FOCUS ON STRATEGIC IMPLEMENTATION OF PREVENTION-ORIENTED IMPORT SAFETY PROGRAMS

FDA FSMA Regional Outreach Meetings Report

FDA Office of Foods and Veterinary Medicine (OFVM)
Strategic Communications and Public Engagement (SCOPE)

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Regional Outreach Meetings

Introduction:

The FDA held three one-day public meetings in strategic regions (California, Michigan and New Jersey) to provide importers and other interested persons an opportunity for in-depth discussions on the implementation of import safety programs under the FDA Food Safety Modernization Act (FSMA), including the Foreign Supplier Verification Programs (FSVPs), Accredited Third-Party Certification, and the Voluntary Qualified Importer Program (VQIP). Using professional facilitators at each regional meeting, the FDA invited the public to participate in a structured dialogue designed to assess the state of importer readiness, elicit feedback, ideas, and comments regarding FSMA programs, and identify training and outreach ideas that could be helpful in expediting industry compliance with FSVP requirements.

Key Goals & Objectives:

Before the meetings took place, OFVM's Strategic Communication and Public Engagement team (SCOPE), in collaboration with the FSMA Imports team, established specific goals and objectives to ensure progress in achieving and fulfilling FDA outreach and education targets. Ultimately, the goal of the Regional Outreach Meetings was to give the public an opportunity to provide information, share experiences, and raise issues on implementation topics related to import safety. These topics include: increasing awareness and reaching the regulated community, potential partners on outreach and implementation, state of readiness, barriers to implementation, training and education for industry and regulators, guidance needs, promotion of best practices, technical assistance, compliance and enforcement issues, and long-term FSMA implementation success.

SCOPE and the imports team also worked to accomplish the following objectives:

- Develop long-term partnerships with key import community stakeholders who could serve as catalysts for regional and national networking and relationship building.
- Identify leading partners to help foster understanding of final rules and guidance, and support regulated industry's compliance with FSMA regulation.
- Gain a better understanding of industry's current status with the implementation process, and identify any concerns or recommendations where the FDA may be able to provide assistance.
- Increase understanding among stakeholders of FDA's implementation plans and solicit their input and feedback.
- Generate a spirit of shared ownership of FSMA implementation among the regulated community and increase awareness of available support networks and resources.

The regional meetings were held in Costa Mesa, California, Rutherford, New Jersey, and Detroit, Michigan. They were structured to first provide information on the FSMA requirements and then transition into facilitated discussions of three topics: the state of the import industry, VQIP, and education/outreach. This report highlights and summarizes the main feedback from participants and findings from the facilitated sessions.

Section 1 – Summary Report for Facilitated Session #1

The first facilitated session at each regional meeting focused on identifying the current state of import food safety methods, the state of industry FSVP readiness, challenges to meeting FSVP requirements, potential solutions for overcoming those challenges, and potential training ideas that would be helpful to industry. During this session, facilitators led small groups through activities and discussions in response to the following questions:

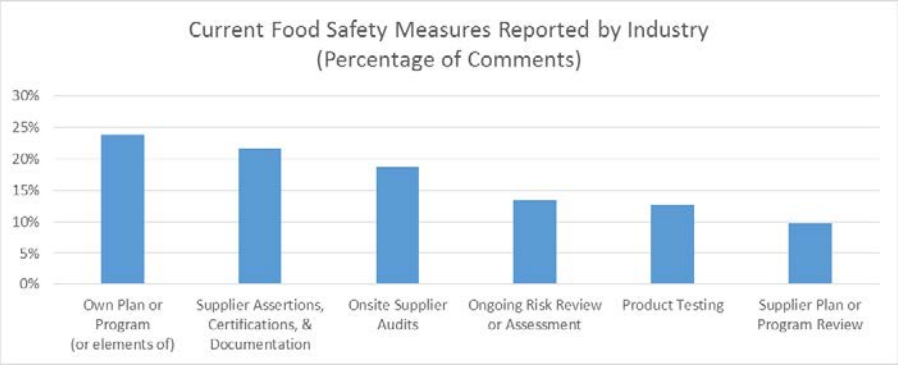
Q1: How do you currently verify the safety of the food you import?
Q2: How ready are importers to comply with FSVP requirements?
Q3: What are the challenges in meeting FSVP provisions, and why?
Q4: What do you recommend, or what would be helpful to overcome these challenges?
Q5: What trainings would be helpful? How do you suggest they happen?

This section of the report summarizes the major trends that emerged from discussions, identifies the prevailing themes for each question, and provides additional detail for each theme by citing the most common or insightful examples given by meeting participants.

Question 1: How Participants Currently Verify the Safety of Food Imports

Food safety verification was a familiar topic to each meeting participant, and those participating in the facilitated sessions were prepared to cite specific examples of their current food safety methods and procedures. After consolidating and reviewing all feedback provided by industry members from each of the three regional meetings, the most-cited current safety measures fell within six main themes:

1. *Own Plan or Program (or elements of)*
2. *Supplier Assertions, Certifications, and Documentation*
3. *Onsite Supplier Audits*
4. *Ongoing Risk Review or Assessment*
5. *Product Testing*
6. *Supplier Plan or Program Review*



As illustrated in the graph above, most participants indicated that they have their own plan, using some form of industry-recognized processes or methods, such as Hazard Analysis Critical Control Point (HACCP) plans, Global Food Safety Initiative (GFSI) schemes, or other food defense and food safety programs to verify the safety of food being imported into the United States. Secondly, importers indicated that they rely on assertions (import letters, letters of guarantee, etc.), certifications (Certificates of Analysis (COAs)), and other forms of documentation (supplier hazard or risk documentation) provided directly by the suppliers asserting that the food they are selling is safe. The third most cited verification activity was onsite supplier audits. Importers (large and small), brokers, and

food producers indicated that they periodically visit or engage third-party auditors to conduct audits of foreign facilities to ensure that the supplier maintains safe practices, procedures, and operations on an ongoing basis.

Though not as frequent as the first three themes, meeting participants also indicated that they perform ongoing risk reviews and assessments of the products, manufacturers, markets, and countries from which they import foods. The most common risk-monitoring activities included conducting hazard analyses, monitoring news, reviewing public records, analyzing hazard and risk data, and reviewing ingredients of their imported products on a periodic basis. Product testing came in as the fifth most-cited activity. While participants described a host of different testing techniques and methods, most testing activities came down to direct product testing, test data reviews, border inspections, and inspections upon arrival.

Finally, the practice of reviewing foreign supplier food safety plans or programs was the least-cited food safety verification activity by meeting participants. These types of activities typically occurred as part of a supplier approval program or as regularly scheduled reviews of supplier plans or supplier programs and data.

Question 2: How Ready Participants Are to Comply with FSVP Requirements

Participants were invited to reflect on their current ability to comply with each of the requirements of FSVP, using checklists that briefly summarized each of the requirements of FSVP. Participants took several minutes to indicate whether they were or were not ready to comply with each respective FSVP requirement. Though responses were generally positive across the board, when carefully reviewing the relative proportions of three different groups[1] – Food Producers, Large & Mid-Sized Importers, and Small & Mid-Sized Importers[2], subtle differences and commonalities emerged[3].

