

Collaborative Food Safety Forum (CFSF)

Proposed Rule for Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals: Workshop Summary

January 8, 2014
Washington, D.C.

Background

The Pew Charitable Trusts (Pew) and the Robert Wood Johnson Foundation (RWJF) are co-sponsors of the [Collaborative Food Safety Forum](#) (CFSF or Forum). Invited representatives from federal and state agencies, industry, consumer advocacy groups, and associations attended a workshop on January 8, 2014 to discuss specific aspects of the Proposed Rule for Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals¹ as a part of implementing the FDA Food Safety Modernization Act (FSMA).

The proposed goal of the workshop was to hold productive, problem-solving deliberations concerning the following topics and questions:

- Present and discuss targeted aspects of the Proposed Rule for Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, particularly:
 - What types of supplier verification mechanisms can be used that are risk based and are adequate to provide assurance that imported food meets domestic standards?
 - How should importers determine what mechanisms are appropriate for particular foods or suppliers?
- How is the importing entity identified and what FSVP requirements must it meet?
- How are “very small” importers determined, what are their FSVP requirements and why?
- How should alignment of FSVP requirements and the requirements of the Preventive Controls and Produce Rules be accomplished?

The proposed outcomes of the workshop were the following:

- A summary document (this document) reviewing the presentations and main points of discussion to help inform individual comments on the proposed rule.
- A key themes document highlighting the main ideas that emerged from the discussion

This workshop opened with a welcome and remarks from Sandra Eskin (Pew) followed by a review of the workshop’s goals, outcomes, and agenda by Abby Dilley (RESOLVE).

¹ Note that the focus of this workshop was on importers of food for humans

Overview and Discussion of Proposed Rule for Foreign Supplier Verification Programs for Importers of Food for Humans and Animals

Brian Pendleton, Senior Policy Advisor, Office of Policy, FDA, presented the overview of the proposed rule, highlighting key questions related to particular aspects of the proposal on which FDA is seeking comment, as well as associated general categories of comments submitted to date. Mr. Pendleton began with the conceptual principles to frame the proposed rule approach, definitions of key terms, and details on who is responsible for meeting what requirements. Mr. Pendleton's slides can be found [here](#).

Under the proposed regulations, importers, for the first time, would need to perform risk-based verification activities to ensure that their foreign suppliers produce food consistent with U.S. food safety requirements.

Mr. Pendleton presented the two options that FDA has proposed for supplier verification activities for hazards that the foreign supplier controls or that the foreign supplier verifies are being controlled by its raw material or ingredient supplier. These options differ primarily according to the nature of the hazard and the specified verification action to be taken regarding certain serious hazards, specifically, hazards to be controlled by the foreign supplier that have a reasonable probability of resulting in serious adverse health consequences or death to humans or animals (SAHCODHA). Each are outlined below.

Option 1

- If a foreign supplier controls the hazard at its establishment, and there is a reasonable probability that exposure will result in SAHCODHA, the importer would be required to conduct or obtain documentation of on-site auditing of the foreign supplier.
 - Currently, the proposed rule does not discuss the specific documentation required and FDA would like further input via the comment process on this.
 - On-site auditing would be an important aspect of this option as it would allow for observation of physical conditions in a facility, interviewing employees, reviewing records, and verifying information in a manner that might be difficult to achieve with other methods.
- For microbiological hazards in certain raw agricultural commodities, on-site auditing also would be required.

Option 2

- For *all* hazards that the foreign supplier will either control or verify that its supplier is controlling, importers would need to choose verification procedures from the following:
 - On-site auditing;
 - Sampling and testing;
 - Review of supplier food safety records; or
 - Some other appropriate procedure.

A highlighted difference between Option 1 and Option 2 is that in Option 1, for those foods with SAHCODHA hazards, on-site auditing is mandatory. For Option 2, while the importer must consider the seriousness of the hazard in determining an appropriate supplier verification activity, on-site auditing would not be mandatory and alternative supplier verification activities determined to be effective could be conducted instead.

