one. What do we do with that government audit, that certification, let's say? After the audit inspection we came to, do we give it to the FDA? Do we translate that certificate? Because we actually do have a GMP certificate issued by COFEPRIS. Do we offer that to the FDA office at Mexico City at the embassy? Or do

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we submit it to the FDA here?

MS. LINDAN MAYL: Okay, so --

MR. WATSON: Because there's no information on any other websites, either COFEPRIS nor FDA, on what to do with that certification, or that certificate, sorry.

MR. PENDLETON: This is Brian Pendleton. With respect to this, I'll comment and maybe Sharon can.

FSVA regulation doesn't require the importer to send, submit us any information unless we ask for that specific information ourselves as part of our inspection and oversight. So rather, the requirement would be to obtain and to maintain documentation of your supply verification activities.

And if you were going to rely on some sort of certificate as your verification activity, possibly with some other information to meet your requirement to show that the supplier is using processes and procedures that provide the same level of public health protection -- wow, that's a mouthful -- then you would just -- you would maintain that

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certification and whatever documentation that you did for your supplier verification activity so that we could see that if we did inspect the importer.

MR. WATSON: We invited the FDA to come in and inspect our facility, the Mexico office.

MR. PENDLETON: Thank you very much.

MS. BARRETT: Thank you.

MR. WATSON: Thank you very much. This is very valuable, this talk.

MS. BARRETT: Thank you.

We'll come over to this side for a question.

MS. de KLAUMAN: Thank you. My name is Anna de Klauman, and I'm an agricultural counselor with the Embassy of Denmark. Thank you very much for having this meeting; it's very useful. I have a couple of questions on the FSVP.

So even though it doesn't enter into force, earliest May 2017, there's already a lot of dialog and a lot of attention both from the importer and also the foreign supplier. So my question is, how would FDA suggest that the foreign suppliers handle this dialog with importers who already now start to put forward a

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lot of new requirements that do not necessarily --
that is not written in the regulation?

Nobody wants a bad relationship with their importer. And it's difficult. We need to handle that because we have not seen the guidelines yet. One of the things that we've already seen is requirements for a lot of documents in English. And, yeah, I think that foreign suppliers are really uncertain on how to handle that. So I was wondering if you had any suggestions on how to move forward.

I was also wondering if you could reflect a little bit on the FDA audits that we have. We have FDA coming to our countries and inspecting facilities. And how the statutes of FDA orders are viewed vis a vis private audits? Because when a foreign supplier tells their importer, "Our plant, our factory has already been FDA audited, and everything looks fine," then sometimes that's all. It really doesn't matter, because we have our own requirements. So in the future, what are your reflections on FDA audits vis a vis private demands?

And then I have to ask, when do you think

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the FSVP guidelines will be public? And then, I have heard -- I don't know if it's true, and it's a really simple question. Do companies have to reregister with FDA within the FSMA? Or can they use their existing registration? I've heard some companies talking about that. I guess it's pretty simple.

MS. BARRETT: Let's pause and go to the panel and maybe tackle these.

MR. VENEZIANO: This is Domenic Veneziano. I'll take your last question first, the reregistration. You don't have to register under FSMA. You have to register under the Bio-Terrorism Act, which is an every-two-year requirement. So you have to renew every two years.

MS. de KLAUMAN: So it's nothing new?

MR. VENEZIANO: That's correct.

MS. de KLAUMAN: Okay.

MR. PENDLETON: This is Brian Pendleton. Thanks for your many questions.

The first one is right. We recognize and we've heard in our outreach to date concerns about, from both importers and foreign suppliers about how

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they can make their foreign suppliers aware of what they need to comply with, as well as what the type of information that importers need to obtain from their foreign suppliers in many cases to meet their FSVP requirements.

And I know we are doing outreach to -- we have outreach internationally that we are trying to do to spread the word about FSMA and the effect of FSMA as much as possible. And we're having meetings like this to talk with importers.

But right, even though it's not until May of next year that the first importers will need to comply with FSVP, they do need to be talking with their foreign suppliers to make it clear the type of information that they, the importers, will need to meet their FSVP requirements.

And perhaps in some cases, that's going to mean making the supplier aware that they have to comply with the preventive controls regulations or produce safety regulations in some cases.

But we certainly realize that that needs to proceed both from the importers as well as FDA doing

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as much as we can to make the new FSMA requirements known to those who need to comply.

The second question you had, I think, was --

MR. VENEZIANO: Can I just add to that?

MR. PENDLETON: Sure.

MR. VENEZIANO: I mean, obviously, the requirement -- this is Domenic Veneziano. The requirements don't go -- the compliance dates move until May of 2017. Obviously, if you want to do business with an importer, the importer can put in requirements, whatever they want, and you have to comply with them if you want to do business.

But I would say, you know, if you're looking for advice in terms of going back to them, you let them know that the guidance for FSVP isn't out there yet. And you're not sure what you have to comply with in order to meet that. And you respectfully request that you kind of wait for that.

But you still have to do business with them. So they can put in place and put in contracts anything that they want to except that. And I think they're trying to get ahead of the curve in terms of what is

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expected.

But there are a lot of people giving presentations, so that there are a lot of people trying to give advice on things that, the only thing you really have to work with is the current regulations that's out there and not any of the guidance document that goes with that.

So, obviously, the guidance documents are going to provide a lot more information that's currently in the regulations.

MR. PENDLETON: Brian Pendleton. I just want to add that, so we are making training available. We've started to do so on preventive controls. And we eventually will have a training module component with respect to supplier verification that could, would be relevant for compliance with the supply chain program provisions under preventive controls, as well as FSVP.

So those are things that we are doing. The training is not mandatory for FSVP importers, for example. But we'll be making that information available.

With respect to FDA audits, I think you're

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talking about inspections that FDA conducts of foreign suppliers for their compliance with preventive controls or produce safety in the future.

I mention that there is a provision in the FSVP Regulation about, in some cases the importer could rely on an inspection that's conducted by FSVP of the foreign supplier for compliance with whatever the application FDA Regulations are, that the importer could substitute that for an onsite audit that might be conducted by, say, a qualified third-party auditor under certain circumstances.

But outside of that context, an FDA inspection versus an audit that's performed for other reasons -- again, if you're going to rely on an audit to meet your FSVP requirements of supplier verification, then it has to meet the certain requirements that we've talked about.

You have to use a qualified auditor. The scope of the audit has to include compliance with the applicable FDA food safety regulations. And I guess the other important requirements is that the documentation of that audit, there need to be certain

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things that are included in the results of that audit that you get and that you had maintained.

So those requirements have to be met whether that audit is conducted by a third-party auditor or a government official.

MS. BARRETT: Thank you, Brian.

And Sharon has one quick comment, and then I think we need to go on to our next question if we can. And I will ask for people asking questions if we can limit it to two, to start. And then you could always come back. So, thank you.

MS. LINDAN MAYL: Yes. This is Sharon Mayl. I think the reason there is confusion is because you used the term "FDA audit" and we use the term "FDA inspection." So I think what you were asking is whether an importer can rely on an FDA inspection. And that's what Brian was answering. So I think --

MS. de KLAUMAN: Yeah. I mean, just basically, when a company asks me, "So, what is the value of an FDA inspection if we can't really tell it, show it to demonstrate that we are fulfilling" --

MS. LINDAN MAYL: No, and I think what Brian

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is saying is that you can use an FDA inspection, because it's clearly going to be to FDA safety standards if our investigators are going out and looking at a farm facility.

MS. de KLAUMAN: So we just have to convince the importer about that.

[Inaudible interjection and laughter.]

MS. BARRETT: Okay. We're going to go across to the other side of the room for a question.

MR. ICHTER: Yes, thank you. My question is a follow-up on the discussion we just had and touches on the relationship between the importer and the foreign supplier.

The problem with this situation is that it mixes regulatory issues and commercial issues.

Let me explain. Let's try to project all this in reality. I spent half-a-day with an importer in New Jersey not long ago. Two hundred or three hundred containers of food imported a year. I tried to bring up the subject. I was talking Chinese.

The guy had no clue what I was talking about. He had never heard of FSMA. He had never

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heard of FSVP. So that's one set of importers out there among the 40,000 food importers in the United States that you people will have to deal with at some point.

On the other end of the scale, you know, you have what I would call the over-zealous importer. And my question relates to that. We have a situation, and I was doing some outreach work with the French dairy industry last week in Paris. And I had a lot of questions regarding this.

You know, we are facing (inaudible) by importers to submit food safety plan, all audit reports, integrally audit reports, by a given date or as they were discounting you buying from that supplier. And the given date is like May 2016. It has nothing to do with your order.

And of course, everything has to be, as my colleague said, the food safety plan (inaudible) it has all to be translated in English because these people don't want to read a foreign language, even though the reg states it's okay.

The second issue, which is a much more

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important issue, is when you give them an audit or a poll, it touches on process. And you bring up the issue -- and this was put to me several times by suppliers -- the issue of confidentiality and trade secrets, which seems to be very important to our supplier, at least. We have no guarantee on how this is going to be used.

So the question is -- I mean, of course, we have a law firm now in between, which is going to try to help us to draft some kind of confidentiality agreement. But it is worth what it is worth.

And I don't recall -- I read the comments, but I don't recall, do we have to submit the integrality of the audit? Or just the conclusion of the audit? And how can we protect for processes and trade secrets contained in these audit reports?

MS. BARRETT: Panelists?

And I'm sorry, sir. I'm not sure if we got your name and affiliation in the record.

Ralph Ichter. I represent -- sorry, I forgot to tell you. I'm CEO of Euroconsultants, Inc., and I represent in this instance the French dairy

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industry.

MS. BARRETT: Okay. Thank you.

Panelists?

MS. LINDAN MAYL: I think there were a number of questions wrapped into your statement and your questions. So I want to --

[Inaudible interjections and laughter.]

MS. LINDAN MAYL: I was tricky.

MALE VOICE: Nicely done.

[Laughter.]

MS. LINDAN MAYL: We caught that.

So, in terms of what the -- again, I think this gets back to what the woman from Denmark was saying as well. What importers are asking for right now, obviously it's somewhat between an importer and their supplier. And I think we all recognize at FDA that there is a huge outreach component to this, which we'll talk about to make sure that people understand what's required and when things are required.

With respect to confidentiality and trade secrets, again if you're talking about between the supplier and the importer, I'm not sure I understand

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it completely. But with respect to FDA, we're governed by the same laws that would govern any information that we have that gets to confidentiality and trade secrets.

Again, I think you were talking about FSVP. And I want to remind you that, with respect to FSVP, nothing needs to be submitted to us with respect to that.

MR. ICHTER: No, FDA, the importer. Well, you know, if you have a process that's described in details in a document to all the importers, someone can set up a plan in Vermont and copy your files. It's as simple as that. That's now a concern, not the FDA.

MR. PENDLETON: Brian Pendleton. As Sharon mentioned, the FSVP and a number of our regulatory controls, they are subject to the requirements that we have, the regulations on public disclosure, and it's Part 20 of our regulations.

And so if there's confidential commercial information, if there's trade secret information in the documents that we are reviewing, if we're

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inspecting importers, you know, that's going to be -- we're not going to disclose that under those existing regulations that we have.

So it's going to be treated the same. It's going to be protected under those regulations. We specified that the public disclosure regulations that we have apply to FSVP records.

In terms of -- you're right that the FSVP importer does not have to have the whole audit report. They need to maintain the conclusions of the audit. There is some other information there, the dates. If there is a corrective action taken, they need to have documentation of that. But it's the conclusions of the audit, not the entire audit report, that the importer needs to maintain.

MR. VENEZIANO: Let me just --

MR. ICHTER: Thank you. That's important, yes.

MR. VENEZIANO: This is Domenic Veneziano. Let me just add a couple of things related to the confidentiality in the work. Under FSVP importer, the importer is responsible to ensure that the products

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are in compliance and meet the allergen requirements of 402(w). They're also required to do an audit if they believe that one is necessary.

The confidential aspect of that is going to have to be between the foreign supplier and the importer in setting up the contract, because I think it's impossible to do an audit and not look at the processes that are being developed.

MR. ICHTER: That's right.

MR. VENEZIANO: So the confidential aspect in the trade secret is going to be implied in the work that gets done by the FSVP importer, and I think you're going to have to work out the confidentiality and trade agreements within the contract as it gets developed.

If you're concerned about doing that, maybe you don't want to deal with that importer or vice-versa under the FSVP aspect of it. But I think it's almost impossible not to actually take a look at the processes and procedures if you're going to do an adequate audit.

MR. ICHTER: Okay. Thank you very much.

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MS. BARRETT: Okay. Thank you.

I'm going to go to Kevin and see if we have a couple of website questions.

MR. ROBINSON: A couple of clarification questions. The first one from Margaret Eckert from Eurofoods Regulatory Advisors, for FSVP.

"I understand that candies, cookies, crackers, et cetera, would be exempt from FSVP. But they would need to fill preventative controls. Is that correct, or are they exempt from both?"

MR. PENDLETON: This is Brian Pendleton. Thanks for the question.

I was mentioning that there are certain foods such as candy and cookies might be -- they're not exempt from FSVP. But it's possible that you might do a hazard analysis, and can food -- that there aren't any known or reasonably foreseeable hazards that require a control.

So in that case, obviously, you have to do a hazard analysis to reach that conclusion. But if you did that and found that there are no hazards requiring some control, then you don't need to do food and

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supplier evaluation. You wouldn't need to conduct any specific supplier verification; you wouldn't have to conduct supplier verification activities, period.

But the manufacturer of a package of cookies in a foreign country is going to be subject to preventive controls in that foreign country. So I hope that addresses that.

MS. BARRETT: Okay. Do we have another question?

MR. ROBINSON: This question is from Bob Rada from the Blommer Chocolate Company.

"For Brian: During your presentation you made some comments about products needing processing, such as cocoa beans and coffee beans, and possibly not needing inclusion in FSVP because they would be changed before consumption. Can you please clarify?"

MR. PENDLETON: This is Brian Pendleton. Yes, we have provisions stating that if you determine that the food that you're importing really can't be consumed without it having to undergo a process that is going to address the hazard in the food, and we give examples in the regulation of coffee and cocoa

beans.

There may be some others. But if that's the type of food that you're importing that really it can't be, generally not possible to be, consumed unless it undergoes a treatment that addresses the hazards in the food, then in that case you don't have to do the supplier verification activities. You don't have to analyze the food and supplier if you can reach that conclusion and document your reasoning for that.

MS. BARRETT: Okay. We're going to go over to the mic. And again, if you could speak directly into the microphone -- I think the transcriber is having a tough time getting some of the questions.

MR. LIEBERMAN: Erik Lieberman, U.S. Food Imports LLC. I have a couple of questions.

The first one relates to the audits that are performed for purposes of FSVP compliance. Those audits are required to consider all applicable FDA food safety regulations. Does this include compliance with the food defense rule? And if applicable, in some circumstances, the Sanitary Food Transportation Act rule is applicable to a foreign exporter. Do

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auditors have to look at compliance with those standards as part of the FSVP audit?

[Pause, inaudible conversation among the panelists.]

MR. PENDLETON: Okay. No problem. Go!

[Laughter.]

MS. BARRETT: Do you need a moment to deliberate?

MS. LINDAN MAYL: I think this is one of the questions that we're going to have to clarify in the guidance in terms of with respect to the scope of it. You are right in that the law itself and the regulation itself -- well, the regulation itself says they have to consider all applicable food safety regulations.

And I think that there is some confusion. You know, I keep going back to, and I'm hoping I'm saying the standard right about "reasonably foreseeable hazards." And that is something that you want to look at in terms of whether that is something you need to verify.

But we are going to be providing further

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clarification in the guidance document. So hang on for that one, and we're going to --

MR. LIEBERMAN: Sure.

MS. LINDAN MAYL: That's why we sort of looked at each other, because we know that that's something that needs some clarification.

MR. LIEBERMAN: Okay. Excellent.

MR. PENDLETON: Brian Pendleton. Yeah, I just can't remember what we might have said in the preamble about specifically whether that includes the food defense regulations that you're talking about.

MR. VENEZIANO: This is Domenic. I will say that if you identify it as a potential hazard, then it should be covered under that. But as they said, I think it needs to be brought out a little bit more in terms of clarification associated with it.

But the responsibility of doing an audit and addressing it is to identify all potential hazards associated with the importation of food. And I think one of the hazards could be the intentional contamination or adulteration of a food. And how do you prevent that would be to ensure that there's a

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food defense program in place.

MR. LIEBERMAN: But then when you get into that, you're required to consider intentional adulteration for purposes of economically motivated adulteration as part of the hazard analysis.

MR. VENEZIANO: Um-hm.

MR. PENDLETON: Right.

MR. LIEBERMAN: But the regulation doesn't specify that you have to consider intentional adulteration for purposes of acts of terrorism as part of that.

But then again, that food defense regulation is applicable to certain foreign facilities. So we'll get further clarity from the Agency on that.

I have one other question related to the definition of the "importer." And this keeps coming up. So "importer" is defined in the final rule as "the U.S. owner or consignee of an article of food that is being offered for import into the United States. And if there's no U.S. owner or consignee at the time of entry, then the importer is the U.S. agent or representative of the foreign owner or consignee."

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"U.S. owner or consignee" is defined as "the person in the United States who at the time of entry either owns the food, has purchased the food, or has agreed in writing to purchase the food." There's not a hierarchy there like there is in the definition of "importer."

MR. PENDLETON: Correct.

MR. ICHTER: So, what happens in circumstances -- and there are circumstances out there in industry where you have one U.S. entity at the time of entry that owns the food, and then you have another U.S. entity at the time of entry which has a written purchase agreement with the foreign supplier. Who would be the importer there? And that's a question that we've been grappling with.

MR. PENDLETON: Brian Pendleton. That's a very good question. There could be circumstances where at the time of entry there is a U.S. owner and there is a U.S. consignee, or even multiple consignees. We regard that, and we'll be talking about that in the draft guidance, that those entities need to work it out amongst themselves who is going to

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take the responsibility for complying with FSVP, because someone needs to do that to ensure that the FSVP requirements are met.

MR. LIEBERMAN: So the Agency would turn to the actual owner first? The entity with the purchase agreement may assume that responsibility contractually. and presumably that could be provided to FDA?

MR. VENEZIANO: Yeah. This is Domenic Veneziano. During the entry process, you actually have to identify the FSVP importer during the entry. So you have to provide that information to Customs to come to FDA.

So you should know before the shipment who is going to be handling the FSVP requirements, whether it's going to be the consignee or whether it's going to be the purchaser of the goods. So you should already have that information before the product gets shipped.

MR. LIEBERMAN: So this would be analogous to the right to make entry, kind of, where you would have several entities, potentially, could have the

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right to be the FSVP importer?

