

NWX-FDA OC

**Moderator: Susan Chittooran
November 13, 2015
12:00 pm CT**

Coordinator: Thank you for standing-by. At this time, your lines have been placed on listen-only until we open for questions and answers. Please be advised today's conference is being recorded. If you have any objections, you may disconnect at this time. I would now like to turn the conference over to Miss (Theresa Rubio). Please go ahead.

(Theresa Rubio): Thank you. I appreciate your joining today's Industry Stakeholder Call. My name is (Theresa Rubio). I'm a Health Program Coordinator in FDA's Office of Health and Constituent Affairs and will be serving as moderator for today's call.

The purpose of today's call is to discuss FDA's food safety foreign supplier verification and third-party accreditation final rules under the FDA Food Safety and Modernization Act. I'm joined by Michael Taylor, the FDA's Deputy Commissioner for Food and Veterinary Medicine, Dr. Susan Mayne Director of the FDA's Center for Food Safety and Applied Nutrition, Dr. Daniel McChesney, Director of the Office of Surveillance and Compliance at FDA's Center for Veterinary Medicine as well as FDA experts on the rules.

Dr. Samir Assar, Director of the Produce Safety Act in the FDA's Center for Food Safety and Applied Nutrition, will be talking about produce safety rules. Brian Pendleton, Senior Policy Advisor, FDA's Office of Policy and Planning, will be talking about the foreign supplier verification program rules and Charlotte Christin, Senior Policy Advisor to the Office of Food and Veterinary Medicine, who will talk about the accredited third-party certification rule.

This portion of the call will be in a listen-only mode. After the presentation, we will open the lines for questions. I'll now turn the call over to Deputy Commissioner Mike Taylor.

Mike Taylor: Thanks (Theresa). And thanks everybody for joining today. We have arrived at, we had another really significant milestone for food safety in terms of the issuance of these three rules.

I first just want to thank everybody who's worked so hard on this, certainly the teams within FDA that have been at this for a long time and have been very persistent, very resilient and I think creative in developing rules that (respond) a lot to the input from our community, rules that I think meet the test of being good for food safety and being workable across the whole system.

And of course, that being good for food safety and being workable across the whole system, and of course that means thanking all of you who have put so much effort into the comment process, the dialogue, the hosting of us on various and sundry farm and factory tours. We could not have done this without that sort of engagement from our industry stakeholder community. We thank you for that.

You know, the (TC) rules that we issued in September were a huge step because we took the (primitive tool) principles that Christin codified as a regulatory framework back in the '90's for meat and poultry, seafood, what have you, was established as a regulatory framework. It was a very big step to take that framework in the guise now of FSMA to apply those to all commodities and to build this comprehensive prevention system that we've aspired to.

We see the steps we're taking today to be in a way even more groundbreaking in that it's taking the framework prevention and philosophy and applying it to parts of the food system where we have not directly regulated before. And that's of course on farms, safe growing practices on farm for produce and importers and the role that USA importers now will have under the farm supply verification rules to take responsibility and be accountable for verifying the foreign supply chains and ensuring the food importers meet our standards.

These are huge steps. They build on and they're possible because they build on of course principles and practices that many in the food industry have been observing and certainly principles and practices the food industry pioneered. The food, you know, the leaders in this community really have set the standard and so we now see our rules being the framework in which we can work with the community as a large to bring practices up to, comprehensively up to these appropriate norms that have evolved over the last few years.

So it's a very big deal. It's obviously getting the rules out is a big step but it is just a step. We all know just how much work there is to be done to prepare for implementation. That's working with FDA to change what we do. It's working with the industry to provide the guidance and technical assistance to facilitate compliance, working with our state partners.

Certainly in the import arena, working with the import community but also with our foreign government regulatory partners. Lots to do to build a system that really can succeed and what this directs us to achieve which is having a comprehensive system of prevention that assures that food is safe and has been reliably verified to be safe regardless of where it comes from.

So again, thanks to all for your engagement. We look forward to the months and years to come and if you have questions, if you've had a chance to look at the rule, you'll have plenty of opportunity to Webinars and other events that we're planning to dig deeper. But we welcome the chance to give you some initial information today.

Before we ask the folks that constructed these rules to present, I'd like to ask Dr. Susan Mayne, the Director of CFSAN to add some opening remarks. Dr. Mayne.

Dr. Susan Mayne: So thank you Mike. The staff at the Center for Food Safety and Applied Nutrition take great pride in being involved in developing rules that will go a long way toward addressing the burden of food borne illness in the United States. We have experience with preventive control systems for specific foods such as seafood, juice and eggs but the produce safety rule moves us forward by addressing the issues with raw agricultural commodities which has you've noted, have been responsible for many outbreaks of food borne illness over the years.

Just recently we experienced a multi-state outbreak of Salmonella Poona linked to cucumbers. Late last year, a multi-state outbreak of Listeria Monocytogenes linked to caramel apples. And a multi-state outbreak of Salmonella Enteritidis linked to mung bean sprouts. So of course not all

outbreaks are related to produce. So our preventive control rules are also critical in addressing these other outbreaks.