FDA intends to align the FSVP requirements with any supplier verification provisions that are included in the Preventive Controls (PC) final rule. The PC proposed rule discusses circumstances under which supplier verification for raw materials and ingredients might be appropriate and requests comment on whether and, if so, what supplier verification requirements should be included in the final rule. FDA looks forward to receiving further comments on this matter.

FDA anticipates allowing additional time for importers to come into compliance after the FSVP rule takes effect, generally 18 months. For importers whose suppliers would be subject to either the PC or produce safety regulations, compliance with FSVP would be required six months *after* the foreign supplier is required to comply with the PC or produce regulations.

Definitions, “Good Compliance” and Comparability

Following Mr. Pendleton’s overview, there were several comments, questions, and additional discussion regarding his presentation. Deliberations focused in on the definition of SAHCODHA and associated clarity around the universe of importers subject to FSVP requirements, as well as the concepts of “good compliance standing” and comparability of other nation’s food safety systems (as compared to the U.S. system).

While SAHCODHA is an established FDA term, it is less familiar to some stakeholders, and a few participants were uncertain how the term would be interpreted by FDA. There was also confusion around which certain foods would be considered SAHCODHA, or “high risk,” and therefore would be regulated as such. Along with suggestions for providing additional information in the final rule as to the term and its use in defining priorities for compliance with FSVP requirements, the discussion developed into a broader conversation concerning variables potentially determining how supplier verification should be conducted and who, in particular, needs to be in compliance, including consideration of the food but also consideration of suppliers’ systems for controlling hazards.

The discussion of “good compliance standing” touched on several issues, including what criteria should be used in making a determination of good compliance standing, whether and how standing should be considered in evaluating risk, good compliance of a supplier with a foreign country’s food safety system, and whether a foreign food safety system may be considered “comparable” to the U.S. system.

Some participants advocated for the inclusion of consideration of a supplier’s history of hazard control or “good compliance” as part of the assessment of risk – in other words, considering the risk posed by the specific food *and* the track record of a facility, supplier, and/or a country’s

oversight system in controlling hazards to target auditing or other supplier verification requirements. While conceptually, considering demonstrated hazard control in the determination of risk was of broad interest, how practically to implement this type of approach without it being too costly and unwieldy for FDA was the subject of additional discussion. Participants also considered the implications of this requirement on U.S. trade obligations, in particular, the desire to harmonize standards with both Codex Alimentarius and WTO agreements was emphasized.

It was noted that trade barriers already are of concern given that the requirements for importers are different from those for food facilities (i.e., there is no requirement for a food facility to verify control of hazards in raw materials and ingredients obtained from suppliers (though these suppliers may be subject to hazard control requirements such as preventive controls, water quality standards for fresh produce, etc.)) It was also noted that, as with all aspects of implementation of the proposed rule, FDA has had their information technology staff looking at what information will be required at entry. To this point, certain pieces of information are highlighted in the proposed FSVP requirements, including the importer's name and DUNS number, but other information could be required to help assess compliance with FSVP. FDA would like some additional comment on specific proposed information to include.

Under the proposed rule, good compliance standing of a supplier with a "comparable" foreign food safety authority will be determined by the foreign food safety authority. However, FDA may also have a role in further defining (in the final rule) what the parameters of good compliance standing may be. It was suggested by some participants that FDA provide an accessible list of countries deemed to have a comparable food safety system as these determinations are important for informing importers of food and facilitate compliance with FSVP.

Risk-Based Determination of Mechanisms to Verify Control of Hazards

A more specifically focused discussion of the options set forth in § 1.506 of the proposed rule, outlined above and in Mr. Pendleton's presentation slides, began with opening comments and perspectives on this particular piece of the proposed rule. It was then followed by discussion of clarification on terminology, general principles, and reactions to the two options, along with development of a possible alternative approach to determine appropriate verification mechanisms.