MR. VENEZIANO: That's correct. And you'd have to figure it out in terms of who's going to be responsible for complying with 805.

MR. LIEBERMAN: Okay. Okay. And if an entity has a written purchase agreement with a U.S. entity and that U.S. entity orders on behalf of the other U.S. entity, does the written purchase agreement need to be with the foreign supplier, basically, for someone to be considered an FSVP importer?

Or if, say, a U.S. retailer submits a written purchase order to a U.S. importer, and then that U.S. importer brings the product in on their behalf?

MR. VENEZIANO: This is Domenic. If I understand the question correctly, it could be a consignee who has an agreement with a purchaser.

MR. LIEBERMAN: Yes.

MR. VENEZIANO: Internally, right?

MR. LIEBERMAN: Right.

MR. VENEZIANO: I think that could happen. And again, you have to figure out, is it going to be

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the purchaser who is going to be the qualified individual?

MR. LIEBERMAN: Okay.

MR. VENEZIANO: Or is it going to be the consignee? And in the entry information, it's going to be two separate entities. It will be the FSVP importer who they deem to be the appropriate person, as well as the consignee under the normal process.

MR. LIEBERMAN: Okay. That's very helpful.

MS. LINDAN MAYL: Right. And also, remember that the rule builds in additional flexibility for the FSVP importer to rely on the work of others, whether that's the hazard identification, the risk evaluation, or the verification activity. So it could be that someone is taking responsibility, but a retailer, for instance, has audits with that supplier. And so they could rely on that.

Again, it just -- but it does involve that importer and whoever is taking responsibility to have a qualified individual to review those activities. But I think, you know, this is going to take some time to work out. But I suspect as time goes by, those

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kinds of relationships and those kinds of responsibilities will begin to get worked out among the parties.

MR. LIEBERMAN: But ultimately, the FSVP importer is the entity that FDA will go to for enforcement. So you can use someone else to do the FSVP activities, but the buck stops with you as the FSVP importer.

MR. VENEZIANO: That's correct. This is Domenic. That's correct.

MS. BARRETT: All right. Thank you.

We're going to go to this side and take a question, and then we're going to go to the web and take two more, if we have any. If not, then we'll continue down the line.

MR. EARLE: Bill Earle, National Association of Beverage Importers. We represent importers of beer, wine, and spirits. We're exempt from the FSVP.

But I have a question about the VQIP program. It looks like alcoholic beverage importers could join that program. What do you see as the relationship between FDA and the newly stood-up

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Centers for Excellence and Expertise that Customs has got operating? Particularly the APP Center in Miami.

Second question is, would gray-market importers essentially be prevented, by definition, from the VQIP program? Basically not being able to establish that source to entry relationship.

MR. VENEZIANO: This is Domenic.

So, on the first one related to the Center of Excellence and Expertise, that's a program that's headed up by Customs and Border Protection. They've changed. There's ten Centers of Excellence and Expertise, three that really pertain to FDA, and for foods it's the one out in Florida for the ag aspect of it.

They have under their program, it's pretty much going to be -- it's a virtual office that looks at the importation of products. And right now they are handling accounts associated with C-TPAT program, the Customs and Trade partnership program. We already work closely with them in terms of our field staff, in terms of making admissibility decisions.

There is a pilot program that's going on

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under Customs for C-TPAT, which FDA has participated in. And under the program, for the first time we get the right to look at information. So in the past under the program, the importer self-assessment program and the C-TPAT program, people had to agree to share information with FDA. And we would comment or not comment on that.

Under the pilot program, they now provide us that information, and we give them the advice of whether we believe they're bringing in legitimate products that are in compliance with our regulations. And then they can make decisions accordingly.

Under the VQIP program, we're going to do the exact same thing. We've put language in there that says, "We will share information with all other government agencies that it pertains to and who has jurisdiction of that information" so that we can kind of bring out a one-trusted-trader program.

So one of the biggest complaints we've seen over the years is that people that are participating in C-TPAT get held up by FDA. And we're looking at facilitating it so that we're harmonizing that

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requirement. And the statute for FSMA actually asked us to consult with CBP in terms of that process.

So we've incorporated C-TPAT into the VQIP program. We've also suggested that we are going to provide them with information of who's in compliance and who's not. And when someone does get revoked out of the program, to also provide that information to other governments. And they can do what they will with that information.

So it may not be related to their program, and it may not cause you to be kicked out of C-TPAT in any way, but at least they know the information and vice-versa. We're working with them to expedite C-TPAT participants as well as VQIP participants.

So we're working closely with them, and we're kind of modeling our call center, or our help desk, in something like the Center of Excellence and Expertise aspects.

I will also add that the Center of Excellence and Expertise are more on a post-entry aspect, where now all violations are going to go through the Center of Excellence and Expertise, which

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is a little different than FDA's process. I hope that helps.

MR. EARLE: The gray market?

MR. VENEZIANO: The gray market. Yeah, I think you'd have to -- I think it's going to be a tough situation for a gray market to participate. I think there's a lot of entities that you're going to need to do.

I don't think, and I haven't evaluated enough to say that they're going to be totally excluded out of the program. I think it's going to be a little bit difficult for gray market to get all the information to participate in certain aspects of it.

I also see an issue with FSVP in terms of, who's manufacturing it and the processes in play, because you're going to have to understand that they're in compliance with it. And if the gray market is only purchasing products and then bringing them in, you may not have all the information to comply with both VQIP and FSVP.

So I think it might be a little bit difficult to get the gray market in to meet those

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specifications in the requirements. But I would have to look at it in more depth to dependably say they're not going to be able to participate.

[Inaudible interjection.]

MR. VENEZIANO: Yeah. That's true.

MS. BARRETT: All right. Thank you.

Kevin, do we have any webcast questions?

[No audible response.]

MS. BARRETT: No, we don't at this time. So we'll go ahead in the room.

MS. HERMIDA: Hi. Maile Hermida, with the law firm Hogan Lovells. I'm wondering if the VQIP -- sorry, the FSVP guidance is going to give any input on conflicts of interest. And I'll just set out three different scenarios that I've come across to see if you have responses on them or want to put them on your radar in terms of the guidance.

First is, there's lots of companies where they have a foreign presence and a very small U.S. entity that deals with the importing. So they're a big European food company, and then there's a small U.S. entity that imports.

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Can the U.S. company rely on the hazard analysis that their European counterpart did for purposes of that FSVP? Or would that be a conflict of interest, because they're essentially checking on themselves?

Situation two would be the big U.S. company does a corporate-wide hazard analysis. If a foreign entity applies, the U.S. companies -- the two entities are interrelated so that the U.S. is having to do FSVP, but they've also written essentially the food safety plan that they're checking. Is that a conflict of interest?

And then, the third situation is, what about outsourcing? So if the foreign company relies on a consultant to develop their food safety plan, can the U.S. importer rely on the same consultant to do FSVP?

Essentially, are there -- can you give some more guidance on what the checks are in the system and what the requirements are for who can do the hazard analysis in these kinds of scenarios so you're not checking on yourself?

MR. PENDLETON: Brian Pendleton. Thanks for

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the question. Yes, we will need to talk about, in the FSVP draft guidance, the conflict of interest provisions that we have. And we need to coordinate with the preventive controls draft guidance because they have similar versions in their supply-chain program part of that guidance.

So we need to be looking into what we mean by the conflict provisions that we have, because they are the same. We need to be addressing that.

I think that you could rely on a hazard analysis that was conducted by the entity that you suggested in your example, I believe. We talked about even in the proposed rule that you could rely on hazard analysis that was conducted by the foreign supplier itself, as long as you looked at that hazard analysis and assessed it to yourself.

So there's a lot of flexibility in that. I don't remember the second item, but in terms of outsourcing, could you rely on the same entity that -- I'm sorry. I lost the --

MS. HERMIDA: Just to clarify. The problem is that business here is in the business of getting

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stuck in and out of the country. So when you say, "I know you can look at someone else's hazard analysis and rely on it," it's who the "you" is. Essentially, they would be looking at their food safety experts, who are located in the same place where they're having to do the assessment.

So the FSVP would be developed and implemented by the same people who wrote the food safety plan. I'm wondering if that -- that's the situation I'm really getting at. So you're not even relying on someone else. The "you" is the same person who is the "I." I hope the transcribers have fun writing that one down.

[Laughter.]

MR. PENDLETON: So the importer is the same as the supplier?

MS. HERMIDA: Sharon seems to be nodding.

MR. PENDLETON: Yes.

MS. HERMIDA: Yes, eventually. It would be the same person doing the work.

MR. PENDLETON: Well, if you're the importer, you're allowed to do a hazard analysis

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yourself, and you can rely on that. So -- but I'm not sure exactly how -- I am not grasping all of the details.

But we will definitely have to address this to provide more clarity about what we mean about the conflicts. And then when we do come out with our draft guidances, both in preventive controls and FSVP, people have a chance to comment on that and provide their thoughts on how we should implement those provisions.

MS. HERMIDA: I'll submit it through the TAN so you guys can have more details to respond to it.

MR. PENDLETON: That would be great. Thank you.

[Laughter.]

MS. HERMIDA: That would be helpful.

MR. PENDLETON: Thank you.

MS. BARRETT: Okay. We're going to go again over in the room.

MR. WONG: Yeah. This is Adam Wong from Blue Buffalo. Just to clarify on the individual requirements qualified individual under the current

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supply verification program. I would like to know if that's similar standard requirement under the preventive controls for human food and animal food.

And would that also be the same, similar standard under the VQIP program? Because I think there was not clear slides on the VQIP program under the qualified individual.

[Pause.]

MR. PENDLETON: It's Brian Pendleton. Certainly I know we're coming out with training for what would be a guidance on what is going to be a preventive controls qualified individual. And that's someone that an importer certainly could rely on to meet their qualified individual requirements, also it's probably more -- in some cases, it might be more than is necessary for a person who's conducting some of the FSVP activities to have.

But -- and as I mentioned, we will be providing training with respect to supplier verification duties under both preventive controls and FSVP. And persons who obtain that type of training would expect to certainly meet those requirements for

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being a qualified individual, but that doesn't mean -- it's not going to be required for that.

As I mentioned, the definition and the requirement is rather flexible with respect to the education, training, and experience that's needed, or a combination of that. And so we expect that there could be many ways that a person who's conducting FSVP activities for an importer could meet that.

Sharon, did you want to add?

MS. LINDAN MAYL: Yeah. I just want to also clarify that when we use the term "qualified individual," it may be that different individuals are qualified to do different things. An individual who is qualified to do a hazard analysis isn't going to -- it's not going to be the same qualification as an individual who keeps the records, for instance.

So every activity under FSVP must be performed by someone who is qualified to do that particular activity. So it's not one standard across the entire rule that, you know -- it could be one person. But there's some flexibility. You wouldn't necessarily need to have a degree in, you know,

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microbiology to keep records, for instance.

So I just want to just clarify that when we use the term "qualified individual," it sort of changes with respect to the activity that's being developed. But certainly with respect to similar activities between FSVP and PC, we would be expecting similar qualifications, for instance, for someone that is doing a hazard analysis under each rule or keeping records under each rule.

I'm looking at -- I'm sorry.

[Crosstalk.]

MS. LINDAN MAYL: I'm sorry. I'm looking at someone in the audience that might want to clarify that. Would you like to step up and clarify that? This is Jenny Schott. And I'm sorry. That was Sharon Mayl who was just talking.

MS. SCHOTT: Thank you, Sharon. Jenny Schott, FDA (inaudible).

We have a "qualified individual" definition in FSVP, and a somewhat similar "qualified individual" definition in the preventive control that are essentially individuals who have the education,

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training, expertise, a combination of these, to do their assigned duties. And as Sharon says, that may differ depending upon the job they're doing.

In the preventive controls rule, we have further a preventive controls qualified individual. And this is someone who is a qualified individual, has education, training, and experience to do the job, but they have also the additional qualifications of having attended training of a standardized curriculum, or they have job experience that allows them to develop and implement a food safety plan.

So again, it really comes down to the people that are doing certain activities need to have experience, the education, training to do that job, whatever it is.

MS. LINDAN MAYL: Thank you for clarifying that, Jenny.

MS. BARRETT: Thank you. We'll go ahead and take a question over here, and then we'll check on our webcast audience.

MR. ICHTER: Thank you. Just a quick question relating to the imports --

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MS. BARRETT: And again, if I could have you say your name.

MR. ICHTER: Yes. Ralph Ichter, the French Dairy Association.

The imports of food products for promotion purposes like trade shows, market testing, and things like that. As this -- I mean, I'm relating this to the temporary exemption for the FSVP. What is the situation with this type of situation? A product that has never been brought in, and it's just brought in a bag or container to do market testing.

MR. PENDLETON: Brian Pendleton. Thanks for your question. There is an exemption for food that is imported for research or evaluation. But there are some limitations on that. So the food can't be intended for retail sale and can't be sold or distributed to the public.

So if you're going to bring in food at a trade show that could be handed out to persons who attend the trade show, that would not be eligible for the exemption.

MR. ICHTER: But it's not sold. It's given.

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MR. PENDLETON: I'm sorry?

MR. ICHTER: It's not sold. It's given out.

MR. PENDLETON: If it's just distributed, then it's going to the public, and the public could consume that food and it could affect them. So it's not excluded.

MR. ICHTER: I mean, do you realize what you just said? I mean, this is a crazy situation. It happens all the time. There are food trade shows all over the country. People bring food in for the purpose of that trade show. Do they have to go through FSVP to bring on their food for a trade show?

MR. PENDLETON: If they're going to be -- if you're importing food and you're going to be handing it out to people, anyone can go to the trade show and eat that food, then yes. It would be subject to FSVP. It's not eligible for the exemption.

MR. VENEZIANO: So, this is Domenic. So if you think about how many people attend those trade shows, I just came back from the New England, the Boston Seafood Show. Thousands of people, right, eating product. There could be a huge outbreak as a

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result of issues associated with food that's being distributed at that trade show. So technically right now, underneath FSVP, you'd still have to comply with those regulations.

It's a different situation if you're talking about research and development, where you're evaluating a food and it's not meant for consumption.

MR. ICHTER: But most of the time, it could be a variation for products that might come from a plant that already exports other product to the United States. And so therefore, the plan probably has been audited. It's (inaudible) and what-have-you.

So, I mean I'm trying to get into a situation where we don't have to go through stacks of paperwork for the purpose of, you know, showing off some food in a fancy food show in New York in June. So that's -- it's a gray area, that's my understanding. Will you address this in the guidance?

MR. PENDLETON: Certainly, yeah. And we talked about this. I mean, obviously, we addressed it in the proposed and final rule, as well. But there are several comments about the scope of that

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exemption. But we'll be talking about it further in the guidance, yes, sir.

MR. ICHTER: Thank you very much.

MS. BARRETT: Kevin, are there any webcast questions?

MR. ROBINSON: This question is from Bracey Parr, with the Registrar Corp.

"FDA hasn't published the industry guidance, but they stated in the final FSVP rule that the DUNS number will be acceptable. I'm just wondering if that will be the only acceptable identifier in the end."

MR. PENDLETON: This is Brian Pendleton.

So we are -- as I mentioned, we are working on the draft guidance. And our recommendations for compliance with the requirements to ensure that you are identified as the importer at entry will be included in that.

We still intend that the use of the DUNS number is going to be one of the ways, it may be the only way we do; I can't say yet. We haven't come out with the draft guidance. But we'll still looking at that issue. And we know that we need to address that

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in the draft guidance when it comes out later this year.

MS. BARRETT: Thank you.

Kevin, are there other questions?

[No audible response.]

MS. BARRETT: No? Okay. We'll go to the gentleman over here.

MR. WATSON: Quick question on GFSI. My name is Nick Watson, with Nopal Export Chia Growers.

My understanding is that if we comply with an inspection and certification GFSI, good global food safety initiative, then FSMA is no longer necessary. You recognize PRC, SQF? I read that.

[Laughter.]

MS. CHRISTIN: This is Charlotte Christin. My question --

[Crosstalk.]

MR. WATSON: It does say GFSI has -- oh, they shut down my microphone.

[Laughter.]

MS. BARRETT: Charlotte, go ahead.

MS. CHRISTIN: So, for -- this is Charlotte

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Christin. For purposes of the third-party certification program, facility or their food must meet FDA requirements. So that would be the Food Drug and Cosmetic Act and FDA regulations. So in terms of GFSI, it would have to be a scheme that meets, that assesses compliance with FDA regulations.

And private schemes don't currently do that, although we do understand that many of them say they meet or exceed legal requirements. But the specificity of what's in our regulations is what, you know, needs to be ensured is in those private schemes, to be able to say that it assesses compliance with FDA requirements.

MS. BARRETT: Okay. I think we have GFSI response coming. Karil?

[Laughter.]

MS. KOCHENDERFER: Not so much a response as a confrontation.

[Laughter.]

MS. KOCHENDERFER: My name is Karil Kochenderfer, and I represent the Global Food Safety Initiative in North America. For those of you that

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want any information about GFSI, I'd be happy to elaborate on it, and I'd be happy to take your questions as well.

I often refer to GFSI as a B-to-B (phonetic) FSMA, already operational in the marketplace. Science, for the most part, takes business and industry to the same place that it takes policymakers; it is objective.

That said, we are complements; we are not identical. GFSI is a marketplace tool that will help you prevent, if not enhance, food safety. But it is not a government regulatory program.

We hope to come out with studies within the next quarter showing that many of the same mechanisms that you use on a private basis in the marketplace will take you 80 to 90 percent down the road towards complying with FSMA, but they are not used to -- GFSI is not used to comply with FSMA; they are complementary tools.

So again, if anybody wants more information on GFSI, if these are additional information that you think is useful, I would be happy to make it to your

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organization or to your company or to you privately.

Thank you.

MS. BARRETT: Thank you.

I think we have time for one more question.

MS. WASSERMAN: Jessica Wasserman. Can I go ahead?

MS. BARRETT: Yes. Talk right into it.

Thank you.

MS. WASSERMAN: Jessica Wasserman, Wasserman and Associates.

[Pause.]

MS. WASSERMAN: Is it on now?

MS. BARRETT: Yes, that's better.

MS. WASSERMAN: So, you've mentioned several times that in theory, if you are auditing, showing the credentials of your foreign food, that you need to only be comparable to the U.S. standard or equivalent, so that, in theory, you could show that if your standard met the same level of food safety, that that would be acceptable. But that seems in contradiction to everything else you're saying.

So it's not easy to show the same level of

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safety. But say someone did show, you know, did some kind of outside study that showed that, you know, "In our country, our food, this particular product, we have much -- our outcome is better than yours. You know, our cheese is safer in Denmark than your cheese in the U.S. for the same product. So we don't want to go through with it and do every jot and tittle of the U.S. standard."

What would you say to that?

