

Collaborative Food Safety Forum (CFSF)

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

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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 U.S. Food and Drug Administration's (FDA) Food Safety Modernization Act (FSMA). The participants were asked to exchange information, share different points of view, and problem solve on priority topics or issues where there was a range of perspectives. The group was not asked to reach a consensus.

Themes by Topic

Points highlighted below are organized by agenda topics.

Risk-Based Determination of Mechanisms to Verify Control of Hazards

Following presentations, participants discussed their analysis of the two options presented in the proposed rule for verifying hazard control. Below are descriptions of each option followed by advantages and disadvantages of each option identified and discussed by the group.

Option 1 – Onsite Auditing for High Risk Hazards

As described in the proposed rule, “high risk” food hazards for the FSVP is defined as hazards that could pose a “*serious adverse health consequences or death to humans or animals*” (SAHCODHA), as well as *microbiological hazards in raw agricultural commodities*.

- 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 onsite auditing of the foreign supplier.
- For non-SAHCODHA hazards controlled by the foreign supplier, and all hazards that the foreign supplier verifies are controlled by its suppliers, the importer would need to conduct one or more potential activities to verify control of these hazards:
 - Onsite auditing;
 - Sampling and testing;
 - Review of supplier food safety records; or

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

- Some other appropriate procedure.
- For microbiological hazards in raw agricultural commodities, onsite auditing also would be required.

Advantages

- More aggressively protective of public health with a focus (i.e., audit) on foods containing high-risk hazards (SAHCODHA)
- Single standard for foods containing high-risk hazards more easily enforceable (perhaps requiring fewer Agency resources than less prescriptive approaches) and provides clear direction to companies unable or unwilling to identify and implement proper verification activities

Disadvantages

- Too prescriptive or “one size fits all,” and thereby could stifle innovation and the evolution of better approaches for supplier verification, possibly resulting in better protection of public health
- Likely more costly for industry

Option 2 – Supplier chooses verification activities for all hazards.

- In selecting the verification activities, the importer would need to consider:
 - Risk presented by the hazard;
 - Probability that exposure would result in serious harm (SAHCODHA); and/or
 - Food and foreign supplier’s compliance status.

Advantages

- More flexible for industry and therefore might encourage innovation
- Better aligned with current practices and therefore avoids unnecessary costs for food industry

Disadvantages

- More complex and resource intensive for FDA to enforce
- Demands more of importers in establishing appropriate verification activities
- Provides less specificity in assuring that all importers will implement appropriate verification activities for foods containing high-risk hazards

Alternative Option – On-site auditing is the approach to SAHCODHA hazards, unless validated alternative approach is used

Discussions progressed from analysis of the two options offered in the proposed rule to consideration of a third option initially presented by a participant and further developed by the group.

- An annual onsite audit is the “default” approach to verification of control of SAHCODHA hazards.
 - 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 demonstrated to provide adequate assurance that the hazard is 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 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 reinforces control systems.
- Alternative frequencies to a required annual audit (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, 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 similar domestic system, such as New Zealand).

While a variety of details would need to be developed to implement the 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

The definition of importer in the proposed rule was presented and discussed. Language in the proposed rule indicates the following:

- All importers must establish and follow a foreign supplier verification program (FSVP), unless otherwise exempted (proposed exemptions include juice and seafood importers who comply with HACCP, importers of small quantities of food for research and evaluation purposes, and food imported for personal consumption);
- The importer under the FSVP is the person/entity who has purchased the food offered for import.

- However, if there is no U.S.-based owner at the time of entry, then the importer is the U.S. consignee.
- If there is no US owner or consignee at the time of entry, then the importer is the U.S. agent/representative of the foreign owner/consignee.

Key points raised during this discussion included:

- The U.S. owner of the food when it enters the country is the FSVP responsible party (i.e., FSVP importer); and
- The FSVP importer is sometimes, but not always, the consignee.

“Very Small” Importer or Foreign Supplier

In the proposed regulations, “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.”

Building on the previous discussion of who is an importing entity and its associated responsibilities, the group further discussed the definition of a “very small” importer and their associated responsibilities. Key points raised by participants included:

- Rather than providing an exemption from or modifications to the standard FSVP requirements for “very small” importers, some participants suggested that FDA delay the compliance dates for the requirements (3 years was suggested), thereby providing additional time for capacity building within the companies falling in to this category.
- Others suggested use of proposed modified requirements as an attainable “floor,” combined with a (Voluntary Qualified Inspection Program) VQIP-like mechanism to spur continued improvement towards full compliance.
- A third proposal was to establish verification processes that are global,(i.e., that would be used by multiple entities) so a small business would not have to pay to verify the same food multiple times, which would create a huge cost burden for those importers with multiple customers.

Alignment of FSVP with Preventive Controls and Produce Safety Requirements

Opening comments and subsequent deliberations reinforced support among participants for alignment of proposed FSVP, Preventive Controls (PCs), and Produce Safety rules. Specifically, supplier verification approaches should serve *both* purposes – meeting requirements for FSVP and the Preventive Controls rules. Alignment is critical in terms of deploying resources most efficiently and effectively. Additional aspects discussed included the following points:

- Alignment of PC and FSVP supplier verification requirements may be necessary to avoid challenges to the FSMA rules under our trade agreements (i.e., in sync with CODEX and WTO). Supplier verification requirements for food facilities were not included in the PC proposed rule, while FSVP would establish supplier verification requirements for importers;

- There was acknowledgement of, and support for, recognizing “comparable” food safety systems in other countries that provide the same level of protection as FDA’s system;
- Participants noted concern with differing terminology and associated requirements. For example, “foreign supplier” is defined one way in the Produce Safety rule and another in the proposed FSVP, which defined foreign supplier as the entity with “last significant processing step” or “last touch” with distinction around “significant process step;”and,
- Established tracks for new or alternative, validated hazard control interventions/preventive controls, similar to alternative routes of compliance for meeting the water safety standards in the proposed Produce Safety rule.

Other Points

Other key themes highlighted by participants included:

- Establishment of metrics to evaluate the success of the FSVP regulations within the context of overall implementation of FSMA. Some related thoughts included the following:
 - Clarity of definitions and requirements;
 - Implementation of, and compliance with, requirements across diversity of importers and foreign suppliers;
 - Alignment of different food safety/hazard control programs;
 - Reduction in outbreaks of foodborne illnesses from imported foods; and/or
 - Public perception of the safety of imported foods.
- Need for concerted outreach by FDA, industry, and academia to bring all food supply chain entities up to speed to understand what the proposed requirements are and gather feedback and input, as well as to understand the final requirements and the associated roles and responsibilities to make the system work to improve food safety.