Brian Pendleton, FDA, further elaborated on the key differences between Option 1 and Option 2 for supplier verification in the proposed rule. He stated that FDA has received many comments advocating for one or the other of the options. Some comments have suggested that Option 1 is most protective of the consumer, while others have found Option 1 to be too burdensome to industry. Other comments have said that Option 2 is better aligned with current industry standards because it allows for greater flexibility to meet the standards while putting the onus on industry to determine the appropriate supplier verification method.

Frank Yiannas, Vice President, Food Safety, Walmart, discussed aspects of the proposed rule with particular emphasis on consumer perceptions about food safety and associated distinctions consumers express regarding domestically produced and imported foods. His presentation highlighted the significant trend in sales of imported foods, noting that 15,000 different food products were sold in the 1980s and jumped to 50,000 different food products in the 2000s. He also discussed the impact on consumer confidence in foods and their safety when a foodborne illness outbreak occurs and noted the significant lag in return of confidence in foods produced outside the United States. In a global economy, this confidence is critical as is the safety of imported foods. Currently, Walmart and/or its suppliers meet [Global Food Safety Initiative \(GFSI\)](#) standards. With GFSI, on-site verification is the default standard of care for imported food.

Mr. Yiannas highlighted the distinctions between *verification* and *validation*, and he emphasized the need to establish and implement food safety systems that not only *verify* whether a control is or has been operating as intended, but also *validate*, through evidence-based research, that a control measure or combination of control measures, if properly implemented, is or are capable of controlling the hazard to a specified level of consistency and safety. He stated that not all verification methods are equal. Some verification methods are only relevant depending upon the hazard. He also noted that for Walmart, validation largely is being achieved through their participation in GFSI wherein the industry has seen a 31% average reduction in recall rates since its implementation. Mr. Yiannas also reiterated that regardless of which option was implemented, the final rule needed to be one that facilitated, rather than hindered, global trade.

Following the presentation, a participant noted that FSMA takes into account a variety of trade agreements including World Trade Organization (WTO) agreements. Mr. Yiannas noted that his concern about trade was general, rather than focused on any one agreement. He also indicated that, in general, most industry groups who are compliant with GFSI would already be compliant with Option 1 and thus, he thought, could be supportive of it. However, he also underscored the need for being open to other current and future validated methods of keeping products safe.

Leon Bruner, Senior Vice President for Scientific and Regulatory Affairs and Chief Science Officer, Grocery Manufacturers Association (GMA), provided an overview of GMA and their perspective on the proposed FSVP rule. Dr. Bruner put forth that as currently proposed, Option 1 is too prescriptive and not based on risk, whereas Option 2, is more flexible and risk-based. Thus, GMA strongly supports Option 2. He indicated that in order to improve market safety, the advancement of management systems was necessary to ensure delivery of safe food. Auditing, as prescribed in Option 1, is important according to GMA, but ensuring that an effective safety management system is in place is the path to improving food safety. GMA also believes that small and very small foreign suppliers will need robust guidance on effective implementation of either option.

For more information, Dr. Bruner's slides can be found [here](#).

Following Dr. Bruner's presentation, participants discussed when audits would or would not be required under the proposed rule. Many participants agreed that before determining the frequency of audits, additional clarification was needed around what hazards would and would not be considered SAHCODHA hazards under the rule. Some participants expressed concern that by having audits as the primary method of verification for control of hazards, it would lead to a "checking the box" mentality by some, rather than encouraging a more robust food safety management system and critical thinking. Other participants were concerned that Option 2 may be too resource intensive for the FDA in evaluating whether appropriate supplier verification practices were being conducted.