Small & Mid-Sized Importers may be less ready to comply with FSVP requirements than their Large Importer and Food Producer counterparts:

As illustrated in the chart on the following page, participants in the "Food Producer" and "Large & Mid-Sized Importers" groups who took the self-assessment were generally more ready to comply with the requirements of FSVP when compared to their counterparts in the "Small & Mid-Sized Importers" group. Though the majority of those who responded from all three groups were generally ready to comply with FSVP requirements (with 63% being the lowest weighted group average), the "Small & Mid-Sized Importers" group was comparatively less ready to comply with FSVP. It is reasonable to conclude that Small & Mid-Sized Importers may benefit from additional support, education, outreach, etc. to ensure industry-wide FSVP compliance.

Industry may benefit from support with how to develop, maintain, and follow FSVPs, how to identify and manage exemptions and modified requirements in the FSVP rules and regulations, and guidance showing under what circumstances risk re-evaluations might be necessary:

Differences aside, participants who volunteered to respond to the self-assessment demonstrated a comparative lack of readiness in the same four areas, regardless the size of their business or whether they were a Food Producer or Importer.

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[1] Groups were formed and maintained informally using participant-defined demographics. Groups were not meant to be rigidly defined and group findings were not meant to be statistically relevant. For our purposes, general trend identification was sufficient.

[2] To keep group sizes manageable, participants who indicated that they represented a "Mid-Sized" business were split between the "Large" and "Small" business groups, respectively.

[3] For each regional outreach meeting, there was a fourth group, "Other". This group typically included industry association, embassy, and foreign representatives, insurance brokers, and other organizations that are impacted by FSVP.

The first area where participants reported that they were least ready across all groups was requirement 7 on the readiness checklist, the requirement to develop, maintain, and follow an FSVP for each food brought into the United States for each foreign supplier of that food. Aggregating responses from all three regional outreach meetings, only 50% of those who took the self-assessments indicated they were ready to prepare and maintain an FSVP for each food for each foreign supplier.

ID	Requirement Readiness Checklist	Food Producers	Large & Mid-Sized Importers	Small & Mid-Sized Importers	Average
1	Conduct a hazard analysis to determine known or reasonably foreseeable hazards with each food you import	88%	88%	73%	**83%**
2	Evaluate risk posed by a food, based on a hazard analysis, and foreign supplier performance	85%	84%	67%	**78%**
3	Approve suppliers and determine appropriate supplier verification activities based on above	91%	80%	61%	**77%**
4	Conduct supplier verification activities	85%	75%	61%	**74%**
5	Conduct corrective actions (When you determine your foreign supplier is producing food you import that does not provide the same public health protection as required under the Federal Food Drug and Cosmetic Act)	88%	84%	65%	**79%**
6	Establish and follow written procedures to ensure foods are imported from verified and approved foreign suppliers based on the above	85%	77%	69%	**77%**
7	Develop, maintain, and follow an FSVP for each food brought into the United States for each foreign supplier of that food	58%	48%	45%	**50%**
8	**If a manufacturer/processor as well as an importer…**				
	8A: Comply with the supply-chain program requirements under the preventive controls rules (means a separate FSVP is not needed)	83%	74%	71%	**76%**
	8B: Implement preventive controls for the hazards in the food in accordance with the requirements in the preventive controls rules	96%	78%	65%	**80%**
	8C: Aware of exemptions and modified requirements: food could not be consumed without application of a preventive control, or when the importer and/or the importer's customer significantly minimizes hazards themselves and package complies with requirements for disclosures and written assurances	39%	70%	65%	**58%**
9	Re-evaluate risk posed by the imported food and the supplier's performance at least every three years or when new information comes to light about a potential hazard or the foreign supplier's performance	67%	77%	57%	**67%**
10	**Aware of exemptions and modified requirements:** not required to do the above if the importer receives adequate assurances that a subsequent entity in the distribution chain is processing the food for food safety in accordance with applicable requirements. In this case, importers must disclose in documents accompanying the food that the food is not processed to control the identified hazard	70%	50%	57%	**59%**
	Average	**78%**	**74%**	**63%**	

The second and third areas where participants reported that they were the least ready across all groups were requirements 8C and 10 on the readiness checklist, the requirements to know what to do in cases of exemptions and modified requirements where FSVP assurances are made in other phases of the supply chain or food production process. For each requirement, 8C and 10, only 58% and 59% respectively indicated they were aware of exemptions and modified requirements of FSVP and knew how to respond in an appropriate manner.

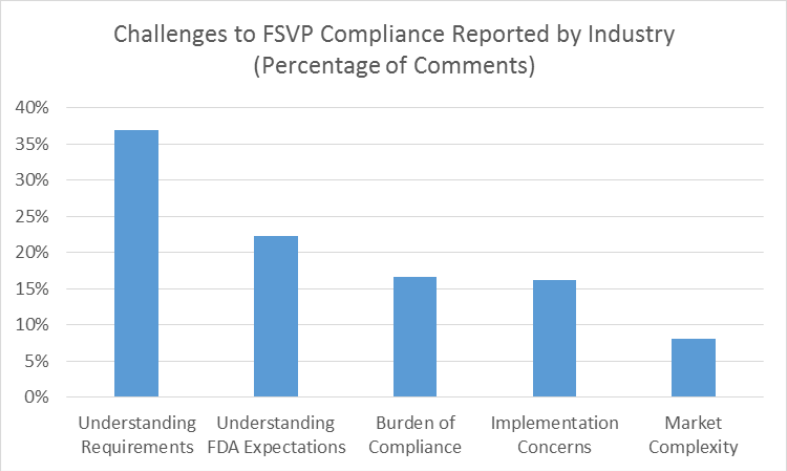
Finally, the fourth area where participants reported that they were least ready across all groups was requirement 9 on the readiness checklist, the requirement to re-evaluate risk posed by the imported food and the supplier's performance at least every three years or when new information comes to light about a potential hazard or the foreign supplier's performance. Aggregating responses from all three meetings, only 67% of those who took the self-assessments indicated they were ready to do so.

There was only one area in which participants demonstrated confidence across all of industry, and that was requirement 1, the requirement to conduct a hazard analysis to determine known or reasonably foreseeable hazards with each food imported.

Question 3: Challenges to Meeting FSVP Requirements

Having walked through each of the requirements of FSVP, participants were better prepared to discuss challenges they face or anticipated facing while attempting to meet each specific FSVP requirement. After consolidating and reviewing all feedback provided by industry members from each meeting, the most-cited challenges fell within five main themes:

1. *Understanding Requirements*
2. *Understanding FDA Expectations*
3. *Burden of Compliance*
4. *Implementation Concerns*
5. *Market Complexity*



As illustrated in the graph above, most participants indicated that they need an increased understanding of FSVP requirements to be able to comply fully. The “Understanding Requirements” theme was an eclectic mix of challenges, ranging from importers unsure how to identify the importer of record, importers unsure who could perform hazard analyses and how they must be conducted, participants unclear whether FSVP is truly required for every product, and many other nuanced challenges with each requirement of FSVP.

Participants also expressed a need to better understand FDA expectations with respect to FSVP readiness and compliance. Hesitant to rely solely on their own interpretations of the law, participants expressed challenges with knowing how much verification and hazard analysis activity was necessary, how much and how long records-keeping activities were necessary, how frequently verification activities must to occur, and many other challenges related to understanding the scope of the FDA’s expectations.

The third most common theme was the burden of compliance itself. Though participants expressed that they are generally willing and eager to comply with FSVP requirements, there are some challenges that are out of their control. Challenges considered to fall heavily on importers include: educating foreign suppliers, combating misinformation, working with documents in different languages, having to overcome language barriers, and working as smaller businesses typically under-resourced and unable to dedicate complete resources to fulfilling the requirements of FSVP.