MR. PENDLETON: It's Brian Pendleton.

Thanks. That's a very good question, very important question that we know we need to address in our draft guidance.

So what does that mean for the importers, for example, under FSVP? What type of variation or difference can they accept in their foreign supplier if they're doing something that is not quite what is required under the produce safety or the preventive controls regulation, but they conclude that it provides the same level of public health protection?

Exactly how do they determine that? How do they document that so that they have that

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documentation that we could look at when we go inspect that importer to see, well, okay, so they're not strictly -- their supplier is not strictly in adherence with PC or produce safety.

We know that's going to be very important, and we'll be addressing that in the draft guidance.

MS. BARRETT: Thank you. This concludes our question-and-answer session for this morning. I do want to give a round of applause to everyone who asked a question and to those who answered it.

[Applause.]

MS. BARRETT: A couple of things to mention just before we break. If you are giving comment, if you have signed up to give comment this afternoon, please do see Juanita Yates. You can go to the registration desk. We've only had a couple of people check with her. We know we had quite a listing. So again, please check in if you're giving comment later.

Also, please keep your name badge on. If you leave the building to go into the cafeteria, my understanding is if you have your badge on as you come in, you do not have to go through security again for

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reentry. So it's important to keep that on.

Thank you. We're going to come back and start at 1:15.

LUNCH

MS. BARRETT: I will ask everybody to take their seats, and we'll get started. I want to welcome everybody back. And again, I apologize. I know there was a longer line for lunch than anticipated. And thanks for your perseverance. Also, too, that security was maybe a little bit more intensive than I had anticipated, coming back in.

[Laughter.]

MS. BARRETT: So I was wrong on both counts. But I'm glad you're here and you're sticking with us. And we are going to change the focus as we begin this afternoon, to look more at the implementation side, around these rules that we've been discussing this morning.

So, to start out, we're going to first hear from our FSMA Imports Implementation Workgroup. And presenting on behalf of the group will be Sharon Mayl. Again, she's a senior advisor for Policy Office of

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Foods and Veterinary Medicine.

After Sharon provides her overview of implementation on FDA's Prevention-Oriented Import System Regulations, then we will have another Q&A panel similar to what we had this morning, but again this time focused on implementation.

Sitting on our panel, we've already seated our panelists for that session. So along with Sharon, we have Charlotte Christin, who you heard from this morning, senior policy advisor, Office of Foods and Veterinary Medicine; Todd Cato, who is our District Director, Southwest Import District Office, Office of Regulatory Affairs at FDA; Lisa Romano, who is our Deputy Director, Office of Food and Feed Operations in the Office of Regulatory Affairs; and Dori De Leon, who is our Consumer Safety Officer, Division of Enforcement, Office of Compliance, Center for Food Safety and Applied Nutrition.

So you're seeing with our implementation team, we're getting a good mix of those who are in the center, as well as those who are in the field. Also, on our import groups and our other implementation

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teams, we do have state representation. So we are really building this program out across the different components areas of FDA.

So to start, and again presenting on behalf of the workgroup, I'll have Sharon come up to the podium.

IMPLEMENTATION OF FDA'S PREVENTION-ORIENTED IMPORT
SYSTEM REGULATIONS

MS. LINDAN MAYL: Welcome back from lunch from our great CFSAN cafeteria. Glad you came back.

Let me see if I can figure out how to work this.

[Pause.]

MS. LINDAN MAYL: So I'm going to try to give you an overview of some of the progress we've made to date of operationalizing these rules. These rules are very complicated, as you know. And I can assure you operationalizing them is also complicated. As Kari said, we have many people, both from headquarters that deal with state involvement, helping us to do this.

So let me give you a quick overview of our

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operational side and then leave probably a lot of time -- hopefully, I can do this quickly -- for questions.

So, I'm just putting this up here to just remind everybody of all the import provisions of FSMA. I'm not going to talk about them all. I'm going to focus on the programs that you heard us talk about earlier this morning. But I just wanted to remind you, also because of what Mike said earlier about sort of the integration of all of the provisions in FSMA, in addition to integrating with our current import operations. So there's a lot going on.

These are the programs that are in our team, the ones that we're responsible for operationalizing. As you can see, there's a couple of lab accreditation and import certification are also under our purview, but we're not going to talk about those today. They're a little bit further behind than some of the other programs.

And you can see in the corner we also have an asterisk with systems recognition because, as you've heard, there is an interplay between that program, which this not a FSMA program; it's something

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that was going on before FSMA. But there is an interaction with that with these programs.

And this is just a representation of the management structure for what we call the Phase 2 side of FSMA, Phase 1 being the issuing of the policy documents, the rules, the guidance documents. And this is just an overview.

You can see the Import Controls Group in the orange, which I'm representing the leads for that here. But you can see underneath of it all of the programs that we're responsible for operationalizing. Again, I'm just going to focus on the three.

So I'm going to go through each of the programs, and I'm going to try to hit the operational areas and just give you a little background, some food for thought. And you can look at that and ask us some questions as we go.

So, as you know and we've talked about, in terms of outreach and industry education and technical assistance for FSVP, there is a tremendous amount of material on our website. We have really ramped up our website with FSMA, and great thanks to our

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communications team, which really has made things very accessible to folks and easier to find.

Many of those materials are translated into some key languages. And we're going to be continuing to work on that.

We've also done a tremendous number of external presentations. Those presentations are also coordinated through our communications team. They've targeted key stakeholders and key events to have us go out and try to do as much outreach as we can on these rules.

We've done about, I think, 60 or 70 presentations since August of 2013. And we hope after this to do a series of regional meetings that you'll be hearing more about, domestically within this country to reach out to importers and continue our efforts. So keep your eyes peeled for that.

You've also heard some reference to the FSVP Alliance course. We have contracted with the Food Safety Preventive Controls Alliance to develop a course specifically geared toward importers that would be subject to the FSVP rule. That course, even more

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specifically, is geared at smaller and medium-sized importers, and it's designed to give them the technical assistance and materials they need to be able to comply with the FSVP rule.

That, of course, is under development, which is why you haven't seen it yet. We are working with the alliance to develop those materials. And you can visit the alliance website and try to keep track of where that course is.

You've also heard about a guidance document that we are in the process of developing, which will help importers, again, give some more details about how to comply with the rule. We've heard some questions here today that are covered by the guidance. And so, again, keep your eyes peeled for that. There will be an opportunity, as always, to comment on that guidance document and provide us with some additional information.

And you've also heard reference to the TAN, which is -- you can access through our website where you can ask questions, preferably or even specific questions. And you can get FDA experts to provide an

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answer to those FSVP questions, or really any questions under FSMA to help you comply.

And we'll say that one of our biggest challenges, of course, for FSVP outreach is, who are we reaching? As you know, importers -- most importers, unless their processors don't have to register, we don't have -- we have importers of record in our databases. But again, that's not a complete overlap with who is the FSVP importer.

And so, you know, part of our efforts is figuring out who really are we trying to reach through these efforts and trying to cast a net as wide as we can to be able to hit the folks that we need to hit? And if we don't, they'll know to sort of keep it going.

I can't remember what one of the commenters said. You know, emissaries of going out and helping us. So we really are dependent on partnerships and folks outside the Agency to help spread the word with respect to the existence of FSVP and also how to comply.

FSVP, unlike the other two programs you

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heard about, is a mandatory program. And so there will be an inspection program, an oversight program for that. We are developing a risk-based inspectional strategy for overseeing importers. We are considering both what we're calling onsite inspections, visiting the importers' place of business, as well as considering the use of electronic records, looking at records.

And again, we're not observing processes as we would be at a facility, but also thinking about what kinds of records could be available if that's a preferred route. So we're thinking about that as well.

We're also -- as you know, there are different requirements for FSVP, what we sort of abbreviatedly refer to as "the full requirements," and then there are those requirements that are abbreviated. For instance, if you're importing from systems-recognized countries or you're a very small importer for -- you're importing for small suppliers, there are different requirements that necessitate different kinds of oversight.

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So we're thinking about all that as we build our importer inspection program. Again, you know, it's a challenge because of the lack of registration for most importers of who we are overseeing. We're spending a lot of time sort of digging through our databases and thinking about how we can prioritize the importers, based on risk.

But I want to emphasize something that Kari mentioned earlier in terms of our approach to oversight, particularly initially. I'm sure if you've attended any FSMA operational meetings, you've heard the term "educate before and while we regulate." It is, we take that very seriously.

Our goal here is to bring about compliance from importers, to have the importers take that responsibility that is required of them. Not necessarily a "gotcha" kind of approach initially. We really need to make sure that importers are aware of this. We need to help them comply with it by giving the assistance that they need, or at least -- obviously, we're not consultants, but pointing them in the direction of how to comply.

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So I can't emphasize too much the need for really outreach and education as a part, initially, of our inspection program. That said, obviously, if we see public safety matters, if we see, you know, egregious problems, we have every ability to take action with this.

But we really do want to bring about compliance. That really is the philosophy. And if you've, as I said, attended any PC or produce or any of the outreach sessions, it really is the theme at FDA.

With respect to regulator training, we're obviously -- this is a new program for us, too. So it's a different kind of inspection than our investigators normally do when they're going to a facility and looking at an actual process. So there we are developing a training course for our regulators.

Like some of our other FSMA programs, we are planning to use the train-the-trainer method, where we will train sort of a cadre of seasoned experts that will then go out and train other investigators. And

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like some of the other programs, we're thinking about regional training hubs, because importers, really, they're all over. They're not just at the border with respect to the definition of an FSVP importer, in the same way that we think of importers through customs and other ways.

So, consistency is a priority. We need to make sure that, as our investigators go out there and visit these importers, that they're using similar oversight across FSVP. And also, looking at it in a similar way as PC is with respect to their supplier program, as well, because as you know, some of the importers will also be PC facilities. So we have to have some coordination with the PC program, as well.

As with all our import programs, information technology, IT, is really key. We're not only automating our inspectional approach, but there are a number of changes going on. We are creating what we're calling the FDA data dashboard, which will consolidate, hopefully in a more usable manner, the publicly available compliance information of suppliers.

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As you know, one of the requirements in FSVP is to investigate the compliance history of your supplier. And currently, that data is not as easily accessible as we'd like it to be. So we're looking at creating a dashboard, sort of a one-stop-shop for importers to help them be able to check on the compliance status, the FDA compliance status of their suppliers.

There will be some modification to entry data. Again, I want to emphasize that the entry process, after the first compliance date, is not changing significantly. We're not stopping every shipment at the border and checking on FSVP compliance. And I can't emphasize that enough. Because there is a misconception out there that there's some kind of preapproval of these shipments.

And that is not the approach to oversight of FSVP, but rather we're going to be enforcing it through the importer in the United States. So after the first compliance dates, shipments continue to flow. Trades continue to flow.

Clearly, if we're visiting an importer and

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we see a safety problem, we have not only the tools for FSVP, but we have the tools that we've traditionally used for problem imported products at the border. We have import alerts. We can detain products. We can test products.

So we have tools to ensure the safety of U.S. consumers, but the main changes you're going to see at entry are some additional data elements. And you've heard us talk about the identification of an FSVP importer. And that is a key requirement and allows us to build our database, quite frankly, of the importers. And there is no registration.

And as again with all our programs, we need to integrate the information that we have. Whether it's through PC and FSVP, our systems need to talk to each other internally so that we can share data among the many programs that we have at FDA and be able to use that data in a risk-based way that makes sense for our oversight.

Again, I'm going to be saying some things that applicable to all of our FSMA programs. We are developing a comprehensive plan for identifying

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performance goals and metrics to evaluate those goals, to be able to see how we're doing and how you're doing in these new FSMA programs.

Again, this is a learning curve for everyone, not only for importers, but also for us as we oversee. So it's very important to us that we develop metrics and be able to track the effectiveness of the programs. And that data will come from the centers and ORA.

And right now we're thinking about the databases we have and what information we're going to be using to develop those metrics.

Workforce planning -- we did get an increase in our budget, as many do know, for FSMA implementation. And obviously, some of that is going to imports. We have new people. We're infesting, quite frankly. We didn't have oversight of importers in the same way that we do with FSVP. And so, as we add to our inventory, we need to think about how we're allocating those dollars across ORA, across centers, and how we're going to plan to do these inspections.

They're complicated, as you know. There are

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different compliance states for different importers. And we are right now thinking about that and working that out. And obviously, as our numbers get a little bit more crisp and FSVP importers are identifying themselves at entry and we have a better inventory, we're going to be thinking about that as we do our workforce planning.

I'm going to move on to VQIP. I think that some of this Domenic covered in his presentation, so I'll try to move a little bit more quickly through this. As Domenic mentioned, we've been very engaged in doing outreach to industry, really from before we issued our first draft guidance to get a sense of what it was that industry wanted from this voluntary fee-for-service program. And we will continue to do that outreach as we issue our final guidance.

And as Domenic mentioned, we're now considering the comments on the final guidance. And we'll integrate them and get that out as soon as we can, as we say at FDA.

Right now the outreach, again, you can submit questions about VQIP through the TAN until we

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get our help desk for VQIP up and running. Domenic mentioned the help desk for VQIP is one of the benefits of VQIP.

And that person -- the people who man that desk will be able to answer importer questions about particular foods, about the application process, interpretation of the VQIP program with the guidance offered for that program.

The staff manning the desk will be able to facilitate review of the VQIP food if, as Domenic mentioned, in certain instances if it's not immediately released because there's a public health problem and there's some reason we had to sample this.

Again, we're not expecting to do that. But if there are questions about where a particular shipment is, the help desk will be able to facilitate the answer to that question.

Again, this is a new program. We need to develop all-new processes and procedures for overseeing this program. It's not a mandatory program, but it still requires oversight. To be able to give the benefits that this program is going to

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offer, we obviously need to make sure that the applicants are, you know, can get into the program.

And there's a lot of internal procedures about the application review, about, for instance, if it does get sampled, how to prioritize that sample, and sort of the queue of lab analysis, as well as, as Domenic mentioned, procedures about if we do need to revoke an application or participation in the program and reinstatements.

So it's not inspections and compliance as we think of it with a mandatory program. But there's a lot of oversight associated with this program.

Again, we are developing internal training for our staff to be able to review the applications and then do the audits, the inspections of the importers once they get through that paper process. So we are developing those training materials right now and developing guides for our inspectors as they go out and do those inspections.

We're also developing educational material for our CBP colleagues. And again, I have to stress that the consistency issues across these programs we

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take very seriously in terms of making sure that the people that are reviewing the applications and doing the oversight are doing it in a consistent and fair manner.

IT -- again, we have made a lot of progress in building the IT system that is needed to have this program. Again, not only includes the application process, which will be an online application process, but also the information received in terms of transmitting it to the appropriate offices, whether it's the PREDICT system and many preceding products, or sharing information with, for instance, third party, because the facilities will need to be certified under that program.

And so, our systems need to talk to each other and be linked. So that is a big challenge, and we're working on that.

I've already talked about our performance metrics in developing data. In this case in particular, because it's a voluntary program, we want to use the feedback and evaluation to be able to refine this program as time goes on. And because it's

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voluntary, people are only going to want to use it if it's a successful program.

So it's key for us to develop baseline metrics right now about entries coming in and see how that improves over time.

Workforce planning, again it really is very dependent on how many applications we get. And that's a real unknown for us. This is a fee-for-service program, but we don't know how many applications we're going to get. So we're starting with sort of a smaller cadre of reviewing the applications, and obviously we'll expand as needed to make sure the program is up and running.

And as Domenic mentioned, it's also a user-fee program. And the two points I guess I'll just reiterate from what Domenic said is that we definitely got the clear message that the fee for the program needs to be known with enough time to be able to make a decision about whether folks want to participate in the program.

So even though usually we do all of our fee notices in August 1st, for the coming fiscal year, we

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understand we need to perhaps get that information out earlier since the application is before then, and for people to make a decision.

And again, we've received comments and are considering a fee structure. We'll consider the burden on small business.

With respect to third party, again I think Charlotte covered a lot of this. So I don't want to go into too much detail. Again, there are materials on the web. Again, it's a voluntary program. We've done a tremendous amount of outreach to the industry with external presentations. So, you know, we've had a lot of feedback already in addition to the notice and comment.

We're making process. And as Charlotte mentioned, we are also developing the model of accreditation standards.

And like VQIP, again, a voluntary program, so the oversight is a little bit different than it would be for a facility or for an FSVP importer. But we are developing internal operational procedures for reviewing the application and oversight activities for

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looking at this program.

And again, we're working with other FSMA programs and the existing FDA programs to establish those procedures where the programs intersect -- again, third-party and VQIP, for instance, where they intercept. But also, the importance for us of knowing who the facilities are and factoring that into our foreign inspection prioritization as well.

Because if a facility, for instance, has gotten certification through this program, it certainly makes it a lower-risk facility in terms of whether we would want to get out ourselves and do a foreign inspection of that program.

Again, we're developing training programs for the different components of the program. One thing that I will note here is that we are using both external and internal materials for these courses. As you all are aware, there is a fairly robust third-party system out there already, and there are some good training materials out there.

And we want to make sure that we're leveraging the training materials of quality programs

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with this program.

The IT issues are similar here in terms of integrating this program with other FDA programs like VQIP, and sharing the information that we know about these firms throughout our FDA offices. So there is sort of a built-in interconnectedness of these programs that really needs to be automated if they're going to function in the way that we hope them to.

I won't dwell here because it's the same thing. We are developing metrics for this program like we are the others, to be able to evaluate how well it's working and make changes along the way, as we see are necessary.

And as with VQIP, this program is dependent on participation. Charlotte mentioned that there is oversight of this program at every level, not only at the A-B's, but also at the C-D level. So we need to figure out who is participating in this program and make sure that we are auditing it appropriately with a robust system so that we can rely on this program in terms of participation in VQIP and the other data we receive from this program.

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And Charlotte mentioned again that this is a user-fee program. The proposed user fees were for A-B's and C-D's, and we cover the cost of application review, as well as the maintenance and oversight of this program. So again, we're working to finalize that user-fee program, and this program will not take effect until both that and the model accreditation standards are finalized.

And I think that's the overview.

[Applause.]

Q&A

MS. BARRETT: Okay. Well, that was a lot to take in. And I'm hopeful that folks have some questions. So as we did before, we have two microphones in the room that you can come up to. You might want to limit it to one or two people at a time so you're not standing too long. And then we'll occasionally go to the webcast audience to see if we've had any questions come in.

When you do ask a question, if you will clearly state your name and your affiliation. And again, if you'd like to direct it to a certain

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panelist, or just clearly up front state what program it's associated with, that's helpful. And I think with that, we can go ahead and get started.

So, Erik, we'll start with you.

MR. LIEBERMAN: Erik Lieberman, U.S. Food Imports LLC.