In the import safety rules, we'll address the needs that target risks associated with both domestically produced and imported foods. We look forward to working with our colleagues here at FDA, with our partners in the states and with the affected industries towards successful implementation.

And now I'd like to turn the call over to Dr. Dan McChesney, my colleague over at FDA's Center for Veterinary Medicine.

Dr. Dan McChesney: Thank you Susan. The Center for Veterinary Medicine has been most focused on the final rules on preventive controls for animal foods which was published in September. But the final rules on imported foods are also critical for animal food whether it is for food producing animals or companion animals.

We know there is a link between the health of animals and humans so it's important that we work together to create a food safety system that is comprehensible. We are incredibly proud of this effort and look forward to working with our animal food industry and our regulatory partners in state agencies as we implement these rules.

I will now turn it back over to (Theresa).

(Theresa Rubio): Thank you. And I'll turn the call over to Samir Assar, Charlotte Christin and Brian Pendleton for highlighting community requirements for the rules. Samir.

Samir Assar: Thank you (Theresa). And as was mentioned, the Produce Safety Rule, establishes for the first time mandatory science based standards for growing, harvesting, packing and holding produce particularly in five key areas found to be routes of microbial contamination such as agricultural water, biological soil amendments of animal origin, workers health and hygiene, domesticated and wild animals and equipment tools and building.

The rule covers a wide variety of fruits and vegetables and contains a separate set of provisions specific to the production of sprouts. I'll review briefly the major requirements and hope that you'll go to our Web site at fda.gov to read more about the Produce Safety Rule.

I'll begin by mentioning that the definition of farm and related terms were revised in the final rule on preventive controls for (unintelligible) foods and that same definition is used in this rule. Operators of facilities whose only activities are within the farm definition are not required to register with FDA as food facilities are not subject to the controls regulation.

The first key area I'd like to highlight is the agricultural water provision area. The final rule adapts a general quality to water proposing a supplemental rule to some changes to ensure flexibility. FDA has retained quantitative criteria for the microbial quality of agricultural water. The final rule establishes two sets of criteria for water that contacts growing produce both of which are based on the presence of generic E. coli which can indicate fecal contamination.

The first set represents a central tenancy of the water quality of what the water might look like on an average day. The second measures the variability of the water and indicates what the water might look like when adverse conditions come into play like heavy rainfall.

For the testing requirements, the final rule still bases testing frequencies on a type the water used, surface or groundwater. More sampling is required for surface water because it is far more vulnerable to contamination and therefore greater variability in generic E. coli levels is expected.

There is quite a bit of flexibility provided in both water quality standards and testing criteria. For example, for use during growing activities, if water exceeds certain criteria, growers are not required to immediately discontinue the use of water. Several options in the rule provide for taking corrective action as soon as possible but no later than the following year to achieve the microbial quality criteria.

In addition, the criteria allow for occasional high readings in generic E. coli and an appropriate time to test. And a farm will not have to discontinue use of its water storage be it small fluctuations in water quality. And there's flexibility in the standards themselves in that growers can provide alternative criteria using different indicator organisms or different numerical criteria altogether as long as they can establish that the same level of public health attention is provided.

We are (unintelligible) the development of an online tool that farms can use to input their water sample data and calculate the values. The bottom line is that we're willing to work with producers on the water standards and we want to hear from them.

Another key area in the Produce Safety Rule relates to biological soil amendments. We've set limits on detectable amounts of bacteria for processes used to treat biological soil amendments including manure and compost.

Bacteria includes *Listeria monocytogenes*, *Salmonella*, fecal coliform and *E. coli* O157:H7.

The final rule requires that untreated biological soil amendments of animal origin such as raw manure must be applied in a manner that does not contact covered produce during application and minimizes the potential with covered produce after application. FDA is conducting a risk assessment and extensive research on the days needed between the application of raw manure as a soil amendment at harvesting to reduce the risk of contamination.

Meanwhile, we do not object to the farmer's complying with the USDA's National Organic Program standards which calls for 120 days interval with crops in contact with soil and 90 days for crops not in contact with soil. It's a prudent step to minimize the risk of contamination while we research the issue.

We are working with the Produce Safety Alliance on a (unintelligible) to provide the opportunity to engage the (unintelligible) further on these issues. The final rules also have requirements for processes that are used to provide stabilized compost which is the end product of composting. The rule includes two examples of scientifically valid composting methods that meet those standards.

Stabilized compost prepared using either of these methods must be applied in a manner that minimizes the potential for contact with produce during and after application. The final rule also includes new requirements to help prevent the contamination of sprouts which are frequently then associated with food borne illness outbreaks.

New requirements will include treatment feeds, test sprout growing environments and taking corrective action if samples test positive for bacteria. Other key areas addressed by the final rule are controls for domesticated and wild animals, worker training and health and hygiene and equipment tools and building.

They'll be ample time for farmers and food producers to come into compliance. Compliance dates are staggered according to the size of business. The results is compliance periods of four years for very small farms, three years for small farms and two years for all other covered farms. And for certain water provisions, an extra two years have been provided.