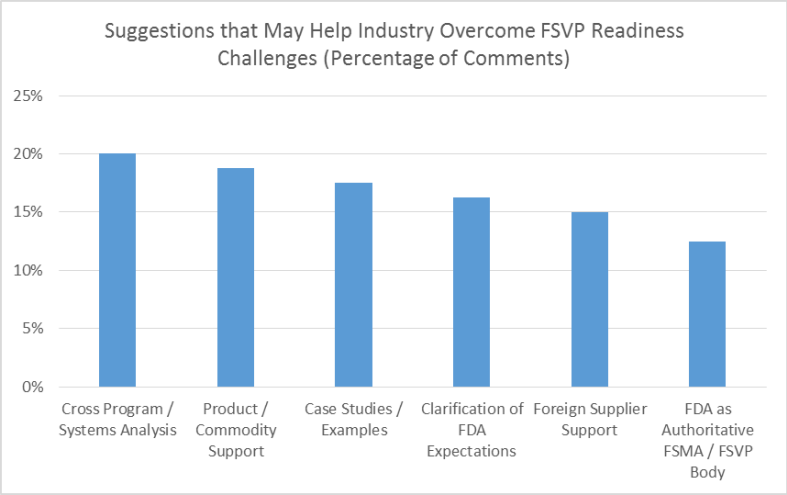
Implementation (or enforcement) concerns also emerged from the analysis of comments. Despite industry efforts to assess and determine compliance activities, FDA enforcement plans and decisions will inevitably impact industry compliance plans and activities in months and years to come. In response to this, participants identified some challenges in "what if" fashion, anticipating changes, gaps, and shifting priorities as the FDA moves from education to enforcement. Participants stated that these anticipated challenges may prevent or slow down industry's ability to make meaningful FSVP compliance decisions for their organizations.

Finally, the fifth theme that emerged was the theme of market complexity. No matter how much effort industry members and the FDA invest into making FSMA and FSVP implementation a success, participants stated that there will remain a degree of market complexity that inherently makes full FSVP compliance challenging. Specific multi-use ingredients, large multi-product shipments, depth of supply chain enforcement, and the wide range of possible foreign supplier operations will likely benefit from FDA and industry communicating often and openly to continue to refine a shared understanding of FSVP implementation.

Question 4: Recommendations to Overcome Challenges to Meeting FSVP Requirements

Reflecting on and responding to the challenges they identified in the previous question, industry participants were then invited to brainstorm suggestions, solutions, and recommendations to overcome those challenges. The most-cited and specific recommendations to overcome challenges to meeting FSVP requirements fell within six main themes:

1. *Cross Program / Systems Analysis*
2. *Product / Commodity Support*
3. *Case Studies / Examples*
4. *Clarification of FDA Expectations*
5. *Foreign Supplier Support*
6. *FDA as Authoritative FSMA / FSVP Body*



As illustrated in the graph above, most participants expressed interest in seeing or participating in the creation of comparative analyses of existing programs, plans, and schemes (such as GFSI) to provide industry with a better understanding of what, specifically, they need to do in order to comply with FSMA and FSVP requirements. As was noted in the responses to question one in this section, the idea of food safety verification activities is not new to the importer, broker, and food producer communities. If a sufficiently large portion of the industry already ascribes to existing food safety programs, cross-

program analyses may bring gains in efficiencies for both the FDA and industry when implementing FSVP.

The second theme, product and commodity support, is the consolidation of comments and suggestions related to the FDA targeting its support materials – including guidances, trainings, webinars, web pages, checklists, template, and other content -- by product, sector, or commodity. Though the FDA is likely insufficiently resourced to assemble content in this manner on behalf of each industry sector, perhaps industry representatives and associations could invest the time and resources necessary to produce this content and then work in partnership with the FDA to verify that it will satisfy FSVP requirements.

The third most common theme was case studies and examples. In comments consolidated under this theme, industry members expressed that they are ready to have advanced discussions around scenarios, examples of what a "model" FSVP scenario might look like, and some samples of documents or templates that are representative of what the FDA might accept for FSVP compliance activities. An opportunity such as this would allow for industry members to abstract program and requirement elements relevant to them, despite the fact that the scenario might be for an industry different from their own.

As was discussed in the second theme that emerged in response to question three, the theme of clarifying FDA expectations reemerged in recommendations for overcoming challenges to complying with FSVP. Hesitant to rely solely on their own interpretations of the law, participants noted that it would be very helpful to know how much verification and hazard analysis activity is necessary, how much and how long records keeping activities are necessary, how frequently verification activities must occur, and many other items related to understanding the scope of the FDA's expectations.

Next, the fifth theme was foreign supplier support. In this theme, industry participants indicated that it would be very helpful if the burden of educating foreign suppliers was shared between the FDA and the regulated industry. Simplified education materials that could easily be translated into other languages, multi-lingual translations of FDA's FSMA website, supporting documents (checklists, guidance, etc.), and education materials that importers can give to their suppliers are examples of the types of supplier education that industry would find beneficial.

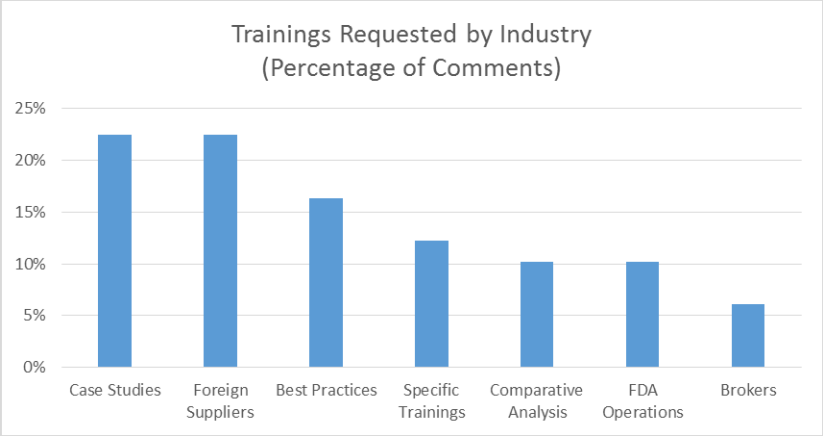
Finally, the sixth theme was the idea of the FDA serving as the authoritative body regarding credible FSVP trainings, auditors, and public-private partnerships. It is generally understood that the FDA is purposefully providing industry with the flexibility it needs to ensure that industry members have the freedom to choose whichever compliance activities make sense for their unique operations. Despite that flexibility, industry members indicated that it will be challenging to identify which FSVP trainings offered by the market are credible and will help companies achieve compliance with FSVP regulations and meet FDA expectations and standards.

