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Foreign Supplier Verification Program (FSVP): The Importer's Perspective

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Pre-Conference Workshop
Making FSMA Work for the Spice Industry

Introduction

FSVP Origins

FSVP Definitions

FSVP Rules

Foreign Supplier Verification Program origins

Food Safety Modernization Act

- 4 Titles under FSMA.
- Title III Improving Food Safety in imported Foods.
- Section 301 – Foreign Supplier Verification Program.
- Publication 10/31/15, all importers must comply 18 months after the final rule or 6 months after their foreign suppliers reach their FSMA compliance deadlines, whichever is later.

Foreign Supplier Verification Program definitions

FSVP applies to all importers of food for human and animals, unless specifically exempted or subject to modified requirements.

This is a major change in the regulation of the importation of foods from the traditional inspection on entry to a system that places the responsibility for food safety on the foreign supplier and importer.

Foreign Supplier Verification Program definitions

Importer has been defined as;

- The person in the US who purchased the food.
- If the food is not purchased, then the US consignee.
- If no owner or consignee, then the US agent or representative of the foreign supplier.

Foreign supplier would be defined as;

- The farm that raised the animal or harvested the imported food, or the last foreign establishment that manufactured/processed the food.

Foreign Supplier Verification Program rules

For each imported food, unless exempt or subject to modified requirements, the "importer" is required to have a FSVP with certain requirements. These are;

- Qualified Individual(s) must develop the FSVP
- Hazard Analysis
- Evaluation of Food Risk & Supplier Performance
- Supplier Verification
- Corrective Actions
- Administration
- Exemptions

Foreign Supplier Verification Program rules

Qualified Individual

A "qualified individual" as defined in the rule is required to develop the FSVP and perform most of the verification activities.

Necessary, training, education and experience are key, so we are ensuring we have PCQI training for numerous individuals in our organization.

Foreign Supplier Verification Program rules

Hazard Analysis

An importer is required to identify & evaluate based on;

- experience,
- illness data,
- scientific reports &
- the known or reasonably foreseeable hazards for each type of food it imports, to determine if there are any hazards requiring a control.

These include:

- Biological (parasites, viruses, bacteria, environmental pathogens)
- Chemical (allergens, radiological, pesticides, residues, natural toxins, decomposition & unapproved food, packaging, additives)
- Physical (glass, metal, stone etc.)

Foreign Supplier Verification Program rules

There may be hazards reasonably likely to cause illness or injury that occur naturally, are unintentionally introduced, or are intentionally introduced for purposes of economic gain, such as substituting a less costly ingredient (horse meat, alternative herbs or non-value components) or one that boosts a foods value analytically (Melamine).

Foreign Supplier Verification Program rules

The hazard analysis must assess the probability the hazard will occur in the absence of controls & the severity of illness or injury.

The evaluation should consider factors that include the:

- Formulation of the food (pH, Aw, Salt, Sugar etc.)
- Condition, function and design of the establishment and equipment
- Raw materials and other ingredients
- Transportation practices (temperature requirements)
- Harvesting, raising, manufacturing, processing and packing procedures
- Packaging and labeling activities
- Storage and distribution (temperature requirements)
- Intended or reasonably foreseeable use
- Sanitation, including employee hygiene

Importer can rely on another entity to perform this task if reviewed.

Foreign Supplier Verification Program rules

In order to ensure we meet these requirements we have developed a hazard analysis based on these requirements which also covers the Preventative Controls rule and the FSVP.

Due to the large number of ingredients we have it was prudent to group similar materials together based on hazards and characteristics so that the hazard analysis would cover each one individually.

Foreign Supplier Verification Program rules

Evaluation of Food Risk and Supplier Performance

An importer must evaluate:

- The hazard analysis for that food
- Any entity in the chain that will minimize/prevent the hazard
- Supplier's food safety procedures, processes & practices,
- Applicable FDA regs. & info. regarding the supplier's compliance
- The supplier's food safety history, complaints, import alerts, warning letters & its responsiveness in correcting past problems
- Other factors as necessary, including storage & transportation

The evaluation of the risk posed by the imported food & the supplier's performance must be re-evaluated every 3 years, or when new information comes to light about a hazard or the supplier.

Importer can rely on another entity to perform this task if reviewed.