Caroline Smith DeWaal, Food Safety Director, Center for Science in the Public Interest (CSPI), presented an overview of CSPI's views on issues around international schemes for protecting food safety. CPSI stresses approaches to food safety that ensure safety for both developed and developing countries. Ms. Smith DeWaal also emphasized that FSVP is considered to be one tool in a much bigger toolbox to manage domestic and imported food safety, and encouraged the group to evaluate this proposed rule with consideration of the whole toolbox. CPSI considers FSVP necessary to fill the oversight gap that currently exists given that while on-site inspection of domestic food production facilities can occur, similar oversight for imported foods is not possible or practical. FSVP is meant to fill this gap. Given recent foodborne illness outbreaks increasingly linked to imported foods, appropriate oversight is important. Further, Ms. Smith DeWaal stated that under FSMA, foreign and domestic facilities must implement a food safety plan that includes hazard analysis, preventive controls, monitoring and records, verification steps, corrective action plans, records of corrective actions, and recall plans. From her point of view, FSVP is intended to ensure these various components of a food safety plan are in place for foreign suppliers.

Ms. Smith DeWaal cited FDA's Seafood Hazard Analysis and Critical Control Points (HACCP) regulations as a model on which FSVP builds and improves. She suggested that the Seafood HACCP approach has not been sufficient because, from her perspective, it is not improving food safety as effectively as is necessary and the lack of on-site auditing is problematic. As an example, she pointed to the 2012 foodborne illness outbreak from tuna scrape, wherein a physical inspection of the facility after the outbreak revealed practices and conditions leading to contamination. She proposed that the consumer would be more protected as a result of the on-site audits (required under Option 1). Mandating such audits would give greater uniformity to FDA for reviewing verification activities. Option 2, on the other hand, would be deficient in protecting the consumer because it leaves importers with too much discretion, requires FDA to evaluate adequacy of verification activities, and is resource intensive for the Agency.

For more information, Ms. Smith DeWaal's slides can be found [here](#).

Some participants disagreed with the assertion that the tuna scrape case example demonstrated that the Seafood HACCP program is deficient; rather, they said it more likely is an example of fraudulent behavior and, as such, does not provide adequate rationale for

mandatory on-site auditing. Different points of view were expressed as to whether mandatory on-site auditing of facilities producing foods with SAHCODHA hazards was appropriate, partly due to concern about a lack of clarity as to what hazards are designated SAHCODHA, partly due to the failure to include consideration of a supplier's history of compliance and reliability, and partly due to the fact that the burden in complying with or enforcing the requirements is borne mostly by the Agency or industry.

Determining Risk/SAHCODHA Considerations

Key questions raised and discussed included:

- What are appropriate requirements for an importer of a food considered a SAHCODHA risk that has been provided by a supplier over a long period of time who has a consistent food safety history? Is this history considered as part of evaluating risk and appropriate level of requirements? Alternatively, should a brand new company with no history be required to do more to demonstrate safe food practices? Should there be special considerations or special "carve-outs" under various conditions? If so, what criteria should be used to determine variable requirements, and how are those requirements enforceable?
- Is auditing the most effective verification method? Could other validated methods be used to demonstrate effective food safety systems?
- What should the key components of an audit include? Many participants concurred that the audit should be of the entire management system, not just on-site verification, and ideas were expressed as to additional factors other than a track record of safe food production, such as history of meeting other contractual requirements, including deadlines for delivery, etc.

Some industry representatives stated that as part of their current practices, a new supplier is assessed to determine whether and what type of audit might be appropriate. First, the inherent product risk is assessed. Assuming the product is high-risk, the company will send someone from their organization to the supplier to do a comprehensive food safety audit, including evaluation of their programs, processes, and people, to assure appropriate control of the hazard(s) associated with the particular food products. Other industry representatives indicated they consider both the inherent risk of the product as well as a track record of good compliance and associated confidence in the supplier's food safety systems. Other factors also are considered, such as volume of food products supplied and associated exposure, changes in the scope of products from the facility, major modifications to the facility, compliance with other management systems, etc.

It was stated by several participants that implementation of FSMA should be structured to focus FDA resources most effectively and that the Agency does not have the resources to inspect every supplier. The goal of the proposed regulation is to establish a system that requires importers to ensure that suppliers are meeting their obligations to produce food in a way that meets FDA safety standards.