It's important to note that sprout requirements will meet the coming compliance one year after the coming rule becomes effective. I want to emphasize the effort we are putting into training and technical assistance on the rule because that effort is critical to successful implementation.

We are working with cooperative extension, land grant university trade association, foreign partners and other stakeholders to develop a network of institutions that can provide technical assistance to the farming community especially small and very small farms. This is in addition to establishing a food safety technical assistance network within the agency to provide a central source of information to stakeholders.

That briefly summarizes key provisions of the final rule. I'll now turn it over to Brian to talk about the foreign supplier verification program around that rule.

Brian Pendleton: Thank you Samir and thanks to everyone on the call for the opportunity to provide an overview of the final (foreign supplier) verification program or FSVP.

The final rule for the first time requires most importers to take specific steps to verify if their suppliers are meeting U.S. food safety standards. For the purposes of FSVP an importer is the U.S. owner or consignee of a food that's offered for import into the United States.

If there's no U.S. owner or consignee at the time at the time of entry, the importer is the U.S. agent or representative of the foreign owner or consignee at that time as confirmed in a signed statement of consent by that person observed as the FSVP importer.

Importers are responsible for taking specific action to ensure that they import safe food including determining if there are any known or recently foreseeable hazards in foods that require a control. In doing so, importers need to look at the biological, chemical and physical hazards that occurred naturally or are unintentionally introduced or are intentionally introduced for purposes of economic gain.

Food importers also need to evaluate the risks proposed by foods based on the hazard analysis that was conducted as well as the foreign supplier's performance which will include its history of compliance with FDA food safety regulations. Importers will have to use that importer food safety evaluation to both approve their suppliers and determine appropriate supplier verification activities.

In conducting those activities, the final rule gives importers the flexibility to tailor the activities to the unique food risks and the supplier characteristics.

Importers can determine appropriate verification activities from among onsite auditing of foreign suppliers, sampling and testing, reviewing relevant food safety records of their supplier or some other activity that the importer has determined to be appropriate.

Under the final rule an annual onsite audit of the supplier's facility is the default verification activity when there's a reasonable probability that exposure to a liability controlled by the foreign supplier will result in a serious adverse consequence or death to humans or animals.

However even in this case, the importers could use another means of verification provided they document that the alternate choice is appropriate based on the (unintelligible) evaluation and that it provides adequate assurance that the foreign supplier is processing the food in accordance with applicable USDA standards.

And finally, importers will need to conduct corrective actions in response to non-compliance. And that could include depending on the circumstances working with a supplier to correct the problem or in some cases, even temporarily discontinuing use of a supplier until the cause of non-compliance is addressed.

One of the most important changes in the final rule is that importers are not required to conduct all of these activities themselves. An importer can rely on another entity other than the foreign supplier with certain exceptions to conduct hazard analysis, to evaluate the food and the foreign supplier and to determine and conduct appropriate supplier verification activities as long as the importer reviews and assesses the relevant documentation of these activities.

I should note that the final rule includes certain exemptions from the FSVP requirements such as (unintelligible) and sea foods, importers of those foods are already subject to certain required verification requirements. There are exemptions for food for research, alcoholic beverages and several others.

And the final rule also has modified requirements for certain importers. These are for importers of dietary supplements, various small importers and importers of food from certain small foreign suppliers and importers from foods from suppliers in countries with which we have a (systems) recognition or equivalency agreement.

The revised definition of very small importer in the final rule is consistent with the definition of various small business and the preventive controls regulation. There's an annual food ceiling of \$1 million for human food and for importers of animal food, the ceiling is \$1.5 million.

The compliance dates for FSVP are somewhat complex because they vary depending on the, whether the food being imported is subject to preventive controls or produce safety regulations or (unintelligible) to neither of those. But in general, the earliest that an importer would be required to comply with FSVP is 18 months after publication of the final rule.

For the importation of food from a supplier that is subject to either the preventive controls of produce safety regulations, compliance by the importer with FSVP is required six months after the foreign supplier is required to comply with the relevant regulation.

We are providing assistance to industry on compliance with FSVP in several ways - the developing of draft guidance or providing recommendations on how importers can meet the FSVP requirements.

We will use the FDA Food and Safety technical assistance network which is already providing, responding to stakeholder questions about the preventive controls regulations to provide a central source of information to support industry understanding of the implementation of FSVP and we are collaborating with the Food Safety Preventive Controls Alliance to establish training and technical assistance programs for FSVP.

That's a brief summary of the key provisions of the final rule on foreign supplier verification program. As Samir noted, we have additional information on the FSVP final rule on our Web site. And with that, I will turn it over to Charlotte Christin to talk about the accredited third party certification regulations.

Charlotte Christin: Thanks Brian and thanks everyone for joining us on the call today. The final rule on accredited third party certification is an important part of the new import system under FSMA. I want to emphasize that participation in this program is voluntary. FDA is not requiring certification in general in (unintelligible).

I will explain certification more in a moment. The final rule on accredited third party certification establishes the framework, procedures, and requirements for accreditation by bodies seeking recognition by FDA as well as the requirements for third party certification bodies seeking accreditation. A recognized accreditation body could be a foreign government, agency or private third party.

