



WEBINAR:

FSVP: A Panel Discussion on Tips for Implementation

Hilary Thesmar, SVP, *Food Safety Food Marketing Institute*

Laura Nelson, VP Food Safety & Global Alliances, *Alchemy Systems*

AFFI AMERICAN
FROZEN FOOD
INSTITUTE


alchemy
Smart action at work.

FSVP Tips for Implementation

What you need to know

Hilary Thesmar, PhD, RD, CFS

FMI

Training



Food Safety Preventive Controls Alliance

- Preventive Controls for Human Food
- Preventive Controls for Animal Food
- Foreign Supplier Verification Programs

FSVP Importer



- *The US owner or consignee of an article of food that is being offered for import into the US. If there is no US owner or consignee of an article of food at the time of US entry, the importer is the US agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under this subpart.*

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Communication among Supply Chain Partners

- If ownership at the time of import is uncertain, or multiple companies fit the definition of importer, communication is needed about FSVP responsibilities
- FDA will track the import documents to identify the FSVP importer and investigate the trail from there

What is in your FSVP?

1. Hazard analysis (§1.504)
2. Foreign supplier performance evaluation (§1.505)
 - Procedures for approving foreign suppliers
 - Foreign supplier approval documentation
3. Documentation of verification activities (§1.506)
 - Determination of verification methods and frequency
4. Corrective actions (§1.508)
5. Reevaluations of your FSVP either for cause or routinely every 3 years (§1.508)

FSVP and Supply Chain Controls

§1.502 (c)

Importers subject to section 418 of the FDCA. You are deemed to be in compliance with the requirements of this subpart for a food you import, except for the requirements in §1.509, if you are a receiving facility as defined in §117.3 or §507.3 of this chapter and you are in compliance with the following requirements of part 117 or part 507 of this chapter as applicable

FSVP and Supply Chain Controls

Receiving facility means a facility that is subject to subparts C and G of this part and that manufactures/processes a raw material or other ingredient that it receives from a supplier.

PC Rule and Supply Chain Program

- Flexibility when applying Supply Chain programs to foreign suppliers
- FSVP Rule 1.502 (c)
- PC Rule 117.405 (a)(2)
Receiving facilities that are importers in compliance with FSVP do not need to duplicate verification

FSVP – Controlling Hazards

§1.507

Provides flexibility in controlling hazards after importation

Resources

- **FDA Technical Assistance Network**

- <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>

- **FSPCA – FSMA Training**

- <https://www.ifsh.iit.edu/fspca/courses/foreign-supplier-verification-program-fsvp>

Q&A

FSVP Final Rule

<https://www.federalregister.gov/documents/2015/11/27/2015-28158/foreign-supplier-verification-programs-for-importers-of-food-for-humans-and-animals>

Boiling the Ocean

Start with the End in Mind for FSVP Compliance



Laura Nelson, VP of Food Safety & Global Alliances

Start with the End in Mind

- ✓ Know your suppliers
- ✓ Acknowledge who is controlling your ingredients /product risks
- ✓ Understand role as an Importer
- ✓ Be aware of compliance dates
- ✓ Execute robust hazard analysis and risk assessment
- ✓ Supplier verifications choices

Know Your Suppliers!

Approved ▲

Supplier \neq Broker

Supplier \neq Distributor

Supplier \neq Consolidator

Supplier \neq Agent

Supplier \equiv Facility where hazards can be controlled



Challenges of Today's Supply Chain!



Ground Turmeric - 25 lb. Bulk

★★★★★ 18 Reviews 6 Questions \ 6 Answers

Coloring the world in ochre hues and bathing it in musky aromas, turmeric is one of nature's most vibrant spices.

 Add to Wishlist

\$107.91

Availability: In Stock

* Required Fields

Size/Amount: 25 lb. *

1 oz.	4 oz.	1 lb.	5 lb.	10 lb.
\$7.00 (\$7.00 / oz)	\$8.82 (\$2.21 / oz)	\$19.84 (\$1.24 / lb)	\$35.88 (\$7.18 / lb)	\$56.16 (\$5.62 / lb)

ADD TO CART

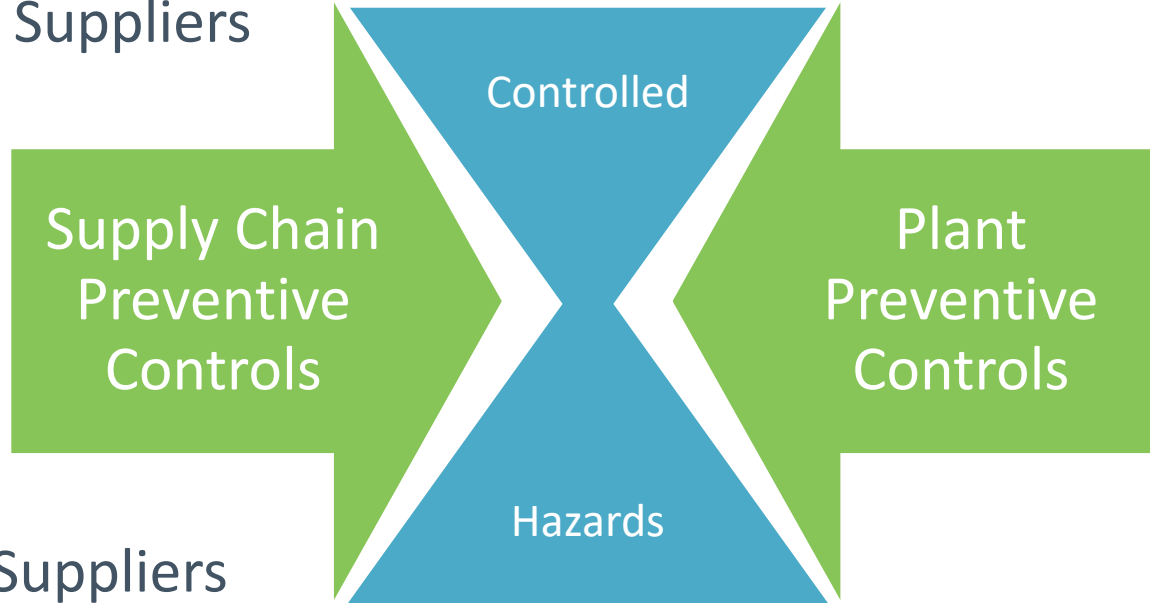
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-OR-