Determining Risk Based on Product and/or Supplier Process

Many participants agreed there are two factors significantly contributing to risk—the inherent risk of the food product (including whether designated as SAHCODHA) and risk associated with the supplier’s performance in controlling risk. Although FDA’s proposal regarding supplier verification activities addresses both factors, Option 1 places a greater emphasis on the risk of the product than does Option 2.

Participants also noted that regardless of the approach to verification selected by FDA (Option 1, Option 2, or a different model), the regulations must ultimately successfully demonstrate an advancement in improving food safety and, by association, protection of the public’s health, as well as a mechanism for revision if such an advancement is not shown

Some participants expressed interest in supporting a “hybrid” approach that would require on-site auditing unless the importer has demonstrated that another verification method provides assurance that SAHCODHA hazards are being controlled.

FDA representatives stated they are open to considering all ways to ensure food safety hazards are being controlled while also being flexible to evolving strategies, including reducing the number of audits for highly compliant suppliers.

A main theme that emerged in these deliberations was how to link risk profiles of foods (specifically targeting those foods with SAHCODHA hazards) with process risks to determine highest priority targets for closer scrutiny by the Agency. In some cases, demonstration of good risk management procedures, determined by appropriate criteria, would reduce the overall risk profile and therefore dictate a different level of oversight.

Several ideas materialized from these discussions, including the following:

- Establish a default onsite auditing requirement for verifying control of high-risk foods that includes the possibility of demonstrating that an alternative verification is just as effective or that less-frequent auditing is because of a history of good compliance. For high risk products, have the annual audit as a default (unless other, validated ways of verifying management of risk are used).
- Use records review, plant visits, testing, and/or sampling in lieu of doing comprehensive annual audits when the importer can demonstrate that such methods are adequate.
- As technology changes, provide the flexibility for importers to validate new verification approaches and adapt requirements and oversight accordingly.
- Audits should be based in part on the adequacy of the supplier’s food safety system, including whether there is a validated approach to hazard control suitable for specific risks and the supplier’s implementation of the system to control the hazard.
- Agree to a set of core requirements for hazard control and then determine an appropriate verification approach, including real-time data, and the frequency of auditing depending upon the overall scheme used.

Considerations for frequency of auditing:

- Consider the inherent risk associated with the product from the foreign supplier, its history of compliance to determine frequency of audits
- Additionally, guidance should allow flexibility and evolution over time regarding frequency of audits, along with clarity around the process to obtain changes in frequency.
 - Generally, factors relevant to determine a history of good supplier compliance could include:
 - Scheme for hazard control used;
 - Volume of high risk (or SAHCODHA) food produced;
 - Comprehensive performance—in addition to hazard control based on risk management audits, compliance with other managements systems (such as meeting product deadlines, turnover of workforce, etc.); and
 - Change in scope of what the foreign supplier is producing, and/or how they are producing—has their plant changed physically? Are they producing different products?

Following discussion of various ideas for improving upon the two options highlighted in the proposed rule, an alternative approach emerged that combines elements of each was developed and is outlined below:

- An annual on-site audit is the “default” approach to verification of control of SAHCODHA risks.
 - There was discussion about SAHCODHA, in particular the need for better clarity around the term and the universe of foods included.
 - Alternative approaches to an audit could be used if:
 - The approach is validated as being able to provide adequate assurance that the hazards are being controlled; and
 - There is some method of verification that the approach is being deployed effectively.
 - Alternative approaches discussed briefly included:
 - Testing and sampling, i.e., end-product testing with a sampling plan with probability of detection at a certain defect rate;
 - Validated intervention to control hazard with “real- time” verification data at critical control points; and/or
 - Performance track record, i.e., history of supplier as compliant/effectively controls hazards, internal processes/management benchmarks reinforce control systems.
 - Alternative frequencies for a required annual audit i.e., the default approach, could be established:
 - More frequently than annual if the hazard is deemed to require more regular review due to history of hazard control, high volume of production, and therefore exposure; a new facility producing a very high-risk food; or other possible criteria (*requires more development*); and/or