Question 5: Trainings That Would be Helpful for Industry Participants

Industry members were asked to identify any training ideas that they believe would be helpful, not only for themselves, but for the entire industry community. After consolidating and reviewing all feedback from each of the three regional meetings, the most requested trainings for industry members to assist in complying with FSVP requirements fell within seven main themes:

1. *Case Studies*
2. *Foreign Suppliers*
3. *Best Practices*
4. *Specific Trainings*

5. *Comparative Analysis*
6. *FDA Operations*
7. *Brokers*



Rather than address each training section by theme, this section will provide the comprehensive list of consolidated training activities recommended by industry members. The complete list combines like-trainings suggested by industry members across all three regional outreach meetings. To see the complete list of trainings, please refer to the chart below:

Suggested Training Topic	Category
Auditing Best Practices	Best Practices
Food Risk Assignment Best Practices	Best Practices
Hazard Analysis Best Practices	Best Practices
Record Keeping & Maintenance Best Practices	Best Practices
Supplier Verification Activities Best Practices	Best Practices
Broker Food Safety	Brokers
Food Safety Modernization Act (FSMA) Train the Trainer for Brokers	Brokers
Examples of Different Scenarios with Discussion and Explanation	Case Study
Foreign Supplier Verification Programs (FSVP) Importer Identification Training and Status Determination Using Examples and Decision Trees	Case Study
Identifying the Responsible Party & Required Credentials	Case Study
Model Foreign Supplier Verification Programs (FSVP) Compliant Company Training	Case Study
Training / Standard with Products Expectations by Industry and Country	Case Study
Certification or Train the Trainer Courses for Foreign Supplier Verification Programs (FSVP) & Preventive Controls Qualified Individual (PCQI)	Comparison
Comparative Analysis and Training for European Union and Other Market Compliance vs. FDA	Comparison
Training on Exemptions Relative to Hazard Analysis Critical Control Point (HACCP) and USDA Whether Documentation Verification is Needed	Comparison
Educating Foreign Suppliers on Expectations, with Guidance Materials	Foreign Supplier
Food Safety Preventive Controls Alliance (FSPCA) Qualified Individual Program: Make a Webinar Program to Show Foreign Suppliers	Foreign Supplier
Train the Trainer for Foreign Supplier Verification Programs (FSVP) Requirements of Foreign Suppliers	Foreign Supplier
Damage Control (When it Goes Bad)	Operations
How to Get Off the Detention Without Physical Examination (DWPE) List	Operations
Training on FDA's Enforcement Plan	Operations
Training on How inspections will be Conducted	Operations
How to Avoid and Respond to FDA 483 Letters, What to Include in an Inspection Program	Specific
International Food Protection Training Institute (IFPTI) Webinars	Specific
Training on Supplier Approval and Verification Program (Part 117, New Subpart G) and the Relationship Between Supply Chain and Foreign Supplier Verification Programs (FSVP)	Specific
What Foods pose serious adverse health consequences or death (“SAHCODA”)?	Specific

Each of the trainings above could be delivered either in-person or via webinar. Recorded webinars are likely to produce the most repeat value for FDA, allowing participants to watch at their convenience.

Section 2 – Summary Report for Facilitated Session #2

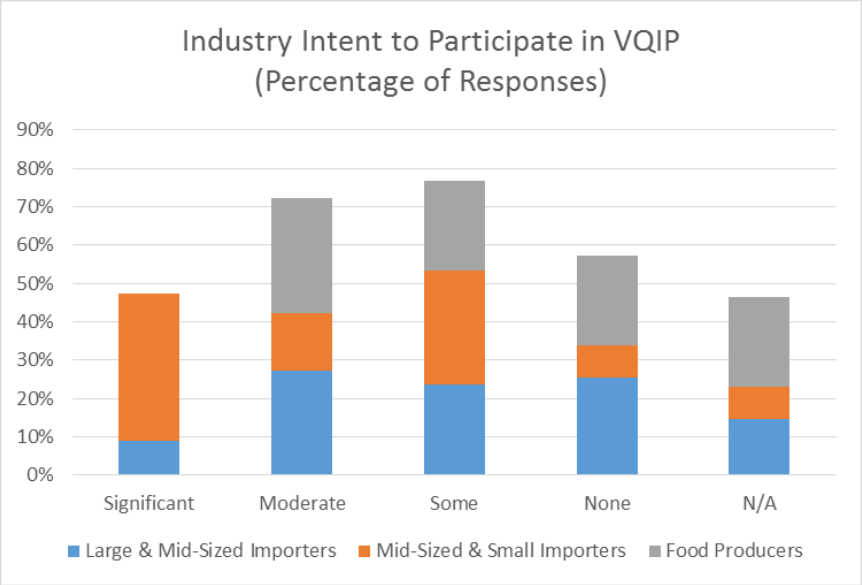
The second facilitated session for each regional meeting focused on the interest level, hesitations, motivations, and information gaps around industry members' desire to participate in the Voluntary Qualified Importer Program (VQIP). During this session, facilitators led small groups through activities and discussions in response to the following questions:

Q1: How interested are industry members in VQIP? How likely are you to participate?
Q2: What hesitations do you have when thinking about participating in VQIP?
Q3: What motivates you to want to participate in VQIP?
Q4: What more would you need to know about VQIP to consider participation?

This section of the report summarizes the major trends that emerged from discussions, identifies the main prevailing themes for each question, and provides additional detail for each theme by citing the most common or insightful examples indicated by meeting participants.

Question 1: Industry Members' Intent to Participate in VQIP

To assess the interest in VQIP participation, facilitators took a quick poll at the beginning of the session. Participants were asked, by a show of hands, to indicate their intentions using the simple scale indicated in the chart below. After consolidating the results from all three regional outreach meetings and clearly plotting the preferences for each of the different groups[4] – Food Producers, Large & Mid-Sized Importers, and Mid-Sized & Small Importers[5], it appears that the average industry member demonstrates at least some intent to participate in VQIP.



Looking closely at the relative proportions of the three groups noted above, however, it was the Mid-Sized & Small Importers group that indicated a comparatively stronger intent to participate in VQIP. For this question, it is possible that the data could have been impacted by either different facilitator

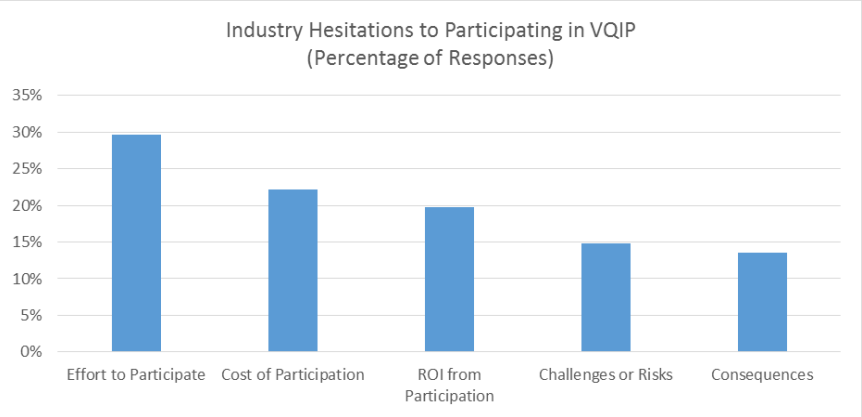
[4] For each regional outreach meeting, there was a fourth group, "Other", however, this group typically included industry association, embassy, and foreign representatives, insurance brokers, and other organizations that did not import foods and were unlikely to participate in VQIP.
[5] To keep group sizes manageable, participants who indicated that they represented a "Mid-Sized" business were divided and split between the "Large" and "Small" business groups, respectively.

personalities, or by the VQIP Program Manager working directly with the Small & Mid-Sized Importers groups, allowing opportunities for additional discussion of VQIP's benefits prior to industry members indicating their intentions. Because of these possibilities, it is best to focus solely on the distribution of the data and to avoid any specific insights about the populations of each group.