Their responsibility would include assessing third party certification bodies for accreditation and monitoring their performance including conducting onsite observations and notifying the FDA of any change in or withdrawal of

accreditation that is granted. A recognized accreditation body also would have to maintain and provide FDA access to records required to be kept under the program.

Third party certifications also would have requirements under the rules which include performing unannounced facility audits and notifying the FDA upon discovering a condition that could cause serious risks to public health. They also must ensure their auditors are competent and objective and they must verify the effectiveness of corrective action to address identified deficiencies in audited facilities.

Certifications that are produced for this program can be used for two purposes. They may be used by importers who establish their operability for participating in a voluntary qualified importer program or (unintelligible) which offers expedited review and entry of food.

They also may be used in specific circumstances where FDA has required that a food offered for importation be accompanied by certification from an accredited third party certification body. To promote international consistency and promote an existing framework that is familiar to the industry, accreditation and certification bodies will be allowed to use documentation of their conformance with ISO IEC standards supplemented if necessary in meeting the program requirements under this rule.

Before discussing timelines, I want to note that audits by participating certification bodies that have performed solely for FSVP for two key supplier verification purposes, are outside the scope of this rule. As to timelines, FDA intends to implement this program as soon as possible after publication of the final model accreditation standards guidance and the final user fee rules both of which will be published separately.

FDA issues model accreditation standards draft guidance in July 2015 and also its proposed rule establishing user fees for accreditation and certification bodies. Accreditation bodies could begin to apply for recognition when the program goes into effect and third party certification bodies could seek recognition after one or more recognized FDA accreditation bodies begin accepting applications. Thank you.

(Theresa Rubio): Thank you to all of our speakers. Now at last I would like to ask the Operator to open up the phone lines and provide instructions for our callers who may have questions. Please state your name and the name of your organization prior to asking your question. Operator.

Coordinator: Thank you. And at this time, if you would like to ask a question, please press star one on your touchtone phone. To withdraw your question, you may press star two. Once again, if you have a question, please press star one at this time. One moment.

(Theresa Rubio): While we're waiting for a question, I'd like to, we will be hosting two Webinars in November covering these final rules. The first Webinar on the program's final rule will be held on November 17 at 2:00 pm. Eastern time.

And the second Webinar on November 23 at 10 a.m. eastern time will cover FSVP, an accredited third party certification final rules. More information about these Webinars are available on the FSMA Web page at www.fda.gov/fsma.

In addition, we are scheduling Webinars immediately around the country to meet with our stakeholders on the new rules. Initially, we'll be participating in

state hosted regional meetings focused mainly on the produce provisions with import focused regional meetings to follow.

We also look forward to continuing discussing implementation issues on a range of topics with stakeholders including the development of guidance documents and training to help industry implement these rules. Operator, do we have any questions in the queue.

Coordinator: Thank you. The first question comes from (Evan Brownfield). Please state your organization.

(Evan Brownfield): Hi. This is (Evan Brownfield). I'm with The International Center for Technology Assessment. My question is for Dr. Samir Assar. During your talk you mentioned sea treatments and treating seas was addressed by the final rule. But I was a little unclear as to how and I was hoping you could expand on that.

Samir Assar: Sure. And I certainly invite you to look at the rule for how we specifically cover the treatment. We generally and it's kind of a carryover from what we originally proposed. It was a carryover from our 1999 guidance that we put out, (unintelligible) guidance.

We don't specify. We specify that you need to conduct a sea treatment but we don't state at this point what the treatment should be, in other words, what compounds could be utilized for that purpose and it's that scenario that we are looking to further elaborate on in guidance documents.

So there's a requirement that the sea be treated prior to use and we will address treatment options as we explore guidance development activity.

(Evan Brownfield): Great. Thank you very much.

Samir Assar: Sure.

Coordinator: Thank you. The next question comes from (Eric Liberman). And please state your organization.

(Eric Liberman): This is (Eric Liberman), U.S. Food Imports. This question's for Brian Pendleton. Who can perform foreign supplier verification activities other than the FSVP importer? I know there's a provision in the rule for other parties to perform these activities. I'm wondering if you can elaborate on that please.

Brian Pendleton: Sure (Eric). A good example would be when the, an importer is importing a raw agricultural commodity and the commodity is the consolidator or aggregate for that commodity. So rather than the importer itself going to each of those individual farms that are conducting an audit or getting records from that farm, the importer could rely on the consolidator or the aggregate to do that and review the information that they would get from a consolidator.

(Eric Liberman): Thank you.

Coordinator: Thank you. The next question comes from (Timothy Wells). And please state your organization.

(Timothy Wells): Yes, this is (Timothy Wells) with (DFM). I have a question on foreign supplier verifications and the talk about identify risks. In identifying the physical, biological, chemical risks, with all the food products we import, I'd like a little bit more understanding of what would be acceptable if the only onsite audit would be having a half a van for that particular imported good, what would happen to a full evaluation?