- Less frequently than annual if the hazard is deemed to require less regular review, due to history of control, low volume of production, and therefore exposure; establishment of validated process that controls the hazard more effectively; or other possible criteria (*requires more development*).
- Audit frequency and approach for a foreign supplier may change over time depending upon factors mentioned, as well as a facility's change in scope (i.e., foods and SAHCODHA profile), food volume, type of verification scheme used, new physical plant, and comparability of regulatory system within which the entity operates (i.e., country adopting a food safety system that offers a comparable level of public health protection as that of the U.S., such as New Zealand).

While a variety of details would need to be developed to implement such an alternative option, many of the participants thought it represented a step forward and drew on many of the positive aspects of each of the options in the proposed FSVP rule while addressing some of the disadvantages.

Identification and Responsibilities of an Importing Entity

Joan Menke-Schaenzer, Chief Quality Officer, ConAgra and Cindy Jiang, Senior Director Worldwide Quality Systems, Food Safety, and Nutrition, McDonalds, initiated the discussion around possible criteria or means of determining the responsible importing entity in regards to FSVP requirements.

Ms. Menke-Schaenzer reiterated participant comments that there needs to be greater input from small importers. In ConAgra's experience, much of their products are bought from importers rather than directly from foreign suppliers. She stressed that the proposed regulations may ultimately impact the overall landscape of food imports—and that it is not known how these regulations will impact transactional brokers.

FDA representatives noted that the intent is to have an entity in the U.S. at the time of importation who is responsible for verifying hazard control by the foreign supplier and understanding what the supply chain characteristics should be for that food.

Ms. Jiang concurred that more small importers should have a voice in the process and suggested additional outreach is very important to successful development and implementation of the FSVP. She also addressed the concern about duplication or proliferation of verification efforts. In some industry examples, the company requires their own audit process at the supplier level. Some discussion highlighted examples where efficiencies could be built into the system. For example, GFSI audits could be used to fulfill FSVP requirements. If separate and distinct verification is required, small importers may not be able to afford multiple audits. This point was a good lead into the next topic.

"Very Small" Importers

Donna Garren, Vice President, Regulatory Affairs, American Frozen Foods Institute (AFFI) and Benjamin England, Founder & CEO, Benjamin L. England & Associates, LLC and FDAImports.com, provided an overview and commentary on the requirements for very small entities under FSVP. FSVP provides for modified requirements for those designated as “very small” importers (VS-I) or importers from very small foreign suppliers (VS-FS).

Ms. Garren suggested FDA revise the definition of “foreign supplier” so that supplier verification is only needed for the entity one step back in the supply chain because, as currently proposed, this requirement exceeds FDA’s legal authority for traceability. Ultimately, she noted, AFFI disagrees with the proposed modified requirements for VS-FS and VSI because, among other reasons, it is not justified as a risk-based approach. Risk, as she framed it, does not discriminate based on size of business. She also recommended that additional time be given for smaller entities to come into compliance with the regulations to allow for additional outreach and capacity building to be done.

For more information, Ms. Garren’s slides can be found [here](#).

Benjamin England, Founder & CEO, Benjamin L. England & Associates, LLC and FDAImports.com, LLC, provided comments on the proposed FSVP rule through the lens of “very small” importers.

In the currently proposed provisions, “Very small” is defined as:

“...including any subsidiary, affiliate, subsidiaries or affiliates, collectively, of any entity of which the [VS-I or VS-FS] is a subsidiary or affiliate, whose average annual monetary value of sales [not profits] during the previous 3 years (on a rolling basis) is no more than \$500,000, adjusted for inflation.” Based on Mr. England’s analysis, the number of importers included within this definition is quite high.