Question 2: Industry Members' Hesitations to Participating in VQIP

Facilitators invited participants to share their hesitations (if any) about participating in VQIP based on the information they had about the program at that time. After consolidating and reviewing all feedback provided by industry members from each of the three regional meetings, the most-cited hesitations fell within five main themes:

1. *Effort to Participate*
2. *Cost of Participation*
3. *Return on Investment (ROI) from Participation*
4. *Challenges or Risks*
5. *Consequences*



As illustrated in the above, most participants expressed hesitations based on the effort that may be required to apply for participation in the program. Participants noted that if the process is complicated, complex, and unnecessary, and requires more work, more paperwork, and a burdensome level of time commitment to complete all required activities, they would be hesitant to participate.

The second theme, cost of participation, was not only the consolidation of concerns or hesitations related to initial sign-up or application fees, but it includes potential additional costs to maintain participation in the program. Additionally, those in the Mid-Sized & Small Importers group expressed concerns that without a tiered fee structure to account for different business sizes, most small business would likely not be able to afford to participate in VQIP.

The third most common theme of hesitations was uncertainty around ROI. After consolidating comments and feedback, it became apparent that ROI deserved its own theme separate from cost. While some industry members are most concerned about whether they can afford to participate, there are others more focused on the benefits of participating and whether those benefits outweigh the costs.

The fourth most common theme of hesitations was the possibility that there may be unforeseen challenges or risks inherent in the program that have not yet been addressed or explained by the FDA. For example, VQIP requires that a foreign supplier's facility be certified after a regulatory audit that establishes whether the facility complies with applicable food safety requirements. Some industry participants noted that the program may be constrained by the number of auditors that will be

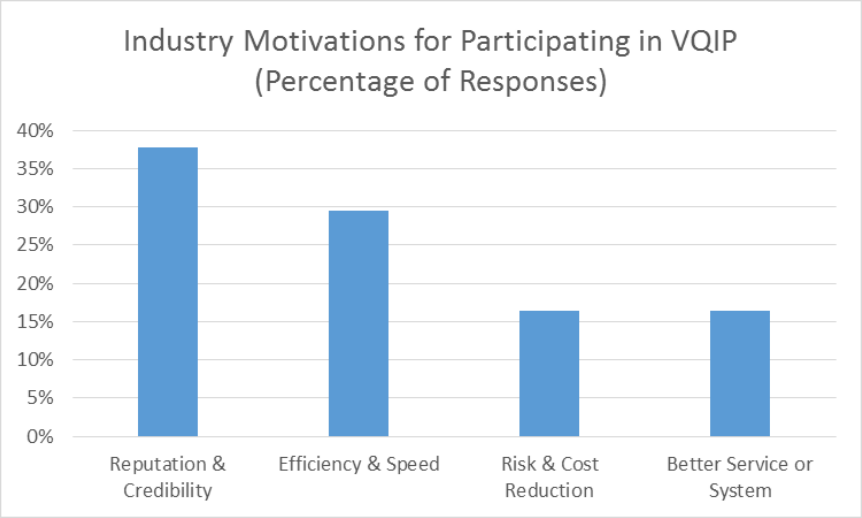
accredited under FDA's Accredited Third-Party Certification rule and that accredited auditors may be hard to find, or may be expensive to work with, especially when in high demand. They fear that their VQIP investment could be impacted by poor foreign supplier performance. For example, it is possible that the supplier could reject audits, or could fail to abide by agreements to ensure that safe food practices are in place, putting the importer's reputation on the line.

Finally, the fifth theme was the theme of consequences, or unintended consequences. Industry participants indicated that by signing up to be evaluated by the FDA to participate in the VQIP program, the importer could be vulnerable with regard to the FDA if unsuccessful in the application process. Additionally, if an importer decided that VQIP was no longer worth the financial investment for their business, some importers were curious to know if there would be any potential hidden consequences to their reputation with the FDA after withdrawing from the program.

Question 3: Industry Members' Motivations for Participating in VQIP

Building on the increased understanding of industry member's perceptions about VQIP, the conversation shifted away from hesitations to industry members' motivations for participating in VQIP. After consolidating and reviewing all feedback provided by industry members from each of the three regional meetings, the most-cited motivations for participating in VQIP fell within four main themes:

1. *Reputation & Credibility*
2. *Efficiency & Speed*
3. *Risk & Cost Reduction*
4. *Better Service or System*



As illustrated in the graph above, most importers noted that it was the boost in reputation and credibility in the eyes of their customers and the FDA that appealed to them most. Some importers noted that because they would be seen as more credible in the market, they could receive boosts in supplier and customer confidence, giving them a competitive advantage over their competitors.

The second theme, efficiency and speed, also appealed greatly to importers looking to gain additional competitive edges in the market. Promising fewer compliance issues, expedited clearances and streamlined entry into the United States, and fewer, faster exams, VQIP could be a wise investment for firms able to meet the requirements and recoup the costs of participation.

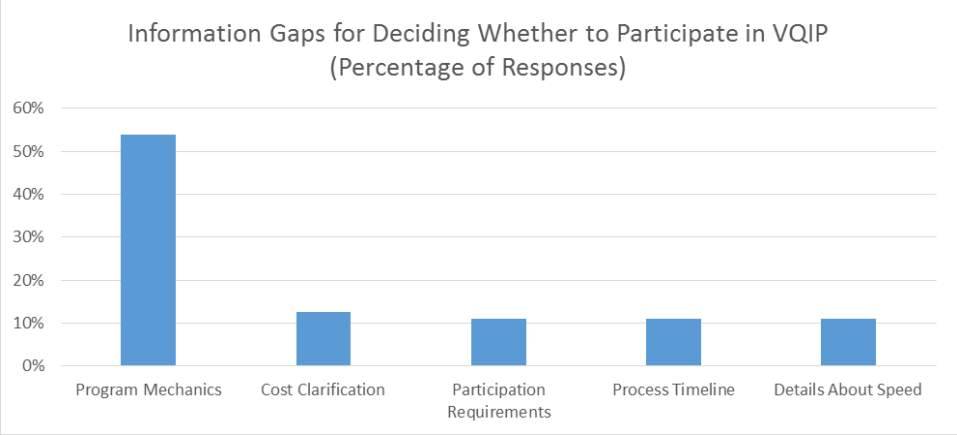
The third most common theme of motivations was the potential to see long-run reductions of risk and cost that come with a reduction in FDA sampling and delays and an overall reduction in disruptions to the supply chain. Though these types of reductions could be challenging for importers to benchmark and quantify, they were nonetheless appealing to the importer community.

Finally, the fourth theme was the possibility of realizing the intrinsic benefits of being part of a better food safety system, offering better service or experiences to customers. Some importers noted that by participating in VQIP, importers will be keeping ahead of global trends in improved food safety and will be inherently rewarded for choosing to implement good business standards and practices.

Question 4: Information Gaps between VQIP and Importers

Facilitators worked with meeting participants to identify any information gaps that prevent them from deciding whether participation would be right for them or their organization. The most-cited information gaps for the VQIP program fell within five main themes as follows:

1. *Program Mechanics*
2. *Cost Clarification*
3. *Participation Requirements*
4. *Process Timeline*
5. *Details About Speed*



Of the five themes listed above, program mechanics and details about speed are ones that require further explanation. The other three, cost clarification, participation requirements, and process timeline are simply reflective of industry members' desire for clarification around those three specific topics.