Man: I'm not sure whether you mentioned evaluation. I heard you talking about the hazard analysis first. But if you're talking about supplier verification, again, that would depend on the activities that the importer would conduct.

Or documentation that they would review if conducted by someone other than themselves would be based on, would either be based on the hazards associated with the food or the risks that the food itself poses as well as characteristics related to the foreign supplier from which they obtain the food.

So they would, in terms of deciding what they need to do, outside auditing or annual onsite auditing or less frequent auditing coupled with some additional verifications through record review or some other approach. What you need to do, it depends on the nature of the hazards in the food and the foreign supplier. Does that...

(Timothy Wells): Well yes, it's very helpful and with that actually with that (unintelligible), it's going to be difficult to ascertain. So onsite auditing almost becomes mandated. That would be my assumption.

Man: Well as I mentioned, we do, the rule does have the default position where onsite auditing, annual onsite auditing is appropriate where there is a serious a (unintelligible) hazard (unintelligible) is accrued although even there if you have a case where the importer might have had a very long experience with a supplier and no problems lingering.

If there were problems, they were very swiftly addressed and the supplier has a very good record of compliance with FDA requirements, it would not necessarily be unreasonable for the importer to conclude that something

different from annual onsite auditing, perhaps auditing of a wider stated period with additional verification measures might be appropriate.

(Timothy Wells): Okay. Very good.

Man: Let me just add that throughout our implementation of FSMA rules raised lot of situations and questions and need for folks to get clarity about what we expect and what would work from a food safety standpoint. And so that's why there will be guidance to accompany these rules and that's why we're open to ongoing dialogues to help people understand what these rules contemplate.

We have established, as we had mentioned, we will, the technical assistance network that we've set up that enables folks to go online right now to the FSMA Web page on our Web site, FDA Web site, and register specific questions. And get the more specific facts that are offered up, more specific than answers we could give.

So again, there's work ahead to be sure that folks have clarity and common understanding of what's expected.

(Timothy Wells): Very good. Thank you.

Coordinator: Thank you. The next question comes from (Rene Romero). Again, please state your organization.

(Rene Romero): Good morning. (Rene Romero) with AMEX Broker in (unintelligible), the San Diego area. My question has to do with the big conferences where we have foreign companies or should I say foreign countries that basically are exhibiting at these shows.

PMA for a summit, (United Fresh) where they have a pavilion and you have many small exhibitors. How, now many of those may fall under the small business category but how are we to handle those that are outside of the small business category?

Many times these shipments are entered under a bond of the customs broker and again these are small quantity shipments. So how should we handle those importations if we know or do not know if it's a small business category?

Man: Thank you for your question. If you're talking about a food that is going to be available and distributed to customers at the trade show, that would be food that is subject to FSVP. So in that case, the importer of that food would need to conduct most of these activities related to FSVP as we mentioned.

So you would, the importer would need to do an assessment of that potential supplier of that food and also to conduct verification of the food consistent with the FVSP regulation.

(Rene Romero): Thank you. I think that deserves just a bit more dialogue because it's like I mentioned, in many cases it's the customs broker that uses their bond but they really don't have any other relationship with the foreign exhibitor. The relationship is with the country that is sponsoring the show. And again, in that case, it would be difficult because there isn't an importer other than the customs broker's bond because in those cases, those exhibitors are looking for buyers in the U.S.

Man: Yes, it depends on the, whether the customs broker is the importer for purposes of FSVP and whether it meets the definition that we have there.

Mike Taylor: This is Mike Taylor. Let me just offer, I agree with you. This is a topic that requires further dialogue. I think we have to be clear though that the fundamental principle here is that before food being imported into this country, there needs to be a FSVP importer who is taking responsibility for its safety.

And we recognize there are people bringing food into the country now that don't see themselves in that business. And that's going to require an evolution of practice. And I think we might in a practical way meet with the community and figure out how to make this workable.

One of the flexibilities built into the rule though is flexibility about actually who has to do the verification. So I'm just going to postulate the possibility and, you know, again there has to be dialogue. And our SME's and there are experts who have to be part of this. But if you're working with a country in this sort of context, you know, our rules are flexible enough so that that country could be the one who is gathering information and doing verification and providing that to the FSVP importer who must take responsibility basically for reviewing it and embracing it.

But again, the flexibility in the rules to try to work with this particular situation that I don't know if a trade show circumstances raise particular special concerns and deserves some special thought and special thinking. But again, these are the kinds of questions we appreciate your raising. Exactly the kinds of questions there needs to be a dialogue on.

When think this rule and the intention of this rule is to work to improve food safety by abiding by these principles that someone in the U.S. has to take responsibility for food brought in from overseas and do that in a way that

doesn't unnecessarily disrupt ongoing practices of trade falling across their borders.

That's something that is important and valuable to consumers and we don't want to disrupt but we do need to figure out how to make this core principle of FSMA, be meaningful in a way that's meaningful for food safety. So I look forward to working with you on that.

(Rene Romero): Thank you both.

Coordinator: And the next question comes from (Miley Hermeda). Your line is open.