Foreign Supplier Verification Program rules

This is a secondary risk evaluation based solely on the vendor and not the food or food packaging. In order to achieve this we have a document handling system called Tracegains which gathers the relevant documentation based on our timing requirements for us to review and approve or reject and then act upon.

The hazard analysis within our system covers both materials for Biological, Chemical and Physical hazards and the manufacturer for their competency thereby giving us a score per material and then by vendor.

Foreign Supplier Verification Program rules

Supplier Verification

Based upon the evaluation of risk conducted, the importer must establish and follow written procedures to ensure, in most instances, that it only imports from approved foreign suppliers and must conduct appropriate supplier verification activities.

You must be able to identify a material back to its source factory, which matches your approved supplier list.

In limited circumstances an importer might justify using a non-approved supplier on a temporary basis.

Foreign Supplier Verification Program rules

Importers have the flexibility to tailor supplier verification activities to unique food risks and supplier characteristics. The options include:

•Annual on-site audits. This is required when there is "reasonable probability" that exposure to a hazard will result in serious adverse health consequences or death to humans or animals (SAHCODHA hazard). However, the importer can choose other means of verification provided they are appropriate & there are assurances the foreign supplier meets U.S. food safety standards. 3rd party audits important. The FDA only need to see pertinent audit information not full audit reports.

•Sampling and testing.

•A review of the supplier's relevant food safety records.

Importer can rely on another entity to perform this task if reviewed.

Foreign Supplier Verification Program rules

In order to ensure supplier verification is carried out it is very important the hazard analysis designates where a SAHCODHA hazard is assigned as that vendor then is required to have an annual audit or appropriate documentation verified.

So for imported products the SAHCODHA hazard could be designated to the foreign manufacturer, a treatment facility (foreign or domestic), a further manufacturer in the supply chain or with the importer themselves.

This is where the need to have a GFSI third party audit in place is key to minimize second party audits.

Foreign Supplier Verification Program rules

Corrective Actions

Importers must take appropriate corrective actions if they determine that a foreign supplier has not used processes & procedures that provide the same level of public health protection as required under the produce safety and preventive controls regs., or that the supplier produces food that is adulterated or misbranded due to allergens.

- The appropriate corrective measure will depend on the circumstances, but could include discontinuing use of the supplier until the cause has been addressed.

Specific corrective action plans should be detailed in your hazard analysis and include alerting the FDA, USDA etc.

Corrective actions must be recorded and reviewed.

Foreign Supplier Verification Program rules

In order to ensure corrective actions are reviewed and recorded this is reviewed monthly as part of our Food Safety Committee meetings.

Remember the decision to not make a corrective action needs to be fully documented also especially the justification.

Foreign Supplier Verification Program rules

Administration

Make sure what you are really doing day to day is reflected in your SOP's and plans. Are you doing what your documents say you do?

Make sure you can prove, that what you said you would do, you did.

If it's not been documented it never happened and if its documented incorrectly then that is what happened.

Record retention is required in English for at least two years and you must make records available to FDA upon request.

Foreign Supplier Verification Program rules

"What have you done with those Food Safety Plans?"

Foreign Supplier Verification Program rules

Exemptions

Importers who are manufacturers comply with FSVP mostly if

- they comply with the supply-chain program PC rules;
- they have preventive controls for the hazards in the food in accordance with the requirements in the PC rules; or
- they are not required to implement preventive controls under those rules due to certain circumstances e.g. coffee beans and they comply with requirements for disclosures and written assurances.

Importers are not required to evaluate the food & supplier or conduct supplier verification activities if they receive adequate assurances that a subsequent entity in the supply chain is processing the food for food safety. Importers must also disclose in documents accompanying the food that the food is not processed to control the identified hazard.

Foreign Supplier Verification Program rules

Where you may have any of these exemptions in place it is very important to have the relevant up to date documentation to identify those materials at any particular moment in the process and later to prove of their proper classification and usage.

Especially important for raw spices and herbs being imported prior to treatment.

We are working to ensure we have the correct documentation in place with all relevant materials to assist with identification and importation.

Foreign Supplier Verification Program rules

No FSVP activity with respect to an identified hazard is required if a risk-based supplier program determines that the identified hazard will be controlled by the importer or their customer. However the determination must be backed by proof.