For the theme of program mechanics, importers asked a wide variety of questions about how VQIP will work, specifically. How will renewals work when it's time for importers and suppliers to renew their registrations? What happens when importers want to add a new foreign supplier? How about a new product from an existing foreign supplier? How will VQIP work with other border control agencies? Is it possible to retain certifications for more than a year? Will VQIP participants be listed on the FDA dashboard? How will auditing work in VQIP? Can the public know if an importer or supplier has been removed from VQIP? The program is new, and there is still much to be decided about its operations, but industry members were ready to know more about how the program would work at the operational and tactical levels as they consider participation.

Finally, the last theme was around details about speed. Because increased efficiency and speed were the only thematic motivations within the FDA's control and ability to influence, many importers and

industry members had questions regarding just how that would work exactly. When FDA says expedited, just how expedited would that be? How much faster would a VQIP member's products cross the border? Does this imply that non-VQIP members' imports would be slowed down? Would the FDA prioritize VQIP participants over non-VQIP participants? Answers to these types of questions would likely impact an importer's impressions of the ROI available to them through VQIP, and could be the deciding factor on whether to participate at all.

Section 3 – Summary Report for Facilitated Session #3

The third facilitated session for each regional location focused on information sharing among industry members, best practices, and suggested outreach efforts to engage with populations who have not yet heard about FSMA. During this session, facilitators led small groups through activities and discussions in response to the following questions:

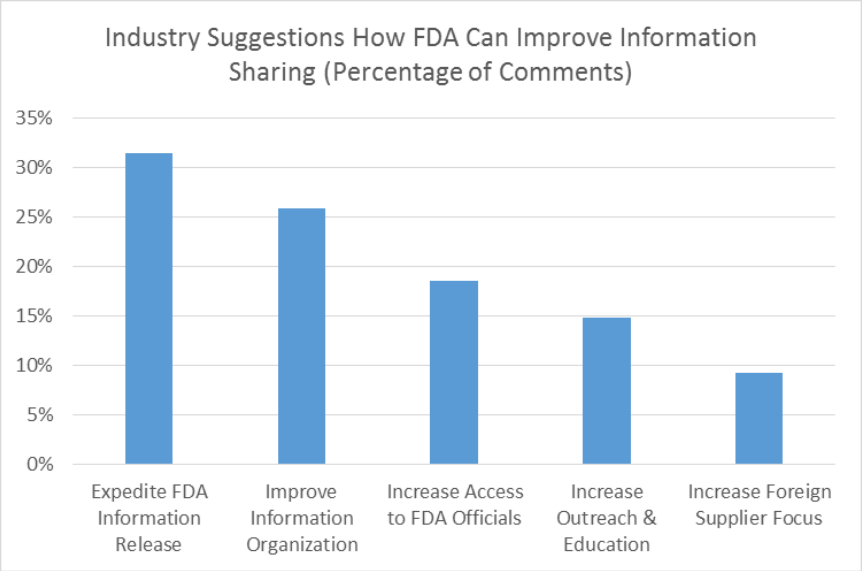
Q1: What can the FDA do to share more helpful information with you?
Q2: What information have you found helpful from industry associations?
Q3: What information do you share with other fellow industry members?
Q4: What can FDA do to reach industry members who do not know about FSMA or aren't aware that this is happening? What can industry do to help FDA reach them?

This section of the report summarizes the major trends that emerged from discussions, identifies the main prevailing themes for each question, and provides additional detail for each theme by citing the most common or insightful examples indicated by meeting participants.

Question 1: How FDA Can Share More Helpful Information

The FDA has established a reputation for being proactive with its outreach and education efforts among the regulated community. Continuing to build upon and reinforce that tradition, the FDA sought feedback from industry during the facilitated sessions to learn how it could share more helpful information regarding FSMA with the regulated community. After consolidating and reviewing all feedback provided by industry members from each of the three regional meetings, the most-cited ways the FDA could improve its information-sharing practices fell within five main themes:

1. *Expedite FDA Information Release*
2. *Improve Information Organization*
3. *Increase Access to FDA Officials*
4. *Increase Outreach & Education*
5. *Increase Foreign Supplier Focus*



As illustrated in the graph above, most industry members noted that any incremental gains in the ability to release information more quickly would be very helpful. This included items such as updates to the

FAQs, increased response rates from the Technical Assistance Network (TAN), the release of FSMA, specifically FSVP, guidances as soon as possible, and the development of tools, templates, and trainings that industry could use to comply with FSVP.

Industry members also expressed a desire for increased organization, clarity, and consolidation of information made available to the public. Many industry members requested that the FDA organize its information by industry sector or commodity group in an effort to mirror the way in which industry organizes itself. Industry members also requested that FDA provide plain language, user-friendly, and searchable information wherever possible.

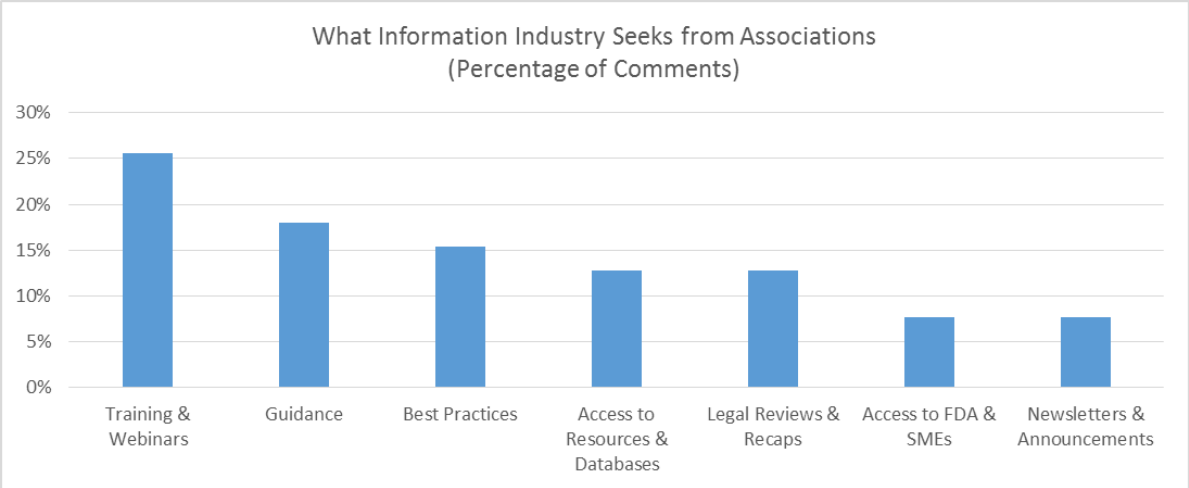
The third most common theme was a request for increased access to FDA officials. Industry members noted that even though the TAN was helpful when it was responsive and thorough, there was still a desire to be able to access FDA officials directly for questions that could easily be answered if industry knew exactly where to go or who to go to. Increased access to local officers, contact lists with noted areas of expertise, and live chat features would be helpful to industry in getting questions answered in a timely manner.

Because industry found the regional outreach meetings and facilitated sessions quite helpful, participants noted a desire to have more outreach and education opportunities available to them. These types of opportunities help industry members keep up with evolving FSMA requirements, allow them to participate in upcoming webinars, and benefit from joint training opportunities with industry associations.