(Miley Hermeda): Hi this is (Miley Hermeda) from (Hogan Levels). Thank you for taking my question. I'm wondering if you can comment on the scope of the produce safety rule and what product fall under it, which ones do not? And whether you need any documentation to not fall under the rule?

Man: Oh, the scope. That, I would say certainly first invite you to participate in a Webinar that's being held on November 17 because I'll get the chance to go into far greater detail into the scope of the rule.

And during that presentation, I'll talk about those that are eligible for exemption and those that are covered, those that are not covered. And, you know, and also the criteria that we applied for establishing our, what we refer to as rarely consumed raw list. And so, you know, essentially we have a, I'll just give you a quick highlight of some of the exemptions that we have in play in the final rule.

One is that if you have less than \$25,000 of produce sales, on an annual average basis or less than or equal to, then, you know, you would not be

covered. If you need what is referred to as the qualified exemption that also is around a total value of annual food sales of \$500,000 and also being distributed, you would be subject to this qualified exemption.

I mentioned the rarely consumed raw products. They're products that are that would fall into that list of rarely consumed raw. And we've done a more robust analysis of dietary consumption information to derive an updated rarely consumed raw list. And we invite you to take a look at that and if you do fall into that category, then you would not be subject to the rule either.

And then there's a, kind of a commercial processing exemption as well where you would have to follow minimal requirements associated with assurances so that if you're producing tomatoes that are intended to be further processed with a further commercial processed, then that offers to (unintelligible) that essentially. Then you'd need to provide witness assurances to that effect.

And so again, a lot to go over and missed opportunities here but I certainly invite you to participate in the Webinar on November 17 and we can perhaps, you know, provide more information around your questions.

(Miley Hermeda): Thank you. It sounds like you're fundamentally saying that that framework is the same as under the proposed rule.

Man: Correct.

(Miley Hermeda): Thank you.

Coordinator: Thank you. The next question comes from (Brent Kobilish). And please state your organization.

(Brent Kobilish): Yes, my name is (Brent Kobilish) from (Cardil). First of all, thank you so much for taking the time to conduct this call. My question's around, for Brian specifically, around the FSVP. I know, I understand under the (PC) rules that if you are a supplier supplying your own business under the same umbrella, you would not be exempt from documentation around preventive controls, et cetera.

So my question around FSVP, if we are supplying ourselves initially from a foreign country and importing that product, that is destined one of our facilities domestically, would we be exempt?

Brian Pendleton: Thanks for your question. No, that is consistent what we did with the (PC) supply chain provision. There would not be exemptions under the (PC) as we note there, as are in the preventive controls regulations. And that certainly would be a consideration as to what kind of supplier verification would be needed if the supplier of the food is in the same, under the same corporate structure as the (unintelligible) facility under preventive controls in the case of FSVP as the importer.

(Brent Kobilish): Thank you very much.

Coordinator: Thank you. The next question comes from (Robert Hons) and please state your organization.

(Robert Hons): Hi, this is (Bob Hons) from (unintelligible). My question is also for Brian Pendleton. I was wondering if the final rule requires importers to send their (SSCP) plans and related records to FDA upon request or whether FDA would only view them during an inspection. And also, if you can say a little bit about how FDA envisions inspections of importers?

Brian Pembleton: Thanks (Bob). Yes the final rule does include a finalized proposed provision that we could request for records to be sent to us to review them solely onsite in the course of an inspection. There's extensive discussion about that in both the preambles to the final rule and (unintelligible).

Mike Taylor: (Bob), this is Mike Taylor. On the question of how we would inspect and ensure that the importers are doing that they're supposed to do, we are developing what really would be a multi-faceted compliance strategy and strategy to assure that the overall import safety systems are working as intended and that will surely include inspections or audits of the importers foreign supplier verification program.

But look to the possibility of the other parts of the input toolkit, both pre (inspection) and post (inspection) elements to bolster that ability to be confident that the right things are happening. To include field exams which could be integrated with the oversight of foreign supplier programs that includes foreign inspection and the possibility to link what we see at an importer sight with what is actually happening in the foreign facility overseas.

Certainly we'll be taking into account and using it where appropriate, the work of foreign governments as a further check on the system. So it will be a multi-faceted effort to be sure that we can answer the question in the whole simple framework of how do we have confidence that food being imported is being produced under the same standard, get the same level of self-protection as in the United States?

So more to come on that. I think that's an implementation topic that we would envision as our think matures, having some dialogue with industry about our plans there.

(Robert Hons): Thank you.

Coordinator: Thank you. The next question's from (Zana Penedum). And please state your organization.

(Zana Penedum): Good afternoon. The organization's Global Gas North America and thank you for holding this stakeholder's session. I'd like to ask two questions. The first is regarding the discussion we had about the FSVP? You've made it clear that there will be a variety of potential requirements which are basically hazard based or specific case based.

I'd like to ask if for this purpose you will be publishing of high risk approach or some other method.

Man: Are you talking about for FSVP purposes or not only?

(Zana Penedum): Basically in that context, yes, but the broader produce world as well. Will there be an official list of high risk sector commodities that would necessitate that a certain action plan be vis-a-vis, that certain hazard analyses are onsite versus, you know, offsite verification? Will you specify clearly what the risks are either by list of commodities or specific risk sectors?