Modified requirements & exemptions apply to the importation of certain foods e.g. juice & seafood (HACCP), LACF (micro. requirements only), USDA products, alcoholic beverages, food for research/evaluation, food for personal consumption & food transshipped through the US.

There are modified requirements for countries whose systems are recognized by the FDA as comparable to the US. New Zealand is the only one currently however the FDA has initiated an assessment with Canada.

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I would like to thank ASTA for the opportunity to speak today, I hope my presentation was informative and interesting.

Any questions?

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Foreign Supplier Verification Program: The Foreign Supplier's Perspective

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Purpose of FSVPs

- To provide adequate assurances that:
  - Foreign suppliers produce food under the same safety standards as in the US, and provide the same level of public health protection as FSMA Preventive Controls or Produce Safety Provisions.
  - Food is not adulterated or misbranded

Overview of FSVP

- Importers are required to develop, maintain, and follow an FSVP for each food imported, unless an exemption applies.
- The requirements vary based on:
  - Type of food product
  - Category of importer, such as very small
  - Nature of the hazard identified in the food
  - Who is to control the hazard

Exemptions

- Importation of juice and seafood whose suppliers are in compliance with HACCP regulations
- Food imported for research and evaluation purposes
- Food imported for personal consumption
- Alcoholic beverages
- Food that is trans-shipped or that is imported for future export and not consumed or distributed in the U.S.
- Products from facilities subject to FDA's low acid canned food requirements (exempt for microbiological hazards only)

Spices & Herbs are not exempted!

Food Safety Plan

- Hazard Analysis
- Preventive Control
- Supply Chain Program
- Recall Plan
- Management of PC:
  - Monitoring
  - Corrective action
  - Verification

Hazard Analysis

Risk Assessment is the Key

- Detail Potential Hazards
- Identify the step in supply chain where it is most likely to occur
- Put a probability of the hazard occurring
- Identify ways to eliminate or minimize the risk

Risk Assessment: An example

Potential Hazard Identification			Hazard Evaluation			Suppliers Control Measure	Ingredient risk to processor	Processor- Foreign Supplier		Final Risk to Foreign Supplier
Sl No	Hazard Identification	Potential Source	Severity	Likelyhood of occurrence	Hazard Significance			Processor Controls	Effect of Control measure	
	PHYSCIAL HAZARDS									
1	Stones	Farm/ Post Harvest Handling	Medium	High	Medium	None	Low	Cleaning system- destoner	Effective	Low
2	Plastic	Farm/ Post Harvest Handling	Low	Medium	Low	None	Low	Cleaning systemPicking Belt conveyor, Aspiration	Effective	Low
	CHEMICAL HAZARDS									
1	Fumigant residues	Fumigation	Medium	Low	Low	None	Low	Monitoring of Fumigant residues	Effective	Low
2	Aflatoxin	Post Harvest Handling	Medium	Medium	Medium	Good Drying Practices	Medium	Pre-acceptance Aflatoxin analysis for 100% lots	Effective	Low
	BIOLOGICAL HAZARDS									
1	Salmonella	Farm/ Post Harvest Handling	High	Low	Low	Good Drying Practices	Low	Steam/ ETO treatment	Effective	Low
2	*E.coli*	Farm/ Post Harvest Handling	High	Low	Low	Good Drying Practices	Low	Steam/ ETO treatment	Effective	Low
	Pest									
1	Insects	Storage	Low	Low	Low	Good Storage Practices	Low	Fumigation, Cleaning system	Effective	Low
2	Rodent Excreta, hair	Storage	Medium	Low	Low	Good Storage Practices	Low	Cleaning system- Aspiration	Effective	Low
	ALLERGENS									
1	Cereals containing Gluten	Farm, Processing	High	Low	Low	GAP	Low	Allergen Control Program, Supplier declaration	Effective	Low
2	Soy	Farm, Processing	High	Low	Low	GAP	Low	Allergen Control Program,	Effective	Low
3	Peanuts	Farm, Processing	High	Low	Low	GAP	Low	Allergen Control Program,	Effective	Low
	Radiological Haazards									
1	Gamma rays, Cesium 134, 137	Farm	High	Low	Low	None	Low	Monitoring	Effective	Low
	Food Fraud									
1	Illegal dyes	Adulteration	High	Low	Low	None	Medium	Supplier Approval program, Testing	Effective	Low
2	Substitution with cheap Material	Substiution	Low	Low	Low	None	Low	Supplier Approval program, Inspection	Effective	Low

