Navigating FSMA's Foreign Supplier Verification Rule

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Today's Speakers

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Agenda

- Nuts & Bolts of Foreign Supplier Verification (FSV)
- Hazard Analysis and Risk Evaluation
- Verification of FSV Program
- Q & A

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Objective of FSVP

"Importers [must] perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards." - FDA

AND document it.

POLL

Is your company a:

- Manufacturer
- Importer
- Broker
- Unsure

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Fact or Fiction?

Unlike before, FSMA now holds imported foods to the same standards as domestic foods.

Fiction?

Imported foods were always required to meet the same requirements: adulteration and misbranding

Fact?

Imported foods were and are held to the standard using a lower burden of proof (evidence) to keep product out

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Other “FSVP” Mechanism

- Importer is subject to Preventive Control Rule and its supplier verification requirement is applicable
- Very small importers or small foreign supplier
- Officially recognized countries
- Dietary supplements
- Other parties control the hazards

Don’t Worry About it

- Seafood and Juice HACCP
  (they have their own requirement)
- Research and evaluation
- Personal consumption
- Alcoholic beverages
- Meat, poultry, and egg products
- Transshipment and U.S. goods returned

Who's Who?

- Importer – Person in the US
  - Importer of record?
    - No: **Purchaser**
  - If none, then, consignee at time of entry:
    - First Consignee vs **Ultimate Consignee**
  - If none, then, **U.S. Agent or rep of foreign owner/consignee at time of entry**
    - NOT U.S. Agent of foreign registered supplier, necessarily

- Foreign Supplier
  - Foreign person who processes, raises or harvests food not further processed by another
  - More than *de miniminis*
  - There can be only one…"Single foreign supplier"

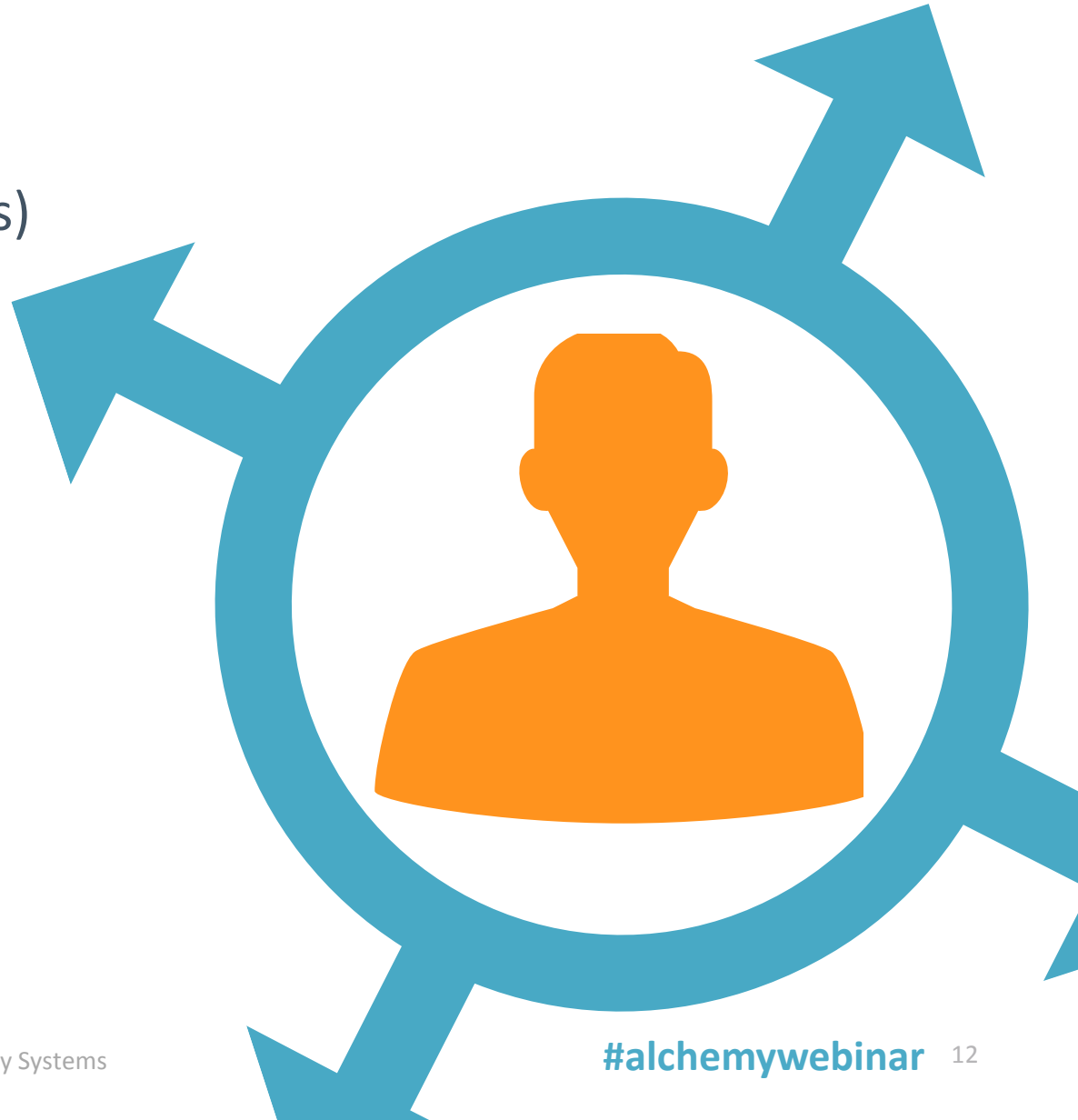
Who's Doing What?