Mike Taylor: This is Mike Taylor. Let me just offer a thought again. Happy to have some dialogue about this. Fresh produce is going to be consumed raw. We consider generally speaking it to be a high risk commodity. And so in terms of the obligations of the importer, the default expectation would be an annual onsite audit.

And there's some opportunities for that to be done differently under different circumstances or certain level of experience and documentation and so forth. And we'll have dialogue about that.

You know, it's another question we were just asked a minute ago about FDA supply strategy. It's another question, you know, how we would deploy our compliance efforts and whether we would be doing some prioritizing as we always do when we enforce any regulatory framework around commodities and countries and there'd be certainly some consideration within FDA of how we prioritize our efforts.

But the basic fundamental is here that a product like that is inherently subject to microbial contamination. There needs to be some verification that the standards and practices that can make that food safe are in effect. And so generally speaking, that's the expectation for produce.

(Zana Penedum): All right. Thank you. And the second question is regarding the third party verification. Could you provide a little bit more specifics on requirements for domestic certification bodies and verification bodies like AMC versus those outside the U.S.?

Dr. Susan Mayne: Thank you for the question. So in terms of what's required of the program, that the law specifically seeks to participation by foreign certification and accreditation bodies and often speak to others third parties which could include U.S. based accreditation and certification bodies. Does that answer your question?

(Zana Penedum): Well, you'll be providing more details in the second session in November, I assume?

Mr. Susan Mayne: Yes, absolutely.

(Zana Penedum): Yes, all right. Thank you.

Coordinator: Thank you. The next question comes from (Russell Statman). And please state your organization.

(Russell Statman): This is (Russell Statman) from (unintelligible). And my question is mainly to Brian but it may relate to produce as well. And it gets back to what Commissioner Taylor was saying which is the enforcement mechanism. Is anything going to change as to time of entry at the port of entry for imported goods? Is there going to be some enforcement mechanism that's built-in where FDA ratifies that everything is in compliance with FSVP? Or is there going to be reliance on other methods that are unrelated to the entry process?

Sort of gets back to what (Rene) was saying before about the whole customs broker issue. And what the customs brokers do, does that change now?

Man: To answer your question, no the FSVP regulation itself is not going to change that dynamic. The rule does require the FSVP importer to ensure that they are identified at entry. As the importer of that food, you need to provide your name and your mail address. And you need your facility identifier. But there is not, FSVP regulation itself doesn't specifically establish a human portion mechanism to, for example, enforce compliance with FSVP.

We would primarily be addressing that through inspections of importers at their, primarily where they keep their FSVP records according to the schedule that we are developing for importer inspections. But there wouldn't be a new mechanism that the regulation establishes itself with respect to verifying compliance at the border.

(Russell Statman): Okay. And if I can just follow-up on the same thing. Where there is no U.S. owner of the food and the foreign company has designated a U.S. agent who has to accept in writing, is FSVP going to require a copy of that writing or is it just sort of an honor system that such a person had agreed in writing? And if they haven't, we'll sort it out later.

Man: If there is any question about whether or not this person has consented to serve as the FSVP importer, we might request to see the consent from the importer himself. If they have not consented, they're not going to have a copy of, if they haven't provided the written consent.

So we would ask them the foreign owner or consignee to show that, to demonstrate that they have, in fact, there's been written consent for this person to serve as their U.S. agent or representative for FSVP purposes.

(Russell Statman): Okay but that's not going to take place at the point of entry. What I'm trying to get at is there's not going to be any new entry documents or data fields that have to be entered at the time of entry, at customs entry. That's what I was pretty much asking.

Man: Right. The rule itself doesn't require submission for example of this written consent to serve as a U.S. agent or representative at entry. And so just to put it in other words, I think what you want to ensure is that we're not going to have a demonstration that everything is being done right.

Man: Exactly.

((Crosstalk))

Man: That there was no FSVP (unintelligible).

Man: No, that's not the case. Like Brian said, a central focus will be on engaging the importers separately from entry by entry activity and really assessing their plans in an environment where we can look at records and comprehensive lists and assess whether they have an adequate plan.

That doesn't mean that we won't be sampling product and it's part of continuing our oversight at the border. But in terms of continuing the entry process per se, again, the FSVP importer identified that there's not going to be an entry by entry verification that the importer is doing FSVP properly.

(Robert Statman): Okay. Thank you very much. Very much appreciate that clarification.

Coordinator: Thank you. The next question comes from (Sonia Solas). And please state your organization.

(Sonia Solas): Thank you. (Unintelligible) Association. And I want to thank everyone for the work and transparency in the room before I give my comment. So the comment I had is related to the produce rule, Section 112-22 that covers training (unintelligible) activities.

I was wondering what entity you have in mind for the (unintelligible) mentioned in this section? And how these relate to the use of consistent training programs for the development of (unintelligible) specific training?

So just, I want to know if you're including additional details in your implementation guide about the use of these corporate (trainings)?