Risk assessment Guide				
Calculation of Significance of hazard				
Likelihood of occurrence	H	High	Medium	Low
	M	Medium	Medium	Low
	L	Low	Low	Low
		H	M	L
		Severity of effect		

Potential Hazards associated ingredient			Hazard assessment at Supplier					Processors Factory		Final Risk to Supplier
Sr	Hazard Identification	Potential Source	Severity	Likelyhood of occurrence	Hazard Significance	Suppliers Control Measure	Ingredient risk to Processor	Supplier Process control	Effect of Control measure	
	PHYSCIAL HAZARDS									
1	Stones	Farm/ Post Harvest Handling	Medium	High	Medium	None	Low	Cleaning system- destoner (whole Chilli, cut chilli)	Effective	Low
2	Glass, Brittle plastic	Farm/ Post Harvest Handling	High	Low	Low	None	Medium	Cleaning system- destoner (whole Chilli, cut chilli)	Effective	Low
	CHEMICAL HAZARDS									
1	Aflatoxin	Agricultural practices	Medium	Medium	Medium	GAP, backward Integration	Medium	Pre-acceptance Afla analysis for 100% lots	Effective	Low
2	Lubricants from processing	Farm/ Post Harvest Handling/ Processing	Medium	Low	Low	None	Low	Preventive maintenance, GMP	Effective	Low
3	Cleaning Chemicals from facility	Farm/ Post Harvest Handling/ Processing	Medium	Low	Low	None	Low	Chemical Control Program, GMP	Effective	Low
	BIOLOGICAL HAZARDS									
1	Salmonella	Farm contamination	High	Low	Low	None	Low	Steam/ ETO treatment	Effective	Low
2	*E.coli*	Farm contamination	High	Low	Low	None	Low	Steam/ ETO treatment	Effective	Low
	PEST									
1	Insects	Storage	Low	Low	Low	Good Storage Practices	Low	Fumigation, Cleaning system	Effective	Low
2	Rodent Excreta, hair	Storage	Medium	Low	Low	Good Storage Practices	Low	Cleaning system- Aspiration	Effective	Low
	ALLERGENS									
1	Peanuts	Farm, Processing	High	Low	Low	GAP	Low	Allergen Control Program	Effective	Low
2	Tree nuts	Farm, Processing	High	Low	Low	GAP	Low	Allergen Control Program	Effective	Low
	RADIOLOGICAL HAZARDS									
1	Gamma rays, Cesium 134, 137	Farm	High	Low	Low	None	Low	None	Not Applicable	Low
	FOOD FRAUD									
1	Illegal dyes (Sudan I-IV)	Adulteration	High	Low	Low	None	Medium	Supplier Approval program	Effective	Low
2	Substitution with cheap Material	Substiution	Low	Low	Low	None	Low	None	Effective	Low
8	Starch addition	Adulteration	Low	Low	Low	None	Low	Purchased in whole form	Effective	Low

Preventive Controls

Preventive Controls

- Supply Chain program requirements under Preventive Controls Rules
  - Process Control
  - Food Allergens Control
  - Sanitation Controls
  - Supply Chain Control
  - Recall Plan

Process Controls

Customer Request to supply “natural” pepper

Salmonella Identified as a hazard likely to occur

1. Declare that goods are not controlled for hazard
2. Document
3. Written assurance from customer that they implement preventive controls

Process Controls

Customer Request to supply “treated” pepper

Salmonella Identified as a hazard likely to occur

1. Establish Hazard Control
2. Validate the kill step
3. Document

Food Allergens Controls

Customer requests treated clean cumin

Peanut contamination as a hazard likely to occur

1. Source validation tests
2. Vendor audit
3. Documentation

Sanitation Program

- **Sanitation controls for the cleanliness of food contact surfaces:** *Cleaning and sanitizing procedures*
- **Sanitation controls to prevent cross contact:** *Cross contamination by improper utensil control & handling, allergen*
- **Sanitation controls to prevent cross contamination:** *Cross contamination by personnel touching insanitary objects*