Finally, the fifth theme was increased foreign supplier focus. Industry participants indicated that it would be very helpful if the burden of educating foreign suppliers was shared between FDA and the regulated industry. Simplified education materials that could easily be translated into other languages, multi-lingual translations of FDA's FSMA website, supporting documents (checklists, guidance, etc.), and education materials that importers can give to their suppliers are examples of the types of supplier education support that industry would find beneficial.

Question 2: Information Shared within Associations

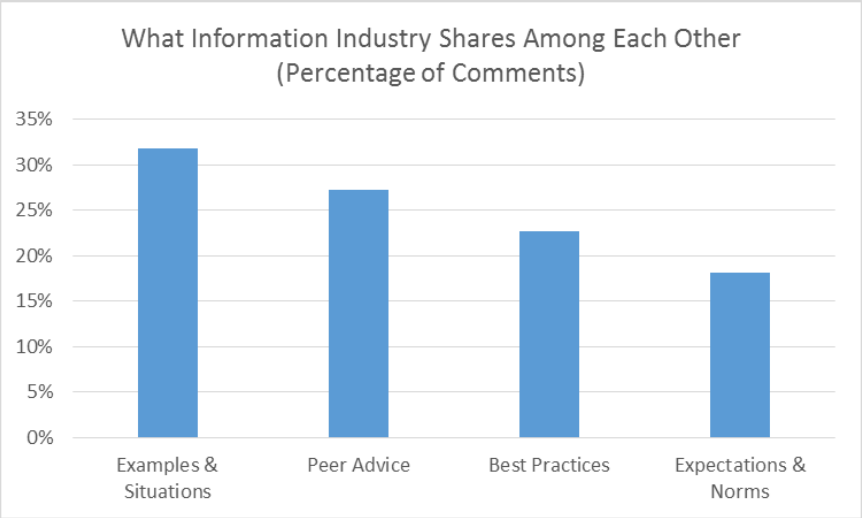
In an effort to better understand how the FDA might partner with industry associations for future outreach and engagement activities, facilitators asked about what types of information industry members often tend to seek from their associations. The chart below illustrates the consolidated feedback provided by industry members from each of the three regional meetings with respect to the most-cited types of information provided by industry associations.



The FDA may be able to use each of these tools, in partnership with industry, to increase shared understanding of future guidance documents, host and conduct joint training and webinar sessions, and encourage the creation, documentation, and free exchange of industry best practices on food safety and hazard prevention.

Question 3: Information Shared among Industry Members

In an effort to better understand what the FDA can reasonably expect industry participants to share with one another in helping to spread the word regarding FSMA compliance, FSVP, and other FSMA-related programs, participants were asked about what types of information industry members often share with each other. The chart below illustrates the consolidated feedback provided by industry members from each of the three regional meetings with respect to the most-cited types of information provided by industry members to one another.



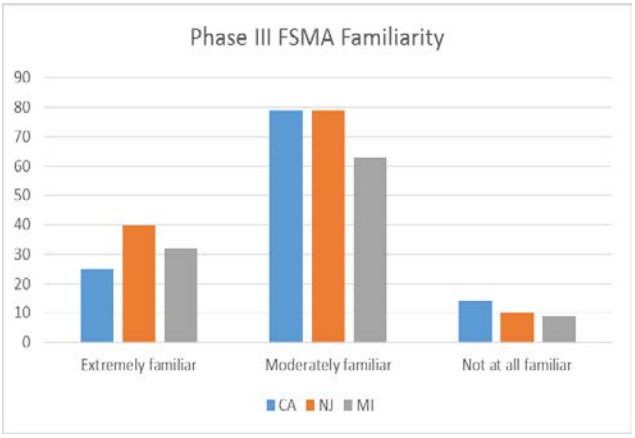
Keeping these four themes in mind, participants noted that the FDA may be able to leverage industry's willingness to discuss examples, case studies, peer advice, and best practices in the future development of materials that all industry sectors could benefit from.

Industry members expressed notable interest in the development of FSVP case studies and examples that help importing companies understand how to apply and comply with FSVP requirements.

Question 4: How FDA Can Reach the Uninvolved

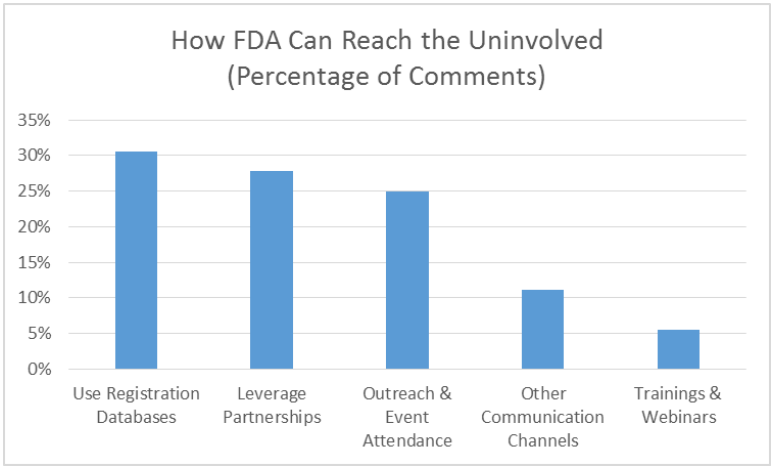
Despite the high level of interest and participation at each of the regional outreach meetings (see page 19), it was recognized that the majority of those who participated indicated that they were either moderately or extremely familiar with FSMA and FSVP prior to attending the outreach event (see chart on the following page).

This meant that though the regional meetings were successful in identifying knowledgeable partners for future collaboration activities, the challenge remains to determine how FDA can reach out to and engage industry participants who are not yet familiar or involved with FSMA compliance activities.



After consolidating and reviewing all feedback provided by industry members from each of the three regional meetings, the most-cited ways FDA could improve its outreach efforts to the uninvolved fell within five main themes:

1. *Use Registration Databases*
2. *Leverage Partnerships*
3. *Outreach & Event Attendance*
4. *Other Communication Channels*
5. *Trainings & Webinars*



As illustrated in the graph above, most industry members suggested that the FDA leverage its large databases of registered importers and brokers to conduct targeted outreach activities by state, sector, and commodity. Participants noted that though there may likely be some use restrictions that would require additional internal follow up within the FDA, it's possible that this form of outreach could target many uninvolved industry members.

The remaining themes suggested by industry members were fairly straightforward – "leverage partnerships" was the suggestion that the FDA consider working collaboratively with industry associations, embassy representatives, foreign representatives, and state and local government employees to increase joint training and webinar opportunities.

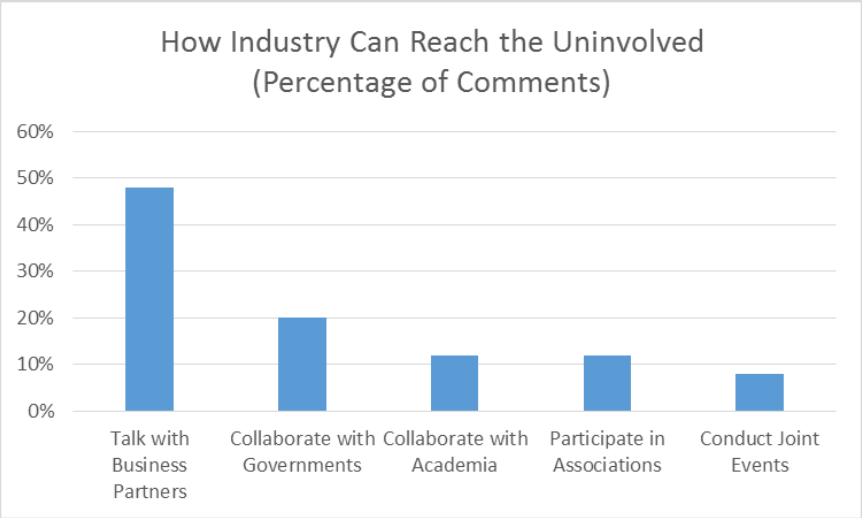
"Outreach and event attendance" was the suggestion that FDA continue to offer outreach events like the regional meetings. Additionally, if resources allow, industry members suggested that FDA attend

events and conferences hosted by industry associations in the imports, broker, and food producer communities.