Samir Assar: Sure. Thank you (Sonia). Appreciate the positive comment. This is Samir. So, and you may be referring to we put out kind of a vision guide online that shares our overall thinking with respect to training and facilitating training and in some respect, technical assistance around the produce safety rule.

It shows how the alliances kind of fit in with some of the training, potential training mechanisms, the FDA, National Coordination Center, the (NIFA) Regional Centers, the FDA Centers, how it all fits together. And certainly we alluded to there will be cooperative agreements in place to facilitate training, you know, targeted audiences.

And so we were still kind of working on, you know, developing the approach, developing the announcement for those training opportunities and hopefully we will be issuing, you know, those cooperative agreements to kind of, you know, moving forward with those cooperative agreements very soon. And, you know, we do envision a community based approach to facilitating training and, which involves input from industry and other stakeholders as we move forward with training.

I definitely appreciate your question but the bottom line is we will be announcing more details about the cooperative agreement soon.

(Sonia Solas): Thank you. I appreciate your response.

Coordinator: Thank you. The next question comes from (Andre Keray). And please state your organization. And please check your mute feature with your handset.

(Andre Keray): Hi. I'm calling from (Home Perishables). And my question relates also to the broker requirements, broker companies. I'm thinking now that we're going to

have FSVP and let's assume that a supplier has done everything that is required and the supplier has the relevant certifications.

Is there a way that we can also (examine) the certification at the time of entry as to expedite the release of the cargo?

Brian Pendelton: Thanks for your question (Andre). I mean I don't, that's not, that certainly is not contemplated under the regulation as we drafted it and I should note that there's not, there isn't a specific certification required for admission under FSVP. It does not require that.

Mike Taylor: (Andre), this is Mike Taylor. Let me just say. Brian is trying to say what the rules are. We anticipate, we're doing now, trying to anticipate, thinking a dialogue about how we continue to refine, how we target our imports, our entry process, our border control activities in a way that focuses our effort where they will do the most good from a (unintelligible) standpoint.

And, so one element that's certainly on the table to consider is whether a supplier has a demonstrably reliable audit, onsite audit, literally required by the FSVP rule or not. But it is a way to distinguish the assurances and elevate the assurances that, you know, that we could have the safety of the product. The formal way for that to happen of course is if a voluntary, qualified importer program which, you know, would mean that if you had an audit which was done under the accreditation program, then that's all about expediting entry.

So I would encourage you to really focus on that and look at that but, you know, we're open to various variations on the team of how we take account of those who are going the extra mile to produce a food, to demonstrate that they've done the right verifications. We want to take that into account in

whatever the appropriate way that can be efficient in managing food safety in a trade environment. So we can have further discussion around that.

(Andre Keray): It's just that I saw how the (motive) for the FDA registration numbers or the initial motivation for it was to, you know, try to identify the manufacturer and try to get a sense of, a quicker analysis of the (unintelligible) right. So in the same way if an importer and the supplier have gone through this concept of certification and all that, it can be a way to, like an FDA registration number that you present your certificate and you're just given more details and information that allows you to expedite clearance.

But of course the voluntary qualification is an extremely extra step because it's quite from what I've seen in the proposed rules, it's quite expensive to do it and it's more like aiming to high risk commodities.

Mike Taylor: We welcome further dialogue on this.

(Andre Keray): Well thank you very much.

(Theresa Rubio): And Operator we'll take one final question.

Coordinator: Thank you. The final question comes from (Casal Low). And please state your organization.

(Calsal Low): Good afternoon. My name is (Casal Low). And I am with FEDEX Express. Thank you for taking my question which is on FDA import operations. I am aware that you are taking a (unintelligible) approach and now I would like to understand if food entries will be processed by the FDA Predict ID tool in each port of entry within the (unintelligible) import district or if you will have a centralized system for food that is different from other import commodities?

So basically, will you have FDA import operatives dispatched in food and purely dedicated to that import category?

Mike Taylor: This is Mike Taylor. We're looking at each other because it's a slightly complicated question. It's a work in progress sort of question. And I don't know whether you're referring to the program alignment or initiative that's going on within FDA but we are in the process of realigning our field forces to be specialized and to be more closely linked with the centers as public health and food safety programs are being implemented.

So there will be a food and (feed) field program, you know, linked with the food safety nutrition and the Center for Veterinary Medicine. How that will play out in the context of the individual aspects of our overseeing the import program remains to be seen.

You know, we have a screening process. It's electronic. We have an inspection activity which needs to be done in a way that very much aligned with how we look at supplier replication in a domestic facility context. Who's going to be actually doing what is a work in progress. And so we'll keep you posted and, you know, welcome the question.

We want to be, as we go through that program alignment another important change that's going on within FDA that's crucial to the success of our food safety program, general, certainly is FSMA and we'll be, you know, welcome questions about it and dialogue as we work that through. We'll be transparent about that.

(Calsal Low): Thank you.

Mike Taylor: Thank you.

(Theresa Rubio): Thank you. And this concludes today's stakeholder call. Thank you for your participation and have a great day.

Coordinator: All participants may now disconnect. Thank you.

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