I had a quick question about the TAN. Where are the answers being posted? Are they being incorporated into other documents? Or where do we get the answers related to the TAN?

[Pause.]

MR. LIEBERMAN: You know what? I have submitted some questions through the TAN.

[Crosstalk.]

MS. LINDAN MAYL: I take it from that that you have not got your answers back yet.

[Laughter.]

MR. LIEBERMAN: No, I haven't. And are they emailed to the questioner?

MS. LINDAN MAYL: My understanding is that they are going to be answered by email, but that if we keep receiving questions that are of a similar nature,

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that we would add them to our frequently asked question list.

MR. LIEBERMAN: Yeah, that would be great.

MS. LINDAN MAYL: So that we're not -- so people can learn from other people's questions, and it also would be the most efficient.

MR. LIEBERMAN: Okay.

MS. LINDAN MAYL: So I'm looking at Jenny. She's nodding.

MR. LIEBERMAN: Great. Thank you.

MS. BARRETT: Thank you.

You have our next question?

MR. BEADLE: Yes. William Beadle with AGQ Labs.

I was just wondering, what's the FDA's plan with the PREDICT model, screening model? Are they planning on releasing that information to the public? And if not, why exactly? Because I feel like that's going to be really useful information.

MR. CATO: Yeah, this is Todd Cato. I'll take that question.

The PREDICT screening model, what

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information are you actually looking to be released to the public? The PREDICT screening model is how we actually do risk assessments of the entries that are being offered that help us develop decisions on whether or not to conduct further review or release the product straight into commerce.

So, you know, a lot of that is very internal information as to how we assess that risk in that. So I'm not really sure what specific information you'd be looking to have released.

MR. BEADLE: Well, just exactly the risk that you guys get. So, you know, under my understanding, you guys will use that model to determine if a shipment needs to be screened for pesticides or if it needs to be screened for salmonella.

MR. CATO: Um-hm.

MR. BEADLE: So that type of information is exactly what importers kind of need in this whole foreign supply verification program to ensure the safety of the shipment, correct?

MR. CATO: There is publicly releasable

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information that will be part of the dashboard that Sharon mentioned earlier. Like for instance, lab results, results of inspections, that we incorporate into that risk model.

But how we actually do the modeling is very internal to FDA. So we don't plan on actually releasing that. But some of the actual compliance information that we gather to utilize that help us develop and put into our risk modeling, that is publicly releasable and will be part of that dashboard.

MR. BEADLE: Okay.

MS. BARRETT: Okay. Thank you. And as a reminder, when you do speak from the audience, if you'll speak close to the microphone.

Jim.

MR. GORNY: Yeah, hi. I'm Jim Gorny, with the Produce Marketing Association.

I notice that there will be education outreach in a module developed for the FSVP for the preventive controls rule and the FSPCA. What about for the produce rule? I think it's really important

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that people understand those foundational rules, so it makes sense to have modules attached on. But the question is, again, with regard to the produce rule specifically.

MS. LINDAN MAYL: Thank you, Jim. And I think I might have skipped over that when I talked about the alliance. The first part of the alliance is to develop that course for the importer.

But again, I think what we're hearing, particularly when we do our international outreach, is the interest in suppliers. And we've heard that here today in terms of, "What are the importers going to be asking me? What's -- not only FDA will be looking at me as a foreign supplier, but the importers will be looking at me, too."

So we are planning to develop a smaller module for the PC rules and the produce rules to help foreign suppliers understand in a general way what the FSVP rule is.

The full FSVP course is designed to help importers understand how to comply. It's sort of a technical assistance for the importer. But thank you

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for reminding me, it's also very important for the foreign suppliers to understand that this program is in place and that someone beside FDA is going to be checking into their compliance. So, thank you.

MS. BARRETT: Okay. Additional questions in the room?

[No audible response.]

MS. BARRETT: I'll give you all a moment. Kevin, do we have any? Okay, or Janesia.

MS. ROBBS: Yes, we do have a question from Laura Dawson, with the Food Physics & Body Dynamics LLC. Her question is, "How are herbs, fresh, dried, or manufactured into granulations handled under these regulations? These herbs are used medicinally by practitioners of Oriental medicine."

MS. LINDAN MAYL: I'm not sure I understand the -- oh, Domenic -- this is Sharon Mayl, but Domenic, you look like you want to come up and answer that question.

MS. BARRETT: Come on up, Domenic.

[Laughter.]

MR. VENEZIANO: I'm Domenic Veneziano.

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MS. BARRETT: You can stay there, too.

MR. VENEZIANO: It sounds like that the intent of the commodity is not used for food. It's used for another purpose. So technically, during the entry process, you might be able to disclaim that as something that's being used. So the product code associated with it might be related to a drug rather than actually a food.

So I don't know the intent of it or the commodity itself. But it seems like it might be another purpose other than for food purposes.

MS. LINDAN MAYL: Yeah. I'll just add to that. Obviously, the FSVP program is only for foods at this point. So it's something that was under the Food Safety Modernization Act. So there are special features or special requirements for dietary supplements.

So I would urge the person who asked that question to take a look at the fact sheets for that rule and take a look at the codified for particular requirements for dietary supplements and if there are additional questions, to submit them to the Technical

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Assistance Network. And this was Sharon. I always forget to say that.

MS. BARRETT: Do we have another question at this time?

Okay. We'll go back to the microphone.

MR. GORNY: Yeah, hi. Jim Gorny again, from the Produce Marketing Association.

Will there be a system set up to adjudicate differences of opinion? So for example, I'm a company and I think I'm in compliance. And FDA says, "No, you're out of compliance." And I've got, you know, a perishable product sitting at the border and it can't cross.

So do I call the help line? Do I call the import district? Who do I call to quickly adjudicate this issue so that my perishable product, you know, doesn't lose massive amounts of value.

MR. CATO: Yeah, this is Todd Cato. I'll take that.

You remember, too, FSVP is not an actual border program, so we won't be holding it at the border for FSVP. And it depends on why your product

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is actually being held at the border. If it was sampled by the local district or local office, then you would resolve those issues through the local office and that.

Now, if you're talking about some sort of VQIP issue, where the product was actually part of a VQIP importer, you will have a specialized help desk that you would go ahead and contact if you have an issue. Even at the local district level, they can help facilitate that contact for you. That's the entire purpose of that help line.

MR. VENEZIANO: Jim, this is Domenic. I'll also add that under the FSVP program, if there is a violation that gets place on an import alert, for instance, as a result of not being in compliance with 805, you have the capability of challenging that at any time.

So, during the inspection process, we're going to want to identify those deviations. You still have the question of questioning that. If we do put you on an import alert as a result of that, you still have the capability of disagreeing with that aspect

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and then can petition to get off the import alert,
based upon coming back into compliance.

So there's always an appeal process in
today's environment, as well as moving forward, one
way or the other.

MR. GORNY: Thank you.

MS. BARRETT: Okay. We're going to go ahead
here, and then we'll come to this side.

MR. ICHTER: Ralph Ichter, from the French
Dairy Association. I had two questions from our
members that relate to the way foreign suppliers
implement the PC rule.

The first question relates to the exemption,
the one-year grace period for the businesses that have
more than 500 permanent employees. The question is,
how do you define a business?

I mean, like if you have a big corporate
umbrella and three different -- three affiliate
subsidiaries, and each subsidiary has two plants,
where is the business? The subsidiary? The whole
corporate entity? What is the definition of the
business?

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And the second question was about the supply chain verification. And I mean, I should have read -- I have read all the FSVP, but I haven't read all the PC rules, sorry. The question was about all material.

How do you define all material for the supply chain verification? Like, you know, I don't know -- salt, pepper, additives, color, you know, food coloring agent, and things like that -- do they have to verify everything? Can you answer the question? Thank you.

MS. BARRETT: Thank you.

Panelists, would you like to respond? We also have experts in the auditorium.

MALE VOICE: It might be outside the scope of this panel. I'm sorry.

[Laughter.]

MS. LINDAN MAYL: Yeah. You've hit some PC questions. But fortunately for you, we have a PC expert.

MR. ICHTER: Oh, okay.

MS. LINDAN MAYL: But we really do urge you guys to limit the questions to import, because Jenny

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was not expecting to have to work this hard today.

[Laughter.]

MS. SCHOTT: Okay. So this is Jenny Schott,
from FDA CFSAN.

With respect to the definition of a
business, it is the business as a whole, including all
subsidiaries and all affiliates. So when you're
counting employees or determining sales, it's
everything.

And then the next question was? The raw
materials? Okay. So, in the PC rule, a manufacturer
or processor has to look at all its raw materials or
other ingredients. So that's everything that they're
getting in to use in manufacturing the food.

And they have to do a hazard analysis. And
they have to determine if there are any hazards that
have been controlled by a supplier. And that's when
the supply-chain program kicks in.

So the supply-chain program does not apply
to all of the raw materials or their ingredients, only
when the hazard has been controlled, a full receipt.

MS. BARRETT: I need you to speak into the

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microphone.

MR. ICHTER: So, I if understand correctly, if they determine there is no hazard with a given ingredient, then it's okay. Okay. Thank you.

MS. BARRETT: That was a nod yes.

[Laughter.]

MS. BARRETT: All right. Thank you. We'll come to this side.

MS. HERMIDA: Hi. Maile Hermida with Hogan Lovells.

I just have a question about what FSVP inspections are going to look like as analogies to food facility inspections. So, will there be an equivalent to something like an establishment inspection report? Will there be 43s? Will it escalate up to warning letters?

And then connected to that, what do you guys anticipate in terms of the role of the states? Are these mostly going to be conducted by FDA, or are you going to have state people be doing these inspections as well?

MS. LINDAN MAYL: Thank you, Maile.

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So, yes, we do anticipate them to be inspections like facility inspections with inspectional findings. If we need to do warning letters, they will -- we will have forms associated with the FSVP that will look quite familiar in terms of that. There are some slight statutory differences that we have to account for. But, yes, they would look like that.

And I'm sorry. The second part of your question was?

MS. HERMIDA: Will state folks be doing inspections?

MS. LINDAN MAYL: Oh, okay. And I apologize. This is Sharon, who is the person who never identifies themselves when they speak.

At this point, we are. Because of the newness of the program, we are currently developing this program for our FDA investigators. I think, as things go on, that could change. But right now we really are developing the expertise and the skill set of the FDA investigators to do these inspections.

That said, obviously if an importer is also

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a facility that is being inspected by the states, the states are being trained under the PC rule. And so if there's a supplier verification component to a PC inspection that's done by states, then that's where there would be state involvement.

But for the non-registered importers, who are the ones that are complying with the FSVP rule and not the supply-chain provisions of the PC rule, our current plan is to begin -- at least begin by using FDA investigators.

MR. CATO: This is Todd Cato. I was just going to add one quick thing.

They will look very similar, like Sharon mentioned. But the other part is, these are records inspections. So I did want to point out that, as we said in the presentation, they will not all be onsite. Some of them we are exploring the option of doing electronically without an onsite actual investigator at the facility.

MS. BARRETT: Okay. Thank you.

We are going to take one moment to go to our webcast audience to see if we have any questions.

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MS. ROBBS: Yes. So we have a question from Dan Kastor from McCormick & Company.

"What is the timing for the completion of the Foreign Regulatory Agency Equivalency study? What are the challenges? As this information may be critical for the FDA resource planning, shouldn't this be completed in advance of issuing further guidance for FSVP?"

MS. LINDAN MAYL: Yeah. I think there's going to be a presentation on systems recognition later, so why don't we hold that question? And we'll let those experts answer it then. And this is Sharon.

MS. BARRETT: Okay. Yes, we'll take one more question from the webcast audience.

MS. ROBBS: All right. So this question is from Bob Rada, from Blommer Chocolate Company.

"Sharon and others have mentioned about certifying third-party companies to inspect foreign suppliers. What does companies who want to inspect their own suppliers do? Do company employees need to go through any special training? Or is it based on their training, education, and experience?"

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MS. LINDAN MAYL: This is Sharon.

So, yes, you can -- under the FSVP program, an importer can do their own, I've been calling it inspection, but their verification activity, whether that verification activity is an audit of the facility if that's what they believe is the appropriate verification activity, or reviewing food safety records, or laboratory testing.

Whatever it is, whatever verification activity they believe is appropriate, given their hazard analysis and their evaluation of risk of their suppliers, they can do themselves so long as they are qualified to do that activity.

So if they are auditing, they need to fit the definition of a qualified auditor. For the other activities, they need to fit the definition of qualified individuals.

There is no specific training required. It is our sense that folks who are doing those activities may be interested in the alliance training if they are going to do an audit. But it is not a requirement of the FSVP rule.

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MS. BARRETT: Thank you. We'll go back to the microphone in the room.

MR. LIEBERMAN: Erik Lieberman, U.S. Food Imports LLC.

I understand the Agency has stated that FSVP is not a border program. However, there are some concerns about the impact of FSVP on the flow of goods across the border. Are there any circumstances where FDA would seek FSVP records as a condition for releasing a hold on a product?

MR. CATO: Yeah, this is Todd Cato.

The only time you may have a problem like that is if you're actually on the import alert where we've already conducted an inspection. But as part of the entry process, it is not the Agency's plan to seek records during the actual entry process or admissibility process itself.

Now, you know, if we've conducted an inspection, found issues with the FSVP, and the firm ends up on the import alert, then of course, they're going to have to correct that situation before they will be allowed to bring in further goods.

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MR. VENEZIANO: This is Domenic.

So on the FSVP, it's not an adulteration of a commodity as a result of failure to comply with 805. So the product itself might still be able to come in if it's coming in from another importer. It may not be able to come in under that importer because the importer is not in compliance with Section 805.

If we find out that the commodity itself is violative, either adulterated or misbranded, they would probably put on a separate import alert and the importer on an import alert. And therefore, you can get off the import alert as an importer by having another follow-up inspection or providing documentation showing that you're now in compliance.

And therefore, the product would still be able to come in.

MR. LIEBERMAN: That's interesting. So say you have a foreign importer of record and you have a U.S. agent that's the FSVP importer. If the U.S. agent -- basically, the product could come in even if the U.S. agent, as FSVP importer, had a potential compliance issue.

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Or basically, you could admit the product. The analysis is separate when you're looking at the FSVP importer and the importer of record? It doesn't relate to the admissibility of the merchandise. Is that what you're saying?

MR. VENEZIANO: Correct. It doesn't make it an adulterated product.

MR. LIEBERMAN: Right.

MR. VENEZIANO: But the importer would not be able to bring it in. Another importer could bring it in. So if a foreign supplier is dealing with two importers, Importer A and Importer B, Importer A is in the import alert, that product might not be coming in from him because he didn't address the hazards.

MR. LIEBERMAN: And when you say "importer," you're referencing the FSVP importer?

MR. VENEZIANO: Correct.

MR. LIEBERMAN: Okay. Okay. I see what you're saying. Thank you.

MS. LINDAN MAYL: And this is Sharon.

I'll just add that, you know, you could envision another situation. One of the things that I

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talked about during the presentation I gave is, for instance, if we were doing an inspection at an FSVP importer and looked at lab results and saw some pretty egregious violations, we would want our IT systems to be talking to each other and to think about, who else might be looking at bringing in this product that we know is -- the product is violative.

So, you know, one of the things that I've been talking about is the information we're receiving from all of these FSMA programs needs to be analyzed in a way, you know, that can affect others. But I think what Domenic is saying is that, in general, if there is not a problem with the product, we don't want to penalize the product unnecessarily.

But if in an import inspection we do find a problem with the product, then we have all the tools available to us that we would normally at the border, plus we might want to target the other importers for an FSVP inspection because we realize that there's a problem with the product. Does that make sense?

MR. LIEBERMAN: Yeah. You bring up a good point, because there is an obligation to promptly

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reevaluate concerns with your FSVP program if you become aware of new information relating to the product.

And this is a question that's been discussed in industry quite a bit. Do you have an obligation to affirmatively go out and seek the information? So would I have an obligation as an importer to check that dashboard regularly to see if there were concerns with the foreign supplier I'm dealing with?

Or is it only if I become aware of new information? So basically, do I have an affirmative obligation to check? Also, if FDA becomes aware of information, when does -- will FDA share that with the importing community?

What happens if I'm talking to another company that's dealing with Aspire, and the guy tells me, "Hey, you know, we were out at the plant. Didn't look so good." Does that trigger a requirement for me to reevaluate my FSVP?

MR. VENEZIANO: This is Domenic.

I think it depends upon the situation at hand. But overall, I believe you have some due

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diligence to actually go on periodically and verify that the people you're doing business with are in compliance with the regulations and are dealing with an issue.

I also think it's up to you to stop business with that supplier if that's going to be the case if, on FSVP if there are issues. I also think the Agency has an obligation to look at all of its thing. And as Sharon kind of mentioned, they all work together.

So if we find out that something is a result of FSVP and there's a violation, we have to look across our entities and determine, is it a result of a third party that did the inspection? And then when we went in to do the FSVP inspection, we found there were violations.

We have to now reassess the accredited body or the auditing body to see if they're doing it correctly. We also have to look at whether they're on a voluntary qualified importer program and reassess whether they should stay on that program.

So I think, overall, we have to take a look at the entire process and look across that, all of

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FSMA, to see what's impacted.

It could result in an FDA inspection overseas. It could result in an inspection domestically as well. So I think, overall, we have to look and see how it gets impacted by the violations that we find. Make sense, Erik?

MR. LIEBERMAN: Yeah, it does. That does make sense.

MS. LINDAN MAYL: And I'm looking at Brian to make sure I get this right. But there is an obligation, as you said, if you become aware of information to reevaluate your program.

But there's also -- I think it's very three years that you need to reevaluate your program to make sure. But I think that a responsible importer would be checking on the compliance status of their suppliers, you know, to make sure that there's not a problem.

MR. LIEBERMAN: Yeah, there's a difference between the regulatory obligation and best practice.

But, so for every -- allergen labeling is obviously part of the FSVP. It must be verified under

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the FSVP. So every time there's a recall for an undeclared allergen, would that trigger a requirement for importers sourcing from those foreign suppliers to reevaluate their foreign supplier verification programs?

MS. LINDAN MAYL: I would think if they're aware of the information about allergens and problems, that is new information that would trigger them to look at their foreign supplier verification.

MR. LIEBERMAN: So every time there's an undeclared allergen recall, they'd have to do it?

MS. LINDAN MAYL: If it's associated with their product.

MR. LIEBERMAN: Yeah, yeah! I mean, yes, no, I know, something they're sourcing. But that would trigger a requirement to reevaluate --

MS. LINDAN MAYL: I think that -- again, this is Sharon.

I would think that if an importer becomes aware of an undeclared allergen on a product that they are importing, they would have an obligation to revisit that, yes. That is new information that could

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affect the safety of consumers.