Check out with 

Who is Controlling Your Ingredient/Product Risks?

Domestic Suppliers



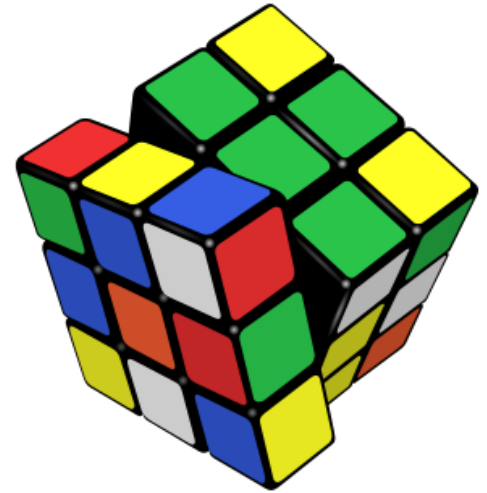
Foreign Suppliers

Your Supplier and/or You?

Proud Importer! So What?

May or may not be subject to FSVP:

- Import certain foods
- Small quantities of food for research
- Foods not sold or distributed in US
- Food produced in compliance with FDA's
Low acid canned food requirements
- Importation of food from foreign supplier with a
food safety system FDA has recognized



[fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472461.pdf](https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472461.pdf)

Compliance Date?

- Dependent on:
 - The size of the foreign supplier
 - The nature of the importer
 - Whether the foreign supplier must meet the requirements of the final rule for
 - Current Good Manufacturing Practice and Hazard Analysis and Preventive Controls for Human Food
 - Current Good Manufacturing Practice and Hazard Analysis Preventive Controls for Food for Animals
 - Produce Safety Rule
- Varies from May 30, 2017 – July 27, 2020



[fda.gov/Food/GuidanceRegulation/FSMA/ucm503822.htm](https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm503822.htm)



Skilled Hazard Analysis

Known or reasonably foreseeable hazards subject to control

- Biological — includes parasites, environmental contamination (RTE products)
- Chemical
 - Radiological
 - Pesticides
 - Drug residues
 - Natural toxins
 - Food decomposition
 - Unapproved additives
 - Allergens
 - Nutrient deficiencies/toxicities
- Physical — glass
- Economically Motivated Adulterants



Skilled Risk Assessment

Evaluation of risks by the food + performance of the foreign supplier

- Hazards
- Application of hazard controls
- Food safety practices and procedures
- Compliance to US food safety regulations
- Food safety performance history

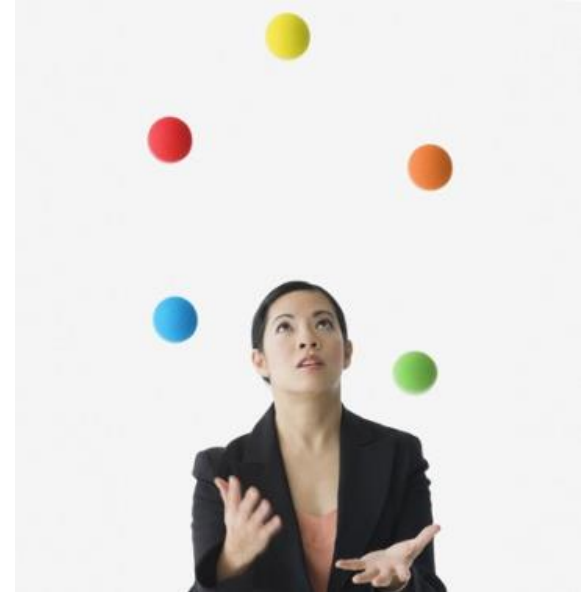


Supplier Verification – Know Your Limits!

What assurances do you need?

- Written assurances
- Onsite audit
- Regulator audit
- Product testing
- Food safety program record review
- Supplier performance evaluation system
- Other?

★ **Consider obtaining expert assistance**



THANK YOU

Laura Dunn Nelson

VP Food Safety & Global Alliances, Alchemy

laura.nelson@alchemysystems.com

254-965-8563

Panel Discussion

Please type your questions into the questions box on your Go-To-Webinar Control Panel to be read aloud during the Q&A session of the panel.

Donna Garren, Ph.D.
Senior Vice President, Scientific
& Regulatory Affairs