Mr. England suggested that the proposed modified provisions could be implemented by those designated as VS-I or VS-FS, and these standards could serve as a “floor.” He also suggested combining FSVP with the Voluntary Qualified Importer Program (VQIP) in such a way as to catalyze not only meeting the modified provisions, but moving more rapidly to compliance with the provisions for all other importers and foreign suppliers.

Additional discussion focused on the qualifications for being a VS-I or VS-FS – the \$500,000 sales mark — and whether or not the analysis included sales from non-imported foods as well.

Alignment of FSVP with Preventive Controls and Produce Safety Requirements

Several industry representatives began the conversation of alignment of FSVP and other proposed requirements under FSMA by providing examples of potential challenges, along with ideas for addressing those challenges.

Mike Robach, Vice President, Corporate Food Safety and Regulatory Affairs, Cargill discussed the alignment of FSVP with the Preventive Controls requirements, as a necessity to avoid

duplicative and costly requirements that do not improve food safety or public health. He emphasized the need for additional harmonization between global and domestic standards. In so doing, there should be less technical barriers to trade. Mr. Robach also urged FDA to work within the confines of the Codex Alimentarius and the WTO in order to ensure that all regulations are consistent with international, science-based standards.

Tom O'Brien, Washington Representative, Produce Marketing Association highlighted his concerns with alignment as well, and again cautioned about issues with WTO agreements. He suggested that produce farms have food safety plans so that they can internalize and see where the risks are and then address them accordingly. While he feels the proposed rules are aligned, he thinks it is the responsibility of the industry to identify the risks—an enormous change for importers, particularly for brokers. This rule along with recent outbreaks has caused them to think about their role in the supply chain and their liability. Mr. O'Brien suggested that moving towards compliance with the FSVP requirements will be a big, first step. However, FSVP compliance does not allow for brokers to fully internalize all the requirements they will face under FSMA implementation. He also noted that there is going to be enormous pressure on FDA to recognize comparable systems in countries sending a lot of produce into the U.S. This potentially puts FDA in a very challenging position to evaluate the strength of another country's system and, particularly if a substantial trading partner, any trade repercussions if their system is not found comparable.

Will Daniels, Senior Vice President, Quality, Food Safety, and Organic Integrity, Earthbound Farm, emphasized that many industry leaders are already managing to comply with requirements similar to those proposed for FSVP, as part of the Preventive Controls proposed rule, and the proposed Produce Safety standards, but encouraged FDA to find points where these programs could be complementary and integrated. He also agreed with Mr. Yiannas's notion that the food safety/hazard control management system must be validated in addition to being verified. In addition, guidance for FSVP should include clear pathways for alternative routes for compliance with requirements, as is proposed for the Produce Safety rule.

There was additional discussion around clearly defining the “foreign supplier,” and thus the party whose hazard control activities the importer must verify. Sometimes it is unclear as to who is responsible for the last significant processing step (i.e., the consolidator, distributor, or other party), and thus who should be responsible for controlling the hazard. The emphasis should be placed on looking at the point in the supply chain in which some sort of impact on the product occurs, along with its associated risk while within the entity's possession. For example, apples could come from a packing plant where they have been washed in a hot bath—this would be the last significant step in the processing where risk could be affected. Some participants suggested breaking down levels of suppliers according to their order in the supply chain and then assigning more or less prescriptive requirements based on those levels.

Outcomes and Next Steps

The outcomes from this CFSF session is a full summary (this document), as well as a key themes document.

A potential next step identified by participants would be to hold a webinar with small importers. However, given the upcoming deadline on comments to the Docket, this might not be possible.

As mentioned in the meeting goals, the purpose of this discussion was to exchange information and ideas on specific aspects of the FSVP rule.

As a reminder, participants who submit comments to the docket may draw on information or insights from the meeting deliberations, however, statements should not be attributed to specific people/presentations at the meeting, and ideas should not be represented as consensus.