MR. LIEBERMAN: Okay. And if there's a recall notice out there, that would constitute -- it would be considered to be aware of that?

MS. LINDAN MAYL: Yes.

MR. LIEBERMAN: Yes. Okay. Even if they weren't actually aware of it.

MS. BARRETT: All right. We'll go back to our webcast audience.

MS. ROBBS: So we have another question from Bob Rada, from Blommer Chocolate.

His question is, "If a foreign supplier is inspected by a certified third-party company or a qualified individual from a customer or importer, based on risk, can other companies use the results of that inspection, or are they required to do their own?"

MS. LINDAN MAYL: This is Sharon.

The answer to that is yes, an importer can rely on an audit of their supplier that perhaps was even, if it's a third-party audit procured by the supplier and shared with all of their importers. So

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it is certainly our hope and intent that this becomes, you know, an efficient process where people have an audit report that they can share with various importers so that importers aren't going and re-auditing.

So the answer to that is yes, with the caveat that, obviously, each importer needs to have a qualified individual to evaluate the quality of that audit and look at it and make sure that they're looking at the correct things and are meeting the requirements of the regulation.

MS. BARRETT: Okay. Do we have any other webcast questions at this time? We can do one more.

MS. ROBBS: So, we do have a question from Maria Carmela Emanuele, from Costa d'Oro Spa.

And she's asking whether or not -- and I'm not sure if we'll talk about it later, but whether or not there will be training courses done in Italy, either done by FDA or other authorized auditors in the Italian language, and whether or not we'll have training in the Italian language.

MS. LINDAN MAYL: This is Sharon. We have

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no -- FDA does not have any current plans to have training courses necessarily in other languages. As I said, there is information on the web that we have translated.

However, the alliances are developing -- there's an international subgroup in the alliances that will be developing and specifically gearing their educational materials to a foreign audience, particularly for the PC and produce rules. So I would definitely keep your eyes on that.

In addition, the training materials from the alliance will be on the internet and therefore accessible to those that are not necessarily in the United States. So there will be that access as well.

MS. BARRETT: Thank you.

Additional questions from the webcast? No?

All right. Additional questions in the room?

[No audible response.]

MS. BARRETT: Okay. Well, seeing none at this time, we will have another opportunity for Q&A at the end of the day.

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But for now, we will go ahead and transition into some presentations that we have from our International Affairs staff. So I want to thank this panel, and we'll ask our two speakers coming up next to come on down.

[Applause.]

[Pause.]

MS. BARRETT: Okay. Well, I want to welcome two speakers from our FDA International Affairs staff who are with us this afternoon. We have Julie Moss, who is our Deputy Director, International Affairs staff Center for Food Safety and Applied Nutrition at FDA.

And Caroline Smith DeWaal, who is an international policy manager of our International Affairs staff also within CIFSAN.

Julie will present first, talking broadly around FSMA Communication and Engagement for International Stakeholders. And then Caroline will speak specifically to systems recognition, a topic that has come up a few times already today.

So with that, Julie.

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GLOBAL APPROACHES TO FOOD SAFETY

MS. MOSS: Thank you, Kari. Good afternoon, everyone.

So, I'm going to talk to you today about FSMA's Communications and Engagement for International Stakeholders. There was a discussion this morning with regards to the FSMA rules and tools, and I do want to share with you that capacity-building is a non-regulatory tool that FDA had in its toolbox.

I have also heard a lot about FSMA trainings, the Technical Assistance Network, and the alliances. And so, what I hope to do with this particular talk is to step up a couple of levels and to share with you the impetus and the rationale behind what we're doing with regards to our FSMA outreach and training activities and to give you a sense with regards to our thought process and our strategic thinking around that.

[Pause.]

MS. MOSS: All right. So the points that I'd like to cover today is -- I'll start off by sharing with you a background on what FDA is doing

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with regards to capacity-building and what our background thinking and rationale is behind it. And then I'll get into more specifics of our FSMA international engagement efforts.

FSMA Section 305 is specifically titled "Building Capacity of Foreign Governments with Respect to Food Safety." The Agency has been doing international food safety capacity-building for many, many years. However, this is the first time that it's being called out in legislation.

This particular section specifically directs the Agency to develop a plan to expand the technical, scientific and regulatory food safety capacity of foreign governments and their respective industries that export food to the United States.

Within 305, it calls out six specific elements that the Agency is to consider within developing its capacity-building plan. One of the elements that is element 4 specifically talks about training foreign governments and food producers on U.S. requirements for safe food. And let me talk about that just a little bit more.

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FDA issued its international food safety capacity-building plan in early 2013. And it consists of various goals, as well as more than 45 specific action items that the Agency is to work on with regards to international capacity-building.

What I want to focus on here for you today is specifically on element 4, about the training component. The key actions included in this section talk about coordinating with other U.S. agencies and engaging other multilateral and bilateral agencies, as well, again, the notion of that we're in this together. The FDA can't do this alone. We need to partner with other agencies.

We need to continue developing training materials through our partnerships. We have a lot of expertise in the Agency, but we know you have more, too. So we want to partner together to develop the curriculum.

We will focus on prioritizing our training and capacity-building activities according to both risk and the need. And we also want to make sure that FDA's foreign offices are supporting our capacity-

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building efforts. And I'm going to call out Section 308, which identifies and delineates FDA's foreign offices to provide technical assistance on food safety.

Another element that we are very cognizant of is our international obligations. Within the World Trade Organization, there is an agreement that covers in part food safety. This agreement is the Sanitary and Phytosanitary Agreement, or the SPS Agreement.

The U.S. is a signatory of this agreement. And in Article 9, to paraphrase, it says that we will provide technical assistance to other member countries either directly or through partners. And we take this obligation very seriously.

So within our WTO obligations and the FSMA capacity-building, Section 305 and the subsequent plan, we have set up a framework and related activities for FSMA communications and engagement. Our overarching goal is simply to support high rates of compliance with the FSMA rules.

And we intend to do this by addressing a

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continuum of information needs of our various international stakeholders.

International stakeholders, as depicted in this slide here, are many and varied. We will be partnering with many of these stakeholders to give and provide FSMA trainings.

We also recognize that many of these stakeholders will be on the receiving end of training and have very different interests, very different needs. And we are cognizant of all of our stakeholders at the table with us with regards to international engagement.

This slide is a snapshot of the communications and engagement framework. It consists of four stages and delineates who leads the work. So I'm going to sit on this slide for just a minute and talk you through it.

Going from left to right, for Phase 1, this is before any of the final rules issue, at this stage we, FDA, are identifying our key stakeholders. We're identifying key audiences. We're identifying key partners. We're also developing and refining our

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messaging and making sure that it meets the needs of our stakeholders so that we can be as informative as possible.

It is at this stage where the two upcoming FSMA rules are sitting with regards to the intentional contamination and the sanitary transport. They're at this stage, defining their messaging and making sure they're interacting and communicating with their targeted stakeholder group.

With regards to stage 2, this is where FDA is disseminating information on our final rules. The onus is on FDA, and so what we are doing is we are raising awareness with regards to the final rules. We're explaining what is in the rules and what's not in the rules. We're helping to demystify any of the thoughts around the rules. We want to provide concrete information about the rules.

We're listening to stakeholders, and we're responding to needs. And this conversation that we're having today exactly fits in this stage 2.

Moving on to stage 3, this is where we're focused on developing education materials and

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performing the actual training and education around the globe. FDA recognizes that we cannot do this alone. So we are relying heavily on partners for this stage 3.

And then moving on to stage 4, this is where we have a feedback loop, where we want to make sure that what we've developed by us and also with our partners, that it is sustainable. So we're monitoring and evaluating for sustained effectiveness with all of the various capacity-building information and outreach activities that we do.

And you'll notice, too, that it's color-coded on the bottom where the blue is identifying the lead as FDA, moving into green, where our partners are leading those efforts.

So the next couple of slides I'm going to talk a little bit more in-depth about how we are engaging, and then there will be a slide about how you all can engage, too.

The Technical Assistance Network has been mentioned numerous times, so I won't go into a lot of detail here. But I do want to be clear that this is a

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way how we are engaging, how we are available and open to you for your various technical questions.

And as a practical nature, the building that you're sitting in here, this is where the Technical Assistance Network sits. The individuals that you saw today from FDA are the subject-matter experts. They and others are the ones that are available to be answering a lot of these questions.

So I want you to know that it's a very active network, and it is available to provide you responses and insights into some of the questions that you have, moving forward. So utilize that resource.

Additionally, we are also doing FSMA outreach. We have the alliances, which were mentioned, and we also have some FSMA readiness training programs. And let me just elaborate more.

With regards to FSMA outreach, we started doing outreach in December of 2015 to international audiences. And we're going to be continuing this FSMA outreach through the summer, likely, of 2016 here.

And this outreach is cadres of FDA experts that are going to be making a series of visits to

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various partner countries and regions with the intention of meeting governments, industry, and academic stakeholders to discuss FSMA and its impact, and to answer questions as well.

Additionally, FDA has and will continue to hold conference calls and webinars to share FSMA presentations with the international community. Many of these presentations, webinars, and recordings are already available on FDA's FSMA website as well.

For the alliances, the FDA has teamed with the Illinois Institute of Technology and Cornell University to establish the Food Safety Preventative Controls Alliance, and the Produce Safety Alliances. The alliances are public-private entities formed to support safe food production by developing core curriculum, training materials, and outreach programs to assist stakeholders to become and maintain prepared to adhere to the FSMA food safety requirements.

And lastly on this slide, FDA is also collaborating with USDA's Foreign Agricultural Service, the U.S. Agency for International Development, Texas Tech University, and the Inter-

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American Institute for Cooperation on Agriculture, which is also called AICA.

And we're partnering with these organizations to implement FSMA readiness outreach and capacity-building activities in many countries in Latin America and the Caribbean.

Funding for this type of activity is now being sought to try and duplicate it in broader and larger regions around the globe. So we started in Latin America and the Caribbean, and we hope to be able to replicate it in additional regions.

So, how can you engage? This is a snapshot of the website with regards to the alliances, the Sprout Safety Alliance, the Food Safety Preventative Controls Alliance, and the Produce Safety Alliance. And I want to quickly just share the four specific outreach goals and objectives for the alliances.

First, to increase industry awareness about the alliances' education, outreach, and technical assistance programs. Secondly, to develop a comprehensive network of lead instructors interested in participating in alliance training programs that

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are designed to help food industry understand the FSMA requirements. Third, the alliances will identify and develop relevant technical information and educational resources for all stakeholders, but with an emphasis for small food companies.

And lastly, the alliances will establish a network of technical experts that would be available to assist industry and other stakeholders that have technical questions. So you can see there's a parity there. We have FDA's Technical Assistance Network, but there's also going to be a network through the alliances, as well.

And what was mentioned previously, within the alliances, there is an international subcommittee for both the Preventative Controls Alliance and the Produce Safety Alliance.

And these subcommittees are intended to ensure opportunities and educational materials are available to international audiences in a manner that is appropriate and sensitive to various cultures, regions, political situations, languages, and development levels around the world.

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So if you have an interest in wanting to be engaged, the door is open. This is an opportunity for you. And if you're interested, feel free to reach out to me, and I can certainly help you connect the dots.

So, before I close, with anything new comes some unease. But we can do this. My hope is that FDA's efforts to communicate with you, to engage with you, and to offer training opportunities will help lessen that unease. And I think collectively, together, we can make it happen. Thank you.

[Applause.]

MS. BARRETT: Thank you so much, Julie.

And I just want to recognize, too, with our outreach just how much we appreciate many of you in the room and on the webcast, all of your efforts to really help us expand our outreach. So many of you have set up webinars and other programs where we've been able to engage with audiences and expand our reach. And it's really deeply appreciated. So, thank you.

And with that, Caroline, I'll have you come up.

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MS. SMITH DeWAAL: Great. If anybody needs to just stand up and wake up, feel free to do that because it's going to take me a minute to get this working.

[Pause.]

MS. SMITH DeWAAL: All right. I see no one stood up. So, excellent. Someone is stretching in the back; that's great. We're a little ahead of schedule, and we started the morning talking about robust foreign partnerships. And we're at that part of the agenda where I'm going to outline FDA's thinking around this concept.

I head up the team that manages systems recognition, but we also manage equivalence. We manage the produce partnership with Mexico. So we're really at the center of how these partnerships are going to work.

Some of this is very innovative. It was really spearheaded by Camille Brewer, who heads up the International Affairs Staff. And so we're very interested in the discussion that will follow.

For this presentation, I'm going to go

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through the definition. What is systems recognition, some of the benefits that FDA has identified -- we'll go through the three steps of getting recognized if you're a country that's interested, and also talk a little bit about what's happening next with respect to FDA.

So, it's very important to understand that systems recognition is really a formation of a regulatory partnership. It allows our foreign governments to partner with FDA and vice-versa to really advance the food safety objectives of both governments.

And recognition really describes a country's food safety system that provides the similar, but not necessarily identical, system of protection. But where we have identified that the country is providing similar oversight and monitoring, and really providing similar outcomes when it comes to public health protection.

Systems recognition, though, is not a market access tool. It is not required that countries that want to ship to the U.S. be recognized. It's really a

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new tool in our toolbox that will facilitate trade in safer food. But it's not a requirement.

What it does do, though, is it gives us greater confidence that countries that are recognized are going to be reliable partners when problems invariably happen. There will be outbreaks. There will be recalls. There will be import alerts in the future.

But we want to have an active dialog with those governments so we can ensure that those problems are appropriately responded to, rapidly responded to in order to protect public health, and that we develop systems of continuous improvement as partners so that we minimize the likelihood of repetitive events occurring.

How does systems recognition benefit FDA? Well, we think that in the future, it's really going to allow us to focus our resources more effectively so that we can put resources into areas where we most need them to prevent the next outbreak or recall or event.

And we can save our resources from being

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sent to countries to do potentially duplicate inspections, for example, or where we really have trusted partners. That's not where we should be spending our hard-earned inspectional resources.

We also can -- it helps us to identify the countries where we have those partnerships, that we can rely on them when an outbreak occurs or where we have a finding at the border that poses a particular concern -- we can rely on those countries to do the follow-up. And so it creates a dialog at those moments when you most need in order to protect consumers.

I mean, often if there's a problem with an import, there may also be a problem with the food in the country of origin. So that partnership becomes very important.

It also offers the prospect of information-sharing on additional issues. So it's really an open door for the countries that are recognized.

So the process of getting recognized as a foreign government is really a three-step process. The first step really largely happens at FDA. We do

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what's called a pre-screen. We examine the trade, the existing trade, the compliance history. We look at refusals of admissions, import alerts, and outbreaks linked to the country's product. This is largely information either within FDA's own sources, or it's publicly available.

We also look at data from other Federal Agencies, an example being USDA's Global Agricultural Information Network, or GAIN. And this helps -- all this information put together really helps us evaluate whether the country is likely to be a successful candidate for systems recognition.

Step 2 is the completion of our ICAT. Now, this is the International Comparability Assessment Tool. And it is really a document review to see if the programs are truly aligned.

Now, the ICAT is really -- it really is a mirror into FDA's own system. When a country approaches us for systems recognition, the ICAT gives us the ability to share what our system looks like. And we ask the country then to give us the aspects of their system that align with these elements that we've

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shared with them.

So the ICAT consists of these 10 core elements. The first element is the regulatory foundation, and it really is many more than 10 elements. It probably has 10 sub-elements within it. But it does, importantly, include preventive controls as one of the things we look at.

We also look at training and human resources as our second element. Third is the inspection program. Fourth is the ability for the program to do assessment and also their ability to do audits.

We have food-related illness and outbreaks as a component. This looks both at how countries manage outbreaks that occur internally and what their response -- how they prevent those events from occurring again.

We look at compliance and enforcement, and this includes some verification activities. We look at industry and community relations. How transparent is their system? How much are they sharing with their own industry, and importantly their own public, as well?

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Program resources, how are they funded? We compare issues around international communications and harmonization. This has to do with whether they are active in Codex or in other systems which allow for this harmonization. And also, we look at laboratories.

Now, this review is done by a team of technical experts from within FDA. So the ICAT is a tool where we share our information, a government then gives us the information from their system that aligns with ours, and then our technical experts and, presumably, theirs sit and compare the programs.

And it really provides a deep dive into the foreign system, including its regulatory foundation and its approaches to regulating the food industry. We're really looking for countries that have a very strong alignment with ours, very similar philosophies and a preventive approach to food safety.

Step 3 is after this in-depth review of what the country has shared through the ICAT is to actually send people from this team of experts to the country to actually check that what is being done in practice

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aligns with the ICAT submission. And to do this, the team conducts interviews, they review government records, they visit government agencies, and they accompany government officials on facility audits and inspections. We also send people out to look at the laboratories, as well.

So, the foods that are covered under systems recognition will be foods, first and foremost, foods regulated by FDA. So of course, meats and poultry products would not be covered.

We also have some programs like Grade A milk and milk products, and mollusks and shellfish that are managed under unique programs at FDA, and they are generally covered through an equivalent agreement with the foreign government. We don't have too many of those, but that's the theory for how we're managing them. And we have active submissions for equivalence in those areas.

Dietary supplements and animal feed are generally excluded, as well as being outside the scope of systems recognition.

There are also some standards that we

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generally don't cover. We don't cover food labeling, for example, under systems recognition. When food is imported to the U.S., they are expected to have the label that matches our nutrition label.

Same with maximum residue levels for pesticides or vet drugs. We're not trading off on those types of standards. People still have to comply with them.

So, finally, just to tell you where we are with respect to systems recognition right now, we're really moving in a very focused way from the pilot phase of the program to adoption as a formal program. New Zealand was the country that was recognized in 2012. They've been a good partner in the experiment of systems recognition, and we think it's been quite successful. But again, we think it's also improving.

And we have Canada and Australia, which have already gone through the three-step process that I outlined. And they're really at the -- I hate to think it's a fourth step, but we have this step of actually doing the arrangement, which is a legal document, which seems to take a lot of time. So

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they're at that fourth step of getting the arrangement in place.

And then, we also have the European Union, which just filed their ICAT last month. So we're just starting the three-step -- or the second step of the process with them.

And following recognition, this is not a snapshot; this is a continuing process. Countries advise us if they have major changes in their law. And every five years, we also do a reassessment to make sure that that alignment, which forms the foundation of systems recognition, is still in place.

So with that, I think we're done on our panelists.

[Applause.]

MS. BARRETT: Okay. So for those of you who are familiar with our public meetings, we aren't afraid to charge ahead. But we are going to take a short break now, but it will be a little bit shorter, in hopes that we might wrap up a little earlier.

So it's 2:40 now. We'll get started promptly at three o'clock. I would ask again, if you

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intend to give public comment this afternoon and you haven't seen Juanita, if you please would. She'll give you a little guidance on where to sit.