Sanitation Program

Environmental Quality Monitoring Program Schedule

Sample Category	Sample Type	Sample Site	Sample Point	Frequency	Parameters to test
Product contact surface	Equipment (Product contact)	Miilling System	Input Hopper	Based on risk assessment	TPC, Yeast & Mold, Enterobactericea
			Mill interior		
			Collection point		
	Other surfaces	Sampling scoop	Scoop for sampling at product contact area		
Non-product contact surfaces	Floor drains	Production plant within 15 ft. of product contact surface	Floor drains on each processing floor	Based on risk assessment	Salmonella Listeria
	Floor swabs		Collection points		
Non-product contact surfaces	Floor swabs	Production plant area greater than 15 ft. from product contact surface	Receiving dock	Based on risk assessment	Salmonella Listeria
			Finished Goods warehouse		

Supply Chain Controls













Supply Chain Controls

- Know your supplier & supplier's supplier; know your customer
- Traceability back to farms
- Reduce the number of hand offs in the chain of custody

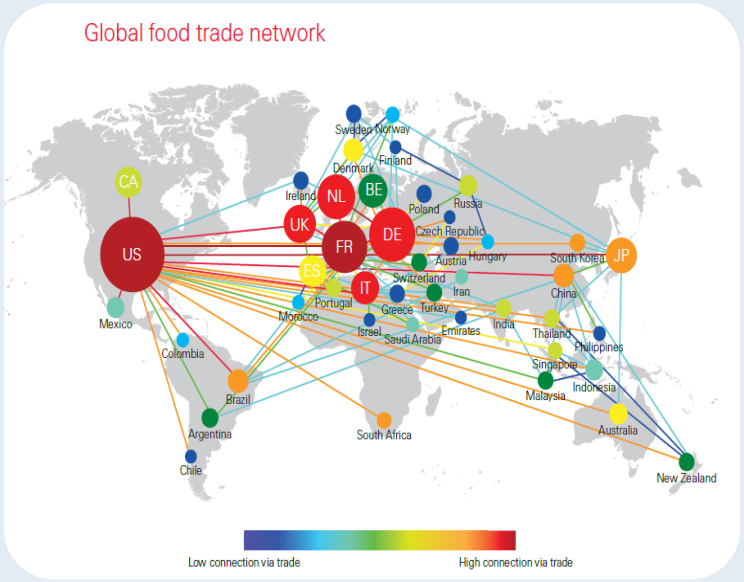
Supply Chain Controls

- Vendor Risk assessment & approval process
- Based on Risk assessment, implement appropriate supplier verification activities
- Verification activities to include;
  - On site audit
  - Sampling & Testing
  - Review of Relevant Food Safety Records

Management of PC

- Written Procedures
- Monitoring at adequate frequency
- Records
  - To document monitoring
  - Exception records

Recall Plan



- Establish Written Recall plan
- Must include procedures that describe steps to be taken and assign responsibility for the following actions
  - Notify direct consignee including how to return or dispose the affected material
  - Notify public about the hazard
  - Conduct effectiveness checks to verify that the recall is carried out
  - Appropriate disposal of recalled food

Recall Plan: A Reality Check

- Have you conducted mock recall in the last 6 months?
- Are you able to trace 100% of the raw material and finished goods?
- How much time did it take to come up with a recall report?
- How would you communicate to the appropriate authorities & stake holders?

As suppliers, are we prepared?

- Compliance status review as per Preventive Controls
- Hazard analysis / Food Safety Plan
- Supply Chain verification activities
- Corrective actions (as necessary)
- Documentation / Record keeping

As suppliers, are we prepared?

- Implementation May 2017
- Preventive Controls for Human Food: In Place(http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361903.htm)
- Produce Safety Standards: Not applicable (http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm)
- Foreign Supplier Verification Program: Customer Scope (http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm)
- Preventive Controls (Animal Food): Not applicable (http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm366510.htm)
- Third party Accreditation: BRC in place, but announced. We shall change to un-announced from 2017 (http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361903.htm)
- Sanitary Transport: Not applicable? (http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm383763.htm)
- Intentional Adulteration: In Place (http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm378628.htm)

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Questions

Thank you

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Case Studies

Doug Marshall, Eurofins

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Thank you!

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Survey Says!