"Other communication channels" was the suggestion that FDA experiment with social media and other nontraditional means of digital communication.

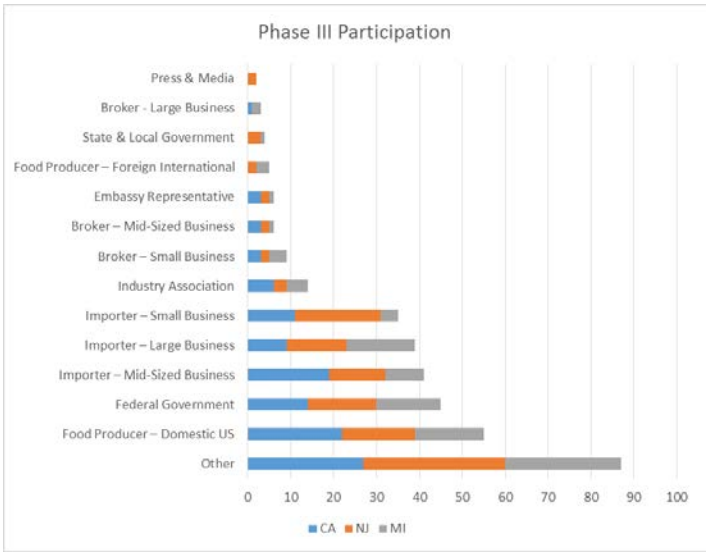
Question 5: How Industry Can Reach the Uninvolved

Finally, industry members attempted to identify ways that they too could support the FDA with outreach efforts that engaged industry participants who were not yet familiar or involved with FSMA compliance activities. The chart below illustrates the consolidated feedback provided by industry members from each of the three regional meetings with respect to the most-cited ways that industry members themselves could improve their outreach efforts to the uninvolved.



Of the themes identified, perhaps the most compelling and agreed-upon theme was the suggestion that industry participants make every attempt to talk with their business partners as much as possible.

This simple gesture would help to increase foreign suppliers' general awareness that FSVP is coming and inspire action on their parts to educate themselves on what that might mean for them.



Conclusion

After visiting three major imports locations throughout the United States, listening closely to 350 importers, food producers, and foreign and industry association representatives, and analyzing data captured during planned facilitated sessions, eight themes from the participants' responses emerged.

1. ***Industry members, broadly speaking, are ready and willing to comply with FSVP, but request help in understanding what is required***. Based on results from the first facilitated session in all three locations, industry members demonstrated familiarity with FSVP and demonstrated that they have been taking proactive measures to ensure the safety of imported foods. To increase their ability to comply with FSVP provisions, industry members have requested help with understanding the requirements in plain language and ask that the FDA make its intentions and expectations clear in as much detail as possible. Additionally, industry members demonstrated that they would benefit from assistance with developing a nuanced understanding of the law, particularly with understanding what to do or how to respond in the case of exemptions and modified requirements to FSVP.

2. ***Compliance with FSVP may be expedited by showing industry members how FSVP requirements vary from existing food safety practices and compliance schemes***. Many industry members expressed that they benchmark their compliance activities against other pre-existing imports safety schemes. Identifying and sharing how FSVP requirements differ from existing safety schemes would allow industry, and especially small businesses, to focus their efforts on compliance program elements they are missing rather than attempting to understand FSVP as a complete system.

3. ***Organizing FSVP compliance information by commodity and sector would help industry members find the information they need and quickly understand changes necessary for FSVP compliance.*** Based on feedback during facilitated sessions, it was noted that industry members tend to organize their operations by commodity and sector and the FDA tends to organize its operations by program area and topic. While it was recognized and well understood that the FDA does not have the resources to address every industry group in depth, participants thought it could be possible to collaborate with industry associations to develop best practices for particular goods and sectors as long as the FDA authorizes or validates whether those resources were sufficient to comply with FSVP.

4. ***Small importers and food producers are at a higher risk of failing to comply with FSVP than mid-sized and large importers and food producers.*** Though an imperfect measure of business size was used during outreach, participants who identified themselves as small businesses repeatedly expressed the concern that they do not have the resources available to participate in VQIP, to educate foreign suppliers on the requirements of FSVP, or to thoroughly research and understand FSVP requirements. Because of this, small businesses are at a higher risk of non-compliance with FSVP compared to mid-sized and large businesses.

5. ***Producing case studies and creating various forms of foreign supplier education would significantly expedite compliance with FSVP requirements***. Based on feedback during facilitated sessions, it was also noted that one of the most effective ways to demonstrate compliance expectations to industry would be through examples, model programs, and case studies. These types of activities typically inspire productive and helpful conversations and empower industry members to quickly understand and apply that understanding to their own unique situation. Many industry members also requested tools and trainings that they could use to educate foreign suppliers. Many participants suggested that it would be helpful to collaborate with

embassies and foreign representatives to produce supplier education materials in foreign languages that importers could send to their suppliers directly.

6. ***Program cost, return on investment, and effort necessary to participate will likely be the three major decision factors for industry members when choosing whether to participate in VQIP***. Because of this, industry members recommended the FDA maintain a continuous, open dialogue regarding the cost structure, benefits, and potential return on investment for VQIP and requested that FDA be clear and specific about what effort is required to participate in the program, both initially, and on an ongoing basis. Additionally, in order to demonstrate the value of VQIP participation, many industry members indicated they would be interested in understanding how much faster items were cleared through borders as a result of VQIP participation.

7. ***Industry members would benefit significantly from the FDA sharing information more freely, quickly, clearly, and concisely***. During the third facilitated session at each location, industry members unanimously noted it would be helpful if the FDA loosened restrictions or removed barriers to the release of information and increased the rate of information release. Whether it was the release of guidance documentation, responses to questions to the Technical Assistance Network (TAN), or updates to the FSMA frequently asked questions (FAQ), industry members noted that because few organizations have resources committed to FSMA or FSVP on a full time basis, delays in responses and guidances are particularly challenging.

8. ***The FDA has opportunities to use its existing facility registration database system and leverage its existing relationships with industry associations, embassy personnel, foreign representatives, state and local governments, and academia to continue outreach efforts and raise FSMA and FSVP compliance awareness.*** When asked how the FDA could engage industry members who may be wholly uninvolved or unaware of FSMA or FSVP, many industry members recommended the FDA make use of its registration database systems to conduct outreach to industry members directly. Additionally, participants expressed that the FDA could create and leverage existing partnerships with industry associations, embassy personnel, foreign representatives, state and local governments, and academia to identify opportunities to work together to expand outreach efforts through conference attendance, annual meetings, training development, etc. It was also noted that outreach and education efforts to foreign suppliers will be of particular importance given the global scope of the effort required.