We'll also have a Q&A session at the end. And Camille Brewer will be part of that panel. So if you did have questions on systems recognition or the international engagement communications, Camille will be available later on that panel to help answer some of those questions.

So, thank you. Three o'clock we'll start again.

BREAK

MS. BARRETT: So, folks, if we can begin to take our seats. As you're taking seats, I'll just mention, for all of you, when you came in today, you received a folder. We do have some extra copies. So if there is someone who couldn't join today in person and you'd like to give them a complete folder, please feel free to go to the registration desk and they can provide you with one or more.

[Pause.]

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OPEN PUBLIC COMMENT AND Q&A SESSION

MS. BARRETT: All right. Thank you all for waiting. We will go ahead and get started. We are transitioning now from having done a lot of talking today and had some really great questions. We do have some time set aside for public comments, and we really do look forward to hearing that, and thank folks who have prepared to do that this afternoon.

Our FDA panelists will be listening to public comments. Most of these folks I think you've seen throughout the day. We have Sharon Mayl, and I'm not going to go through the titles, it's in the agenda -- Charlotte Christin, Brian Pendleton, Domenic Veneziano. Todd Cato, and Camille Brewer, who has joined the panel.

So, again I want to welcome everyone who is offering public comment this afternoon. I thank you for your time in preparing your remarks. As you are aware, we have asked to keep the public comments to about three minutes per speaker.

Hopefully, all of you who are giving comments are located somewhere where you can easily

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get to the microphone. And I will call you up individually by name to have you speak. Please repeat your name and your affiliation for the transcriber when you do come up to the microphone so that we do ensure it's recorded correctly.

The FDA panelists are really here to listen, but occasionally folks do ask a clarifying question. If in your remarks you have a question, we would ask that you hold those until we follow up the public comments session with our Q&A session, and then we'll have time to have that dialog.

So with that, we will go ahead and proceed. And our first speaker is actually Ram. Yes, and you said that you would give your full name for the record. So please come on up to the microphone, and your affiliation as well.

MR. BALASUBRAMANIAN: My name is Ramakrishnan Balasubramanian, Chief Operating Officer for Quality Certification Services. We do organic and food safety certifications and audits. We operate in about 33 states and 11 countries.

We will be applying to the accredited

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certification body under the FSMA when FDA is ready to accept the application.

We believe the ACB's, the accredited certification body's role is not going to be limited to the two situations discussed this morning. To prevent chaos in the recordkeeping system and having to have a GFSI scheme and FDA scheme together, importers pretty soon are going to eventually request certification under FSMA.

A Third World country producer, if he exports to the U.S.A. and Europe, he has to dually be certified to a GSFI scheme and the FDA's certification, which is why consistency among the ACB's are critical. And that's why we are requesting a penalty matrix.

The penalty matrix will lay out what each type of noncompliance, what action can be expected. For example, when can the ACB's can issue a notice of noncompliance and suspension together? When can we issue the revocation? Also, the penalty matrix will be such a transparent process which will guide the importers', suppliers' requests, and even the FDA how

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a gray area noncompliance will be handled and what consequence to expect.

The second thing I would like to stress -- variance. Currently, rules allow states and other foreign governments to request variance. Have you all worked with foreign Third World countries' governments? It takes a long, long time.

We request -- it may be too late. We request the ACB's, according to the rule, are agents of the FDA. So we request that in order to expedite, the fast and easy way is to include ACB's as one of the people who can request variances. This way, the importers, the suppliers who are affected will benefit out of it, and perhaps, the importers, too.

A third one is standardized audit checklist and time frame to complete the audit, and when the certificate has to be included. It must be included in the certification guidance documents. Otherwise, someone this morning mentioned, it may end up like the organic certification. It takes too long to complete. In the meantime, the suppliers would be the ones who would be left to hang.

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Obviously, the FDA can learn from USDA's experience in running third-party accreditation programs.

Audience in the rooms are educated about this matter. If they are confused about the foreign supplier verification program and other requirements, imagine people who are not here. That is so much confusion. So on behalf of our clients we certify and other importers, we urge that education materials such as the videos you described to be developed as soon as possible.

FSMA is a huge task and a process. We appreciate and thank FDA and the staff who are in one in this getting done. Thank you.

MS. BARRETT: Great. Thank you very much.

Okay. We'll go to our next speaker, which is Tony Corbo.

MR. CORBO: Tony Corbo, with the Public Interest Advocacy Group, Food & Water Watch.

First of all, I want to thank FDA for conducting this public meeting, and I want to appreciate the work that the FDA staff has put in to

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putting this on and also in developing the final rules. And that goes for you, as well, Charlotte.

Okay. I want to touch on a couple of things that Mike Taylor kind of mentioned in his remarks this morning. Consumers have to feel confident in the food safety system that FDA is putting together here, and especially on imports.

We are still concerned that FDA is going to be hampered in being able to prevent adulterated food from entering the food supply from imports. The FY 2017 Proposed Budget shows declining port of entry inspections as a percentage. There are going to be 1,200 to 1,300 foreign facility inspections.

Section 201 of FSMA called for 19,200 foreign facility inspections to be conducted by FY 2016. The latest registration figures show that there are 120,000 foreign food facility registrations. So at this pace, we're going to be taking 100 years to visit all of the foreign facilities.

We have the most confidence in FDA actually being able to do these inspections. And it's going to be incumbent on getting the resources to conduct those

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import inspections.

We are also fearful that the new trade deals that the administration is engaged in is going to exacerbate the problem.

In recent discussions that we have had with the Agency, we were discussing some of the food-borne illness outbreak investigations that involve imported products. And we were shocked to learn that at least in one of these investigations, FDA personnel could not visit the area where the suspect product was coming in because it was unsafe. It was even unsafe by the State Department for U.S. citizens to visit.

So it begs the question, why are we importing food from areas that either have internal political strife or are being run by drug cartels? So we hope that as these regulations are implemented, that we really take into account where the food is coming from.

There is a disparity. There is a disparity, and this is something Mike mentioned earlier today, in the perception in the way FSMA is going to be implemented for the domestic food industry versus the

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imported food industry.

The domestic food industry is going to be subject to FDA inspections, whereas the imported food is going to be subject to paper checks by FDA inspectors going to visit the importers.

And unless we get the import inspection regime up to speed on the import side, you are going to have complaints from the domestic food industry that they are not being treated fairly.

As we have stated in the past, we do have problems with private third-party certifications for food safety. We still have concerns. And so, we don't want to see an expansion of that concept to enter the domestic food supply.

On the issue of systems recognition, this is something that I'm familiar with on the USDA side. New Zealand has been the only country. You're about to come up for a renewal of that systems recognition agreement. Canada, I know it has been going on for at least four years, and that agreement still hasn't been reached.

I have a concern when I hear that you're

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going to do a systems recognition for the entire EU. As you're well aware, that is an issue, a concept that has been very controversial in the TTIP negotiations. Your sister agency over at FSIS has been reluctant to recognize the EU as an entire entity to do equivalency.

And it seems that where FDA is going is running counter to what USDA is doing. So I would raise that concern and hope that you collaborate with your sister agency at FSIS. Thank you.

MS. BARRETT: Thank you so much, Tony, for your perspective.

We'll go to our next speaker, who is Anna Merlino. Okay. I don't see Anna. So we'll continue on through the list.

Marsha Echols.

MS. ECHOLS: Good afternoon. My name is Marsha Echols, as you said. I am the Washington, D.C., counsel for the Specialty Food Association, a trade association for the specialty food industry located in New York City. I'm making my comments on behalf of SFA today.

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The Specialty Food Association is the trade association for all segments of the specialty foods industry. That includes importers, distributors, and retailers that offer imported specialty foods.

Most specialty food companies are small and very small businesses. And so, as I make the comment today, please keep that in mind. I am talking primarily about small and many very small companies, both importers and foreign suppliers.

They make and sell high-value foods, as SFA's definition of "a specialty food" makes clear: "foods that exemplify quality, innovation, style in their character, originality, authenticity, ethnic or cultural origins, special-processing ingredients, some of which are imported, a limited supply, and often a specific channel of distribution or sale."

So these are the characteristics of foods that are innovative, create trends, and often are limited in production and capabilities-limited small businesses.

In sum, the businesses that import these foods are often small, very small, and frequently use

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a business method based on bringing high-quality innovated trending foods into the United States. So again, thinking small and very small businesses that can do this.

Foreign supplier verification program's implementation, with the details that are being proposed now and the requirements being proposed could undermine the import segment of a vibrant industry and hinder this business method that is often based on including new and different imported products into the supply.

Although the importer segment of the industry includes many small importers, specialty importers handle several SKU's, which will be subject to foreign supplier verification. Accordingly, according to an SFA mental (phonetic) research study, roughly a third of the importers, specialty food importers carry 50 or fewer SKU's.

But a quarter carry an average of 211 SKU's in 2015, which means that if there must be a foreign supplier verification by ingredient, by its product, or category of product, there is a very tremendous

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burden that's going to be placed on these small and very small companies, and even mid-sized companies.

The survey identified Europe as the most frequent source of the imports, followed distantly by Asia, Central and South America. So as you hear the request from SFA for you to speed up the comparability assessment of the EC, in contrast to the comments that were just made, certainly for specialty food producers, the certification or at least some equivalent agreement regarding products from Europe are very important and crucial to their business.

So, SFA's first recommendation is quickly to make these assessments of comparability and equivalence, and also to make guidance documents and templates and other support, practical support available as quickly as possible. They will be as important to these companies as the regulation or the guidance, full guidance document that you are planning.

If this idea is not carried out with the support and the documentary support, with giving directions, templates, and so on, FSVP implementation

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could have significant negative consequences within the U.S. and for international trade.

This is important as we make the next point, which concerns equivalence and the comparability assessment. I think several of you are familiar with the -- well, you mentioned the SPS agreement at the WTO. And if you remember the rules of the SPS agreement -- well, first, FSMA says that the U.S. will need its international trade commitments.

One of those commitments is specified in the SPS agreement, which says if the U.S. shall accept the measures of other WTO members as equivalent if the exporting member objectively demonstrates that its measures achieve the U.S.'s appropriate level of food safety.

Only Canada, Australia, and New Zealand have been given the opportunity to make this demonstration, which means that you are leaving out the majority of the WTO members and making it impossible for him to meet this WTO requirement that is on the United States. So that the failure is in the United States.

You are not giving the exporting WTO members

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the chance to prove that their systems are equivalent, and much less, comparable to those at the United States.

So foreign suppliers whose products have not been proven to be unsafe, as required by Articles 2 and 5 of the SFS agreement, and whose governments have not had the opportunity to demonstrate equivalence, as provided by Article 4, might not be able to sell their products or have their products enter the U.S. market, which seems to be contrary to both FSMA and to the WTO's agreement.

The last recommendation that we, SFA, has is related. Pending equivalence or comparability determinations, FDA should find that an importer and its supplier meets the FSVP responsibilities by having available for FDA a shorter list, a different list of documents that can indicate and be a satisfactory, temporarily indication of the safety of the food product that is being offered for the U.S. market.

And the documents that FSA suggests FDA consider, at least initially, are documentation from the supplier's government or a named local entity

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regarding the safety of the food and the reliability of the supplier, or an audit if that is available, but something that is an indication of safety, but short of what you are looking for and the time that it would take a comparability assessment to find.

The second assigned statement by the supplier that its food is safe or something acknowledging the responsibility of that supplier. A HACCP plan is a third requirement that SFA is asking you to consider.

The fourth is the usual commercial documents giving the product description, an identifier like a lot number, and so on. And that document would give you the name and address and contact information for the supplier so that you have that.

The fifth document that SFA suggests is the address and identifier of the registered facility so that you have all of those documents that allow you to identify the product, something about it, and its safety and identify the supplier and the facility from which it comes.

So, thank you for this opportunity to make

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these comments on behalf of SFA. The association looks forward to continuing to discuss its requirements, or its suggestions and others that the association has, with FDA, as you work on the guidance documents and other regarding the foreign supplier verification program. Thank you.

MS. BARRETT: Okay. Thank you very much.

We'll go to our next speaker, Erik Lieberman.

MR. LIEBERMAN: Thank you. And I want to thank the Agency for holding today's meeting, and just the openness in which all the FSMA rules -- the openness in which the Agency has been conducting the entire set of FSMA rulemakings. It's been very useful to industry, and we've gotten a lot of good information.

I think the Agency has gotten a lot of good feedback from industry as well. And it's resulting in a much -- in a very well-informed rulemaking, and we appreciate that. And I really think this should be a model for other agencies in the government.

U.S. food imports provide services to U.S.

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importers and foreign exporters to the United States who provide regulatory solutions on issues related to FSMA, food labeling, and other matters, including USDA matters.

I appreciate the opportunity to speak today. While the final rule addressed many of the key questions that arose in the proposed rule, there are a number of outstanding issues that still remain. The definition of "importer," we discussed that earlier.

There are scenarios where you will have a U.S. owner and a separate entity that has a written purchase agreement. And it's a separate U.S. entity that has a written purchase agreement with the foreign supplier. So you have two potential FSVP importers at the time of entry.

We appreciate FDA's response that there is flexibility in determining -- in basically assigning the FSVP role to a particular company so long as both of them could be considered the importer. And we look forward to seeing more guidance on that topic.

The industry does remain concerned about the impact of FSVP on goods entering the country at the

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time of entry. FDA addressed that today and emphasized that FSVP is not a border program. And I think it's fantastic that the Agency is separating the FSVP enforcement from admissibility decisions. And I think that's a very good thing.

Reevaluating the FSVP, importers have an obligation to reevaluate the FSVP when they become aware of concerns related to foreign supplier food safety performance, among other things. And having more guidance on when an FSVP needs to be evaluated would be very helpful.

And we're certainly interested in hearing more about that dashboard that FDA discussed earlier. I think that could be a fantastic tool for industry. So we really appreciate that. I think that's a great idea.

And discussing, too, if there is an affirmative -- where the affirmative obligations lie in terms of monitoring foreign suppliers. That would be very helpful.

Another issue of packing houses that commingle produce from various small farms -- how is

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an importer to do FSVP in that instance? Can the importer rely on the cooperative or the packing house to certify that all of its -- all of the growers it works with are meeting the produce safety standards and other applicable FDA food safety standards?

International average we believe is critical. We would be interested in hearing more about FDA's plans going forward to reach out to the global community in terms of educating exporters to the United States about FSVP.

And food contact substances, there were some discussions today about that. We appreciate the information. We still have questions about the scope of the application of FSVP Rule 2, Food Contact Substances.

And also, what about chemicals that are being imported for use as food contact substances? Are they considered foods at the time of entry, or are they not considered a food until they are actually put in lining a pan, or used in the manufacture of a cutting board?

So would there be an obligation to conduct

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verification on the chemicals that are being used to manufacture pots and pans, coatings in pots and pans, coatings in cans, food packaging, that sort of thing?

So again, thank you for the opportunity to speak today. And we really appreciate all these meetings.

MS. BARRETT: Thank you so much.

We'll go to our next speaker, Natalia Larrimer.

MS. LARRIMER: Hi. Natalia Larrimer with ANSI-ASQ National Accreditation Board.

I just wanted to thank you again for the process that has been implemented to working with you guys. As you know, we've been part of commenting on accreditation, various accreditation comments as well. So I just wanted to continue in that part.

And one thing that I wanted to touch base today on, based on our conversation this morning, one of the things that was mentioned that there are about 19,000 inspections, if I understood correctly, that were supposed to, anticipated to be implemented by this point. And we're only at about 2,000.

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One of the things that I'm not sure if you guys have explored is, there is also the whole third-party accreditation program specific to inspection activities that is already there and set up.

And there is actually a number of accreditation bodies within the United States, as well as globally, that are operating those inspections and would be ready and very willingly working with the FDA to get those numbers cut up and offer our services to you, or our clients would be providing services.

So it would be a similar setup under 17021 that you currently have, except utilizing a different standard that is specific for the inspection, which is 17020.

MS. CHRISTIN: Is it 17020?

MS. LARRIMER: Yes, yes. Sorry.

Another thing that I wanted to discuss is, one of things that my understanding is that FDA, now that the rule for the third-party certification has been finalized, the FDA is looking at setting up requirements for accreditation of testing facilities, so laboratories that are being utilized for testing of

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various samples, and what-not.

One of the things that we are hearing on our end is that some of the misconceptions exist, such as cost for accreditation, one I remember that I heard is that some people think it costs \$40,000 to \$50,000 to be accredited to 17025.

That is not the case. Average accreditation costs for a two-year cycle is about \$10,000. What some people do is bring up PT testing and quality assurance programs into it. But that's part of running a laboratory. When you're looking at just accreditation costs, it's only about \$10,000 over the two-year cycle.

As well as a number of already regulatory authorities, such as CPSC, as both Nuclear Regulatory Commission, EPA -- they're using 17025. And what they do, they use it as a base for technical and quality requirements and then add on their specific requirements that they feel are necessary for their specific operations.

Because what that standard will do is it will focus on specific technical competence of

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laboratory that you, or whoever is the stakeholder, would like, whether it's microbiology. And it's all down to the test method that we could provide that service for. And I think that's it.

MS. BARRETT: Okay. Thank you very much for your remarks.

MS. CHRISTIN: I'm sorry.

MS. BARRETT: No.

MS. CHRISTIN: Just to respond. The lab accreditation program is not user-fee funded.

MS. LARRIMER: Okay.

MS. BARRETT: Thank you. Okay.

We'll go to our next speaker. It's Maile Hermida.

MS. HERMIDA: Good afternoon, and thank you for the opportunity to provide these comments. My name is Maile Hermida, and I'm a partner with the law firm Hogan Lovells, but I'm speaking as counsel for the International Dairy Foods Association.

IDFA represents the nation's manufacturing and marketing industries and their suppliers within the membership of 550 companies within \$125 billion a

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year industry. IDFA would like to highlight two issues regarding the FSMA import provisions addressing VQIP and FSVP.

First regarding VQIP, IDFA is concerned that, as envisioned by FDA in the draft guidance, the significant effort and costs that would be required for industry to participate in the program would not justify the limited benefits that were proposed.

In particular, IDFA feels the program structure was too confining in terms of not having flexibility during the year. And we appreciate what we've heard today that there have been some modifications made in that respect.

IDFA wants to make sure that VQIP is a success so that all the effort FDA put into the program actually works in a way that encourages industry participation. So we look forward to seeing the final this summer.

Regarding FSVP, IDFA is specifically concerned about Section 1.507. And that provides that an importer does not need to engage in supplier verification for a hazard if they conclude that the

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food could not be consumed without application of an appropriate control or they rely on someone downstream to control the hazard, disclose the hazard in writing, and receive an annual written assurance that the hazard will be controlled.

IDFA requested FDA reconsider this provision as applied to raw milk and raw cream imports. The Federal Import Milk Act already requires that imported raw milk and raw cream products must be accompanied by a permit issued by FDA, and issuance of this permit requires that certain sanitary standards be met.

Further, FDA's regulations mandate pasteurization for all milk and milk products in final package form intended for directly timely consumption. Accordingly, FDA should either recognize that raw milk cannot be consumed without application of an appropriate control, analogous to something like coffee beans, or waive 1.507 for raw milk imports.

In addition to the comments specific to dairy, IDFA is supportive of more general comments presented on Section 1.507 by Allied Trade Associations, including the Grocery Manufacturers

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Association, who will speak shortly. Thank you.

MS. BARRETT: Thank you very much.

We'll go to Tara Hartung.

MS. HARTUNG: Hello. My name is Tara Hartung, and I'm with Hartung Brothers Incorporated. We are a producer and green shipper of agricultural commodities for further processing in the U.S. and Canada. We are an importer and consignee of produce at the time of entry. Our customer is the entity providing the preventive control.

When such processing is performed by the importer's customer, the flexibility provided in 1.507 would allow for the importer to modify supplier verification activities, provided it meets certain other requirements to help ensure that the processing is adequately performed before the food is consumed.

So within the pickling industry, much of our compliance efforts as producers are driven by our customer, the wholesaler and retailer.

My concerns lie with the communications at the time of entry in regards to the automated commercial environment and how entry information is

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processed to show that this shipment is for further processing. In the past, FDA Department of Import Operations, CIFSAN, and our broker, BCB International, have worked together in processing entry information, as our shipments are under a strict processing schedule, thus saving valuable resources that otherwise would have been wasted.

And I would like to thank FDA for their time they have spent in the past regarding this communication issue.

However, to my knowledge, the missing link of communication still exists within the importing entry system. Prior notice, the product code builder did not allow for the code to be produced showing that the shipment is for further processing, thus indicating the shipment is for fresh market.

PREDICT uses a product code, along and-or with the AFC code. But we are restricted to the use of the AFC code, as we are not the entity providing a said process number indicating the process in place.

We ask that the implementation of programs discussed today help with the increasing communication

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necessary at the time of entry to ensure transparency of the shipment to help importers for further processing -- for example, the possible use of the DUNS number and incorporating that number within one of the existing importing entry system.

This is especially for the importer who may be importing a commodity that is part of an FDA sampling program such as cucumbers in the fall of 2016.

On behalf of importers and Hartung Brothers, I would like to thank FDA for the opportunity to speak here today.

MS. BARRETT: Thank you so much.

Okay. Our next speaker is Cecelia Carter. I'm not sure that she's here.

So, Kristen Spotz, we'll go to you.

MS. SPOTZ: Hello. My name is Kristen Spotz, and I'm from the Grocery Manufacturers Association. Good afternoon. My name is Kristen Spotz, and I'm the Senior Manager with the Grocery Manufacturers Association.

Founded in 1908, FMA is the voice of more

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than 300 leading food, beverage, and consumer product companies. GMA would like to highlight two very important issues regarding FSMA import provisions. We commend FDA for its transparency and openness to FSMA implementation, holding these public meetings. We thank the FDA for allowing us to make comments, public comment at this meeting.

GMA has been a very active participant in FSMA implementation and has also submitted extensive written comments to all of the rulemaking public docket. GMA is very supportive of a risk-based supplier verification program.

First, regarding FSVP, we are very concerned by the tremendous burdens presented by Section 1.507. this provision requires that an importer does not need to engage in supplier verification for hazard if they rely on someone downstream to control the hazard, disclose the hazard in writing, and receive an annual written assurance that the hazard will be controlled.

This is a parallel requirement in the Preventive Controls for Human Food Final Rule. Our members estimate that each will have to provide

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hundreds or even thousands of written assurances to their suppliers in order to satisfy these provisions.

Moreover, the scope of these requirements expands exponentially when considering food sent to food servers. For example, if an importer provides a not-ready-to-eat food to a distributor, the obligation to provide written assurances flows to the supply chain all the way to individual schools, hospitals, restaurants, and cafeterias.

The cafeteria even here at CISFAN would be required to provide written assurances for an imported not-ready-to-eat frozen burrito that it cooks and serves for lunch. This requirement to provide written assurances is a resource-intensive paperwork exercise that will not add value for food safety or public health.

Rather, the lynchpin under FSMA for food safety is the effective application of preventive controls by the food manufacturer. Our collective resources are better directed to the foundational food safety requirements.

We have an active working group on the

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written assurance issue that is meeting with FDA staff, and we are hopeful that a mutually agreeable resolution can be achieved. GMA welcomes the opportunity to engage in further dialog with FDA on this issue.

Second, regarding VQIP, we want to reiterate a few points from comments we submitted last summer on the draft guidance. Our comments explained that, as proposed, our members are unsure they can support the effort and investment needed to participate in VQIP. There needs to be a balance between administrative efforts required for participation, and the benefit VQIP offers.

To achieve this balance, the benefits need to be enhanced to attract more participants, and importers need more flexibility about which foods are eligible to participate in the program. GMA would be pleased to provide additional input if that would be helpful.

We greatly appreciate the opportunity to present our comments today. We support the need for supplier verification requirements in both the foreign

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supplier verification and Preventive Controls Final Rules. We also anticipate the recognition that there needs to be flexibility towards type and frequency of verification activity. Thank you.

MS. BARRETT: Thank you very much.

I don't know if we still have Karil Kochenderfer? I know she spoke earlier. Okay, I think she's gone. So that will conclude our public comments session. I want to give a round of applause to everyone who presented and offered their comments.

[Applause.]

MS. BARRETT: We really do welcome your feedback and your insights and your sharing your perspectives.

We are now going to move on to a Q&A session. But first, we would like to see if the panelists -- did I miss something? Okay.

[Laughter.]

MS. BARRETT: I'm getting these looks.

I am turning to our panelists. This is something we've traditionally done in our public meetings. After hearing public comment, often the

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panelists may have a reaction to something they've heard or maybe a theme that has been brought up today.

And it's just a chance to sort of check in with them to see if they have some thoughts on what we've heard before we open up the mics again. So I'm going to go ahead and start with Camille.

MS. BREWER: So, thank you. My name is Camille Brewer, and I've been so pleased to hear such intriguing comments and questions. I've been here all day. At every public meeting, I learn something new. So I want to thank you for coming. And I want to thank you for your stamina in being here all day, as well.

I do want to talk a little bit about systems recognition and to, hopefully, clarify some misconceptions.

First of all, we're hoping to have a public meeting later on this year. As Caroline said, we're transitioning from the pilot phase to the program phase. And we want to stay in tune with our stakeholders. We want to hear from you as we modify the program, as we develop new aspects of the program.

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So please look out for announcements about that public meeting.

We've been engaged internally in looking inward to determine what we need to do as an agency to implement the program. And we want to talk about that at the public meeting.

Importantly, we want to discuss another tool that's in development, and that's much more of a commodity-specific recognition regime. And that will pertain to many, many countries. So we're interested in getting your input as we evolve our thinking on that program.

One of the principal misconceptions about systems recognition is that it's like the FSIS equivalence program. One of Caroline's slides very clearly said that systems recognition is a regulatory cooperation program. It is not -- it is not -- and I'll say it again. It is not required to trade. That's a very, very important distinction.

It's a regulatory cooperation program. We're interested not only in the gain in terms of inspections, but in terms of working together on

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capacity-building, research, risk assessment. It's a very broad program of regulatory cooperation. So we want to talk about that a bit more at our public meeting.

One of the things that Caroline mentioned is just the rigor of the review. And to be very clear, we're looking at domestic controls. We are looking at how the other country manages its national food control system. That is fundamental. So there's a misconception that we're looking at export programs. That's not --

(Audio cut off for approximately 12 seconds due to house technical issues.)

MS. LINDAN MAYL: You're burning through those, Camille.

[Laughter.]

MS. CHRISTIN: I must be talking too much. So I'm going to race through this.

So again, please look out for the announcement of the public meeting.

Mr. Corbo mentioned that his concerns about recognizing the entire European Union -- I want to

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clarify that the submission is for the European Commission, the European Commission. And we can talk more about that at the public meeting.

We had a question earlier today about what is in scope for the systems recognition? I believe we have a slide on that. So labeling, MRL's, additives, food contact substances are out of scope. What we're looking at is the foreign food safety's oversight -- oversight.

So for all of these parameters, suppliers, importers, the expectation is that you will adhere to U.S. FDA standards for labeling, MRL's, et cetera.

We had a question from Mr. Lieberman about what next for education? Dr. Moss talked about outreach. This is the initial stage where we are laying out what's in the rule in a rather truncated fashion. And the actual training comes later.

So far, we've visited the European Commission, Japan, India. We'll be going to China, to Mexico, to Chile, to Canada. We're looking to do regional meetings. And countries have not been determined yet in the Middle East and Southeast Asia

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and Africa.

Dr. Moss showed you the slide about the international subcommittees and the importance of participating on those committees, because that really is where the rubber meets the road, where the training will be made more specific to your conditions, more specific to your countries, more specific to even in growing areas. So please participate because training will be taking place via the alliances.

So with that, I'll stop before the battery goes out again. Thank you.

[Laughter.]

MR. CATO: We've still got a couple more, and then we can do that.

MS. BARRETT: Todd, we'll go to you. We'll just sort of go down the line. If you have a comment or observation you'd like to share please feel free.

MR. CATO: Yeah. I was just going to say thank you to everybody for participation and the questions, and also the comments. I think you gave us a lot of good information that we can take back and discuss as we look to finalize our implementation. So

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really do appreciate everybody who came out and, you know, provided their input into this process. Thank you very much.

MR. VENEZIANO: Domenic Veneziano.

Again, I also want to echo thank-you's to everyone who commented today. There's a number of things we need to think about, obviously, as you presented them.

I do want to address a couple of them. Mr. Corbo talked about examinations in FY17 and the decrease of the examinations at the borders themselves.

I will say that although that might be true in terms of overall, I will say that things are going to change in the near future on the import side, where before, we didn't have the foreign supplier verification program. That's going to impact how our risk-based approach of examinations are going to take place.

The systems recognition or comparability is also going to play into a major factor. So, you know, we'll be doing a better job identifying those higher

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risks, identifying examinations at the border that could cause food safety issues overall.

So there is a change in the paradigm of imports in general, based upon preventive in nature rather than kind of any catch-and-release type of issue, where we get lucky in terms of finding violations of the law. So I think it is moving forward, and I think that FSMA provides that preventive aspect of it and makes it a better system than we had in the past.

There was a comment related to the automated commercial environment in providing information during the entry process. We considered that very closely in terms of what has to happen. The impact to making a change or a data element within Customs and FDA in the industry is tremendously huge.

Right now we are backing off as part of the supplemental guidance for data elements that we're having issues with. There's a cost element to increasing that, both on the industry and on the agencies to make that significant change. And we've committed to only making elements that are required

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for admissibility purposes only. And if there's a way to validate the information otherwise, we will do that.

Import for further processing would be one of those data elements, but it would be a voluntary nature. So we wouldn't get it on all cases. It would be something that people can submit. It would be kind of a nicety.

Either way, we're going to have to go out to the foreign supplier verification importer to validate that it's going for further processing and that they have something in place. So we did consider that aspect of it and made a conscious decision not to put it in there for the industry purposes and for our own, in terms of cost.

And then finally, this will probably be addressed during the guidance, but the benefits associated to the VQIP program, we took all of the recommendations that came forward and considered them, whether they should be implemented or whether they shouldn't be.

The ones that we didn't -- and there weren't

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many of them that we didn't. We had obviously good reasons behind why we didn't implement that. But the beauty of VQIP, I think, is it's a guidance, it's not a rule. So moving forward, if we do find ideas or things that we could implement, we can always go back and revisit that down the road.

So, thank you again for all your comments.

MR. PENDLETON: Brian Pendleton. I'm just going to say thanks for the comments you provided this afternoon and your questions throughout the day.

There's a lot of interest that I see around Section 1.507. So we have a lot of issues to talk about there. And I think we have a meeting that's coming up this week with respect to that. So it would be great to have something before the meeting so we could look at it and think about that, to make better use of the meeting. That would be fantastic.

And the other point I wanted to make is something that, an issue that Erik raised this morning about compliance with the Food Defense Regulations. So was looking at the Preamble to the Final Rule, and it may be a little bit off base there, actually.

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Because I think the regulation, if I understand the regulation on intentional adulteration correctly, it doesn't apply to international adulteration that is economically motivated.

I think, if I'm understanding correctly, that it's limited to an intentional terrorism-type adulteration, whereas the FSVP and preventive controls, for that matter, is focused on intentional adulteration that is economically motivated, so adulteration for economic purposes.

So it seems to me then that a supplier's compliance with the forthcoming intentional adulteration final rule probably is not going to be relevant for FSVP, but I think that's something that we're going to need to address in the draft guidance. And then whatever we do say about that, obviously, we'll welcome comments on that. But I think that would be the case. Thanks.

MS. BARRETT: Okay. Thank you, Brian.

Charlotte, did you have anything you wanted to share?

MS. CHRISTIN: First of all, thank you all

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for being here today, and certainly for your eagerness to have a third-party program launched. It's very exciting. Tony, I realize you're less eager. And I know you have concerns specifically about the program, or not the program, but a third-party audit initiative domestically.

I first want to clarify that third-party audits, whether we're talking about the FSMA third-party program or any other reliance on audit information by FDA is by no means to be considered a substitute for FDA inspections. As always, there's an important role for government inspections.

And certainly, whether it's an inspection performed by FDA or an inspection or audit done by one of our foreign regulatory partners, of course, a regulatory inspection, regulatory audit, those are -- as we think about the highest credibility for information or results of auditor inspection, that certainly is most compelling to us.

We do, however, think that there is an opportunity to leverage the work done in private audits. As I said earlier, we realize a lot of

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investment has been placed in both industry's work on food safety, as well as work on trying to strengthen the private audit system.

So, again we're thinking of how might we leverage information from that system. But it must be a credible audit done with competent auditors with a degree of transparency to the government. There's no way that we could just accept something at face value.

So there's a lot of work to be done to figure out, you know, how we meet each of those elements. But if we're able to do that, then we do think we have an opportunity to figure out how to leverage that information.

And I think, you know, FSMA sort of points us in that direction in the discussion with FSVP with respect to same level of public health protection. It's sort of a nod to that sort of concept. And as you mentioned earlier, Tony, we need to consider parity both domestically, as well as in the foreign arena.

So again, there's a lot of work to be done in this area. And we look forward to a continuing

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dialog. But again, if there's an opportunity to use credible third-party audits with competent auditors and transparency to government, we certainly think it's worth exploring. So again, thank you for your time today.

MS. BARRETT: And we're not closing yet. But go ahead, Sharon. Did you have a few remarks? And then we are going to do some Q&A.

MS. LINDAN MAYL: I am actually going to, in the interest of time, move on to questions and save those remarks.

MS. BARRETT: Okay. All right. So we are ahead of schedule, and we do have some time for additional Q&A. Since our last session, you heard some more about the international programs. You heard some additional remarks. So if you do have a question and you'd like to come up to a microphone, please do.

And of course, for our webcast audience, if you have a question, if you'll submit that, and we will look for those questions as well.

And I will ask previously, if you could limit your questions to two to start, and if you'll

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say your name and affiliation when you come up to the microphone.

And, Erik, we'll start with you.

MR. LIEBERMAN: Erik Lieberman, U.S. Food Imports LLC.

So, food contact substances -- within the scope of recognition, or they're not within the scope of recognition? Is there a legal reason for that? Or is that just FDA policy?

MS. BREWER: The authority for systems recognition is just the general authority to enter into agreements with other countries. So there's nothing specific in the statute that calls out systems recognition.

So the sense was, for very specific parameters such as MRL's, such as additives, the foreign supplier has to comply. So if you have another view, we welcome that. And there will be opportunity for additional comment there.

MR. LIEBERMAN: Okay. So --

MS. BREWER: But it's outside of the scope.

MR. LIEBERMAN: Okay. Okay. So, for

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example, if I'm importing pots and pans from New Zealand or food packaging, I would have to do the verification. That wouldn't be within the scope of the -- that would be subject to FSVP. Yes, okay, thank you.

MS. BARRETT: Okay. Do we have another question over here?

MR. STEVENSON: Hi. My question is actually sort of related. My name is Peter Stevenson. I'm with Elanco Animal Health.

My question is in the international, in the systems recognition, animal feed is also not going to be included. Is there a plan for a version of systems recognition for animal feed? If so, what's that plan? If not, why not?

MS. BREWER: Yes. There is a plan. As we've indicated, the initial phase was a pilot phase. We had new tools to test out, the ICAT, for example. So that's going to look a little bit different for animal feed. So the Center for Vet Medicine is looking at what their assessment tool would --

[Audio cut off for approximately 7 seconds]

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due to house technical issues.]

[Laughter.]

MS. BARRETT: I know. It's the control. I think we'll have some technical assistance here, but please go ahead.

MS. BREWER: So this is like Vaudeville. I think I'm getting the hook here. So --

MS. BARRETT: They're really glad to have you on the panel.

MS. BREWER: Yes, we do that. That will be within the next wave.

[Audio cut off for approximately 6 seconds due to house technical issues.]

MS. BREWER: Okay.

MR. STEVENSON: You can just holler at me.

[Laughter.]

MS. BREWER: Okay.

[Inaudible interjections and laughter.]

MS. BREWER: So that will be another tool for us, along with the commodity recognition programs. Thank you.

MS. BARRETT: We'll keep the mic at the

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table. Is there another question? Please, go ahead.

MS. LARRIMER: Hi, Natalia Larrimer with ANSI-ASQ National Accreditation Board. I just had a quick question.

We learned, I guess, recently that OMB has issued a Circular A-119 in 2016, and it basically specifies the use of consensus voluntary standard, which you specified before. But it also says that agencies should be using the existent conformity assessment methods, such as, fancy word accreditation certification basically.

I was just wondering. This new revision of the circular, will that have any impact on any future rules of processes that FSMA, or FDA will be developing under FSMA? Thank you.

MS. CHRISTIN: I hesitate to take the mic, but -- so, yes. Certainly the Agency is going to comply with the revised circular. And as we explained in the Preamble to the FSMA Third-Party Final Rule, you know, we are allowing for reliance on documentation conformance with existing conformity assessment standards except where we have differences

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in the law.

And so, future rulemakings, certainly the NTTAA and revised circular, any subsequent guidance that NIS might issue, we're certainly very cognizant of that and will issue regulations and guidances that are consistent with that.

MS. LARRIMER: Okay. Perfect. Thank you.

MS. BREWER: Thank you.

MS. BARRETT: Okay. I'm going to go over to our folks here. Jason, do we have any webcast questions?

MR. THURMAN: Yes. We have two. The first one is from Mark Mendonca, a food safety consultant with Datahex.

"Are inspections for FSVP via FDA inspector announced to the foreign facility? Or will those be unannounced?"

MR. VENEZIANO: The FSVP inspections, unannounced. There may be times however, and I think Todd brought this up earlier, that we're looking at either onsite inspections or a document review aspect. Obviously, if we're asking for documents, we'll be

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calling up and asking for things.

Records have to be available within a certain amount of time frame as well for our availability.

MS. BARRETT: Thank you.

Go ahead, Jason.

MR. THURMAN: Thank you. The second question is from Maria Cristina Villabon. She's from SCFF LLC.

"Are dehydrated soups and bases products that can be considered as part of the coffee-cocoa beans exemption group for FMSA?"

MR. PENDLETON: You want to talk about this, or you just want to tell me to say no, that there is not -- no. Because that's not something that's where they can't be consumed without undergoing a processing that is necessarily going to address the hazards in the food.

MS. BARRETT: Okay. Thank you.

We'll go over here to the microphone, and then we'll come back.

MR. ICHTER: Ralph Ichter. Last question is

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regarding the dairy business.

Can you, can somebody talk a little bit about the high-risk products and FSVP? It's a narrative I'm not very familiar with. So how is it going to work? Are you publishing a list of product? Is it like broad categories of product or just very narrow type of products? How is this going to work?

MS. LINDAN MAYL: [Not speaking into microphone]

MS. BARRETT: And this is Sharon Mayl.

[Laughter.]

[Inaudible comments.]

MS. LINDAN MAYL: This is Sharon Mayl.

[Laughter.]

MS. BARRETT: Well done.

MS. LINDAN MAYL: I'm going to repeat what I just said, so sorry for those of you that heard it.

I think I'm hearing sort of a combination of two different things. So I want to try to tease it out. So let me start with respect to FSVP.

With respect to FSVP, it is the importer who determines what the hazards are and does an evaluation

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of the risk of the supplier to determine what verification activities need to be done.

So there's no -- FDA is not providing a list of high-risk foods of any sort. It really is a flexible risk-based approach for the importer to determine what the risks are, who's controlling them, and how they're verified that those risks are being controlled.

When you said -- this is sort of the second part of it. When you mentioned the list of high-risk foods, I wanted to make sure, because I don't think we've really touched upon it other than in Charlotte's presentation about what was added to Section 801(q), which is where we may be able to require or may decide to require certification as a condition of entry under certain particular circumstances.

And the statute outlines what we have to look at, which includes the risk of a food, the risk of a supplier, and significantly the ability of the foreign country to control that risk.

So that 801(q) is an additional tool in our toolkit -- we keep talking about the toolkit -- to

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ensure the safety of products, where under particular circumstances that FDA determines, we may require a certification. This is apart from FSVP.

We do not envision using that provision frequently. We think about it, again, as a tool in our toolkit to deal with particular situations where there's perhaps an ongoing processing problem in a foreign country and using it as the most efficient and effective way to ensure that the hazards have been controlled.

But even there, again, FDA is not creating any list of high-risk products for which this certification would be required under 801(q) or defining a high-risk product for an importer. That is for an importer to determine themselves.

And I will just mention that there are situations where an importer may have a product that they're importing that has significant SAHCODHA hazards and may, even under the FSVP rule, determine, although the default is an annual audit for that produce, may determine that there's another appropriate type of verification activity that

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provides assurance that the hazards are being controlled.

So the idea behind FSVP again is a flexible risk-based science-based approach that the importer must use to determine how to verify the supply chain. I hope that answers your question.

MR. ICHTER: Thank you very much. That's very precise.

By the way, is your name Sharon?

[Laughter.]

MS. LINDAN MAYL: I don't know.

FEMALE VOICE: It's the end. You can say it now.

MS. LINDAN MAYL: I'm confused about that, apparently, today.

MS. BARRETT: Thank you. And we'll come over to this side for a question.

MR. FeDUKE: Is my mic working? Okay. I think it is.

MS. BARRETT: Yes, it is.

MR. FeDUKE: I have more of -- sorry. Mark FeDuke, VLM Foods.

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MS. BARRETT: Thank you.

MR. FeDUKE: I have more of a suggestion than a question. I'm just curious. As you folks move forward with your outreach abroad, overseas engagement, I might make a suggestion that you look at looking at an appropriate party to partner with you and kind of bring FSMA down to an operational level, be it an appropriate stakeholder like an importer, like a foreign manufacturer, like potentially an accreditation body.

As a bit of a FSMA fanboy, I've had the good opportunity to attend public meetings here in D.C., in Ottawa, in Chicago, in L.A. And one of the best, most beneficial learning experiences has been when there's been somebody from the trade also co-presenting not as an infomercial but as a means of kind of bringing down what the regulatory environment is and what that means to actually translating it for some folks.

This audience, you know, knows FSMA inside and out. But I think one thing that's been learnt over the past few years is, given the proliferation of free trade agreements, how food crosses international

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borders for a lot of companies is treated as a bit of an afterthought. You know, if there's no duty involved, well, it becomes a subset of logistics.

Then a lot of companies, logistics ends up taking care of regulatory matters for cross-border, and they will throw any old data at stuff and provide sometimes not complete information to the customs brokers.

And if we've had that issue domestically here in North America with stakeholder meetings where folks are trying to scratch their heads, you know, saying that they're importers, but what's an IOR? I mean, pretty basic supply-chain issues a lot of folks here in the States don't know.

I don't know that our trading partners overseas are going to understand the nuances on responsibilities for foreign food processors, let alone what happens in the import process here in the United States.

So, just some food for thought and a suggestion that, moving forward, as we engage overseas, maybe bring us alongside an appropriate

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stakeholder who can help and kind of translate that for folks. Thank you.

MS. LINDAN MAYL: Thank you for that comment.

I don't know if Camille wants to add something, but I'll just say that we do appreciate the notion of partnerships, particularly in the international arena.

We have done a lot of outreach in -- we've done a significant amount of outreach in the foreign community, to the best that we can, both with the foreign governments and even holding public meetings, with the hopes really that it would spur some ideas for partnerships.

I know we've reached out to the embassies. We've spoken before sort of members of the International Chambers of Commerce. So we are thinking about that, and we would welcome ideas in that respect. I would urge you perhaps to reach out to the alliance also, because there is that international subcommittee. And I think these are the kinds of ideas that they would welcome.

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MS. BARRETT: Okay. All right, great.

Thank you very much.

I'm going to go to the webcast, and then I'll take a question up here. Do we have any?

MR. THURMAN: Yes, we do.

MS. BARRETT: Okay.

MR. THURMAN: We have a few. Dan Caster from McCormick & Company would first like to thank the group for the opportunity to have this open dialog today. He has a question: "Are there any in-country ICAT assessments planned for 2016?"

MS. BREWER: I'm sorry. Can you repeat the question? Are there any --

MR. THURMAN: No. It's, "Are there any in-country ICAT assessments planned for 2016?"

MS. BREWER: So you mean ICAT audits?

MR. THURMAN: I'm assuming. I'm limited on what information I have.

MS. BREWER: In this year?

MR. THURMAN: 2016 is what the question is.

MS. BREWER: Hm. I'm looking at Caroline. I doubt it. At this point, we've completed the in-

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country for Canada, for Australia. We just got the ICAT submitted for the European Commission. So it's going to take several months to go through that.

So at this point, we're not planning an in-country audit to the commission, to Brussels, this fiscal year, for sure. And I would expect that it's unlikely, and that's just a guess, for the entire calendar year. So I'm looking at Caroline. Did I get that right? She's nodding her head.

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

We'll take one more, and then we'll go to the microphones.

MR. THURMAN: Sure. Bob Rada, from Blommer Chocolate has a question: "The adulteration or substitution for economic consideration -- are you looking at allergen material or any material used as the adulterant?"

MR. PENDLETON: What kind of material did you say? Allergen?

MR. THURMAN: I can reread it if you would like.

MR. PENDLETON: Yeah. It could be anything.

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If there was an incident or -- again you only have to consider the economically motivated adulteration if there was an incident or that it happened or there was evidence that someone attempted this.

So that's the only way you would have to know if the hazard would be known or reasonably foreseeable. But I think it wouldn't matter which kind of substance it was.

MS. BARRETT: Thank you. We'll go to the microphone and then we'll come back to see if we have some more webcast questions.

Make sure the green light is on.

MS. FACCONI: Karie Faccone. Karie Faccone, from Rema Foods.

I know we talk about qualified individuals throughout FSMA. Can you give me an example of some of the requirements, whether it be training or expertise, that you would accept as qualified to review audits, third-party audits for your foreign supplier verification program?

MR. PENDLETON: Are you talking about the person being -- Brian Pendleton, sorry. You're

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talking about a person being a qualified auditor, not just a qualified individual? Were you talking about audits?

MS. FACCONI: The qualified individual that would be reviewing it, as the importer.

MR. PENDLETON: Okay. I would think that that person who's looking at that has to be able to understand audits. So, I mean, as we talked about today, it could vary widely, the education, training, and experience that you would need to do to affirm your particular FSVP task, whatever that might be.

But it seems to me like to be able to evaluate, to review and assess that the audit that was conducted by someone else -- like if you're looking at the results of the audit, you would have to have an understanding of auditing and of the food safety regulations that that supplier was being audited against or for which the compliance was being assessed.

MS. FACCONI: So, specifically, the requirements for BRC or IFS or any of the GFSI, whatever audit you're reviewing, you should have

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knowledge of it? Not necessarily a certificate or a certification or training?

MR. PENDLETON: Oh, I see what you're talking about.

MR. VENEZIANO: This is Domenic Veneziano.

We're not going to go in looking for a specific certification, certificates of training. I think overall, if you have 30 years' experience doing a job, I think that would be sufficient enough. We wouldn't look for a training program in place of what you have.

I think when someone goes in there, they're going to look at, "Tell me what you have documented in terms of your experience and what makes you qualified in doing that?" And then the second aspect of that is if we find problems with an audit or something, that's when things will come into play as to, you know, why you made the decisions that you made, and what are you qualified for?

But I think overall, if you're looking for a list of curriculums to meet the requirement of a qualified individual, you're not going to see the

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Agency put one out saying, "You need this, this, this, and this." I think it's the combination of all that could be successful in terms of it. You may not have a training program or a training course in mind, but have multiple years of experience doing what you do to meet that qualification. Does that make sense?

MS. FACCONI: Yes. Thank you.

MS. BARRETT: Okay. Thank you. I'm just going to take a poll in the room. Do we have anyone else who would like to ask a question here, physically in the room? Yes, please, let's go ahead.

MS. HARTUNG: Tara Hartung, Hartung Brothers.

Just real quick, do you guys have any ballpark figure what VQIP is going to cost?

MR. VENEZIANO: Yeah, there's something in there. I believe it's \$16,200 is what's the proposal currently.

[Inaudible question.]

MR. VENEZIANO: No. Right now it's only one. And we asked the question in the proposed rule in terms of feedback for that. I mean, I know we got

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some comments back that will be addressed in the final document. But overall, it was just the ballpark figure of \$16,000 and change.

MS. BARRETT: Thank you. Other questions in the room?

Do we have another webcast question? Okay. We'll do the two webcasts, and then we'll do our wrap-up remarks.

MR. THURMAN: Sure. Manual Vasquez from ARCOR (phonetic) Group.

"Our U.S.A. subsidiary import foods from our facilities in Argentina and Brazil, and the facilities comply with current good manufacturing practice and hazard analysis and risk-based preventive controls for food for humans. Should the U.S.A. subsidiary develop the FSVP program? The production plant in U.S.A. subsidiary belongs to the same company."

MR. PENDLETON: I mean, if this gets back to the question -- Brian Pendleton -- they were talking about earlier about when a supplier is in the same corporate structure as the importer, there's not an exemption for that. But that relationship could come

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into play and be a factor in the determination.

But when you're evaluating the foreign supplier as well as what type of verification activity you would need to conduct, how frequently you would need to do activities, I think -- can you restate it one more time? I'm sorry. But there was something else I wanted to address.

MR. THURMAN: Sure. "Our U.S.A. subsidiary import foods from our facilities in Argentina and Brazil, and the facilities comply with current good manufacturing practice and hazard analysis and risk-based preventive controls for food for humans. Should the U.S.A. subsidiary develop the FSVP program? The production plant in U.S.A. subsidiary belongs to the same company."

MR. PENDLETON: First of all, if they're already complying with the new preventive controls rule, that's pretty impressive.

[Laughter.]

MR. PENDLETON: But the importer, the U.S. importer is going to have to have a verification program unless there are no hazards in the food. Then

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they wouldn't have to do supply verification. But they will have to do some type of supply verification to obtain food from a supplier in Argentina.

And again, that's going to depend on the nature of the hazards in the food, as well as the relationship with the supplier. In this case, there may be a very close relationship with the supplier. But there will have to be an FSVP by the importer, as that's defined under the rule.

MS. BARRETT: Okay. All right. And then our last question?

MR. THURMAN: Sure. From Adrienne Gilmore from Eataly, U.S.A.

"We work with our distribution center in Italy, who compiles our orders from all our producers. And we are currently working on getting all the technical sheets for the thousands of items we import from each small producer. Aside from that, is there anything else we can or should be doing now? Or is it best to wait for the guide to come out and training to start?

"We are trying to get a head start with all

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of this, but of course, don't want to do anything unnecessary or head in the wrong direction. Thanks."

MR. PENDLETON: Brian Pendleton. I think that if you don't, you're not sure that you have the staff in-house going to help you comply with FSVP if you're the importer, then it would be good to start talking to somebody who understands the regulation and what the requirements are going to be under it.

Even though, again, the requirements -- compliance will not be required for another year, some of the things might be, some of the requirements might be relatively complex for someone who is not going many of these activities now, or not doing them to the same degree as will be required under the regulation.

Certainly, we expect and hope that the draft guidance, when it comes out, will help clarify a lot of things that weren't clarified in the Preamble to the final rule, for example. But I would think that you wouldn't want to wait until the draft guidance is out. Although again, we hope that's going to be out the middle of this year sometime along that line, sometime this year.

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MS. BARRETT: Okay. All right. Well, thank you, everyone.

We will now have some concluding remarks from Sharon Mayl. So, Sharon, would you like to stay at the table? You're welcome.

WRAP=UP AND NEXT STEPS

MS. LINDAN MAYL: I'm just going to stay here. This is Sharon Mayl.

[Laughter.]

MS. LINDAN MAYL: I want to thank everyone. Really, it's been a long day, and you really have hung in there and given us a lot of great information. I won't repeat everything that my colleagues sort of said earlier about that the food for thought you've given us.

We have heard clearly the importance of guidance documents to address some of these issues. And as you have heard, we take that very seriously and hope that these guidance documents can assist in compliance. You've heard about the alliances in helping you and the industry comply.

I mentioned earlier that we were going to be

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doing a series of regional meetings. And I just want to talk about that a little bit more. We hope to be holding meetings in, tentatively, Los Angeles or the Long Beach, California, area; the Port of New York; and Detroit, Michigan. So we're trying to hit sort of both coasts and somewhere in the middle. Again, this is tentative.

And the time frame for that, I think, is beginning in June --

FEMALE VOICE: Looking mid-May --

MS. LINDAN MAYL: Looking mid-May?

FEMALE VOICE: -- into June. That's the tentative timeline.

MS. LINDAN MAYL: Okay. So we encourage -- I know you are here in Washington. Some of you have traveled. But we're hoping to encourage further participation and further input from folks.

And more specifically, we really are looking to help the public better understand our role, our plans, and what we're doing to drive implementation, as well as solicit important feedback, as we have today, to hear where you are, and also get a sense of

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where industry is in terms of compliance with some of these new rules, and how we can, again, better help to bring about compliance.

So I think that those meetings will continue a dialog that we started today.

You know, all together, I think as you all know here, we're really building a new food safety system. FSMA really is looking at a new paradigm that holds industry accountable for meeting what are new science-based risk-based standards for the safety of imported foods.

FSMA gives us additional tools to make sure that industry is compliant. And complying in the three programs that we talked about today are ways that we can ensure that those that are exporting foods to the United States are meeting the same standards as those that are producing foods within the United States.

So these programs are very important to us. But as Mike mentioned earlier, in addition to all the new FSMA programs, we have existing import operations. That will continue. We're going to continue to make

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decisions, admissibility decisions at the border.

We're going to continue to have PREDICT and a prior notice system. We're going to continue to examine and sample products and continue our capacity-building efforts and the international agreements that we are entering into with other countries to build those partnerships, including systems recognition.

And the challenge for us as an agency is to take both the scientific standards that are going to be required of industry to meet and the implementation and the enforcement tools that we have and integrate those into a larger system for ensuring the safety of imports.

And Mike mentioned early that we are thinking about that, in addition to thinking about the nitty-gritty of who's the importer. And all the things that we're thinking about with these rules, we're thinking about the more holistic approach to ensuring the safety of imports and ensuring that parity between domestic products and imported products.

So you're going to be hearing more about

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that larger, sort of holistic import strategy. And we will look forward to continued dialog with you as we move ahead in these rules, in the Preventive Controls in Produce Rules, in the import strategy, and the partnerships that we can forge with industry, with foreign governments to really raise the bar on food safety in this country, both domestically and abroad, and ensure that parity.

So with that, I'm not going to hold you here any longer. I'm just going to thank you again for the time and effort that you put in just being here, for the comments you offered, for the remarks that you offered. So thank you for that.

MS. BARRETT: Great. Thank you so much. Yeah, really.

[Applause.]

MS. BARRETT: This has been a great group. Thank you all. I just echo everyone's thanks for being with us today. You will see more in the engagement, both domestically and internationally. I want to thank everyone who helped pull this meeting together. And we will be sharing through our FSMA

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listserv in the website additional activities, again on import issues. So, thank you. Have a great evening.

(Whereupon, at 2:52 p.m., the FDA Food Safety Modernization Act Public Meeting: Prevention-Oriented Import System Regulations and Implementation, concluded.)

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CERTIFICATE OF NOTARY PUBLIC

I, NATASHA THOMAS, the officer before whom the foregoing proceeding was taken, do hereby certify that the proceedings were recorded by me and thereafter reduced to typewriting under my direction; that 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.

NATASHA THOMAS

Notary Public in and for the
State of Maryland

CERTIFICATE OF TRANSCRIPTION

I, ELLEN SANDERS, hereby certify that I am not the Court Reporter who reported the following proceeding and that I have typed the transcript of this proceeding using the Court Reporter's notes and recordings. The foregoing/attached transcript is a true, correct, and complete transcription of said proceeding.

04/05/2016

Date

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