- Qualified Individual
  - Education, training, and experience to perform work, or complete standardized curriculum or be qualified through job experience (like HACCP)
  - Must perform:
    - Compliance status
    - Hazard analysis
    - Perform or analyze the verification activities
    - Investigation and corrective actions
    - Reassess
- Qualified Auditor
  - Education, training, or experience to perform audits (different than accredited auditor)

Who's Does What?

Basic Steps

- Hazard analysis
- Risk evaluation
  - Approve the supplier
- ***Verification activities***
- Corrective action(s)
- Reassessment
- Recordkeeping



Hazard Analysis

- Limited to issues of health/safety
- Process:
  - What are the possible hazards
    - Added for economic gain?
  - Identify hazards requiring a control

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Do you require your suppliers to be GFSI certified?

- o Yes
- o No
- o Unsure

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Risk Evaluation

- Consider:
  - Hazards
    - Significant?
    - SAHCODHA?
  - Who controls the hazards
    - foreign supplier or their raw material supplier?
    - Importer or Importer's customer?
  - How is the hazard controlled?
  - Foreign supplier's compliance history
    - warning letter or import alert
  - Food safety performance history
    - importer's tests or audits
  - Any other factors

Verification Activities

- If foreign supplier is controlling the hazard, the **importer** must perform one of the following:
  - Onsite audit
  - Sampling and testing of food
  - Foreign supplier's food safety records
  - Other appropriate activities
- If a SAHCODHA hazard, then onsite audit before importing and at least annually
  - UNLESS, determine why other verification activities are appropriate or audits only need to be less frequent

Corrective Action and Reassessment

- Corrective Action:
  - once aware, must investigate and respond appropriately
  - **As importer and as verifier of foreign supplier**
- Reassessment:
  - become aware of new information about potential risk with food **or supplier**
  - Every three years

Recordkeeping

Word	# of Times
“Written”	~29
“Document” or “documentation”	~80

- What needs to be in writing:
  - Written procedures to do the work
  - Document every step of the process
- Retention:
  - 2 years generally
  - Process/Procedure: 2 years after discontinued use

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If It's Not Documented It – You Didn't Do It!

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Do you train your associates on recordkeeping and documentation best practices?

- o Yes
- o No
- o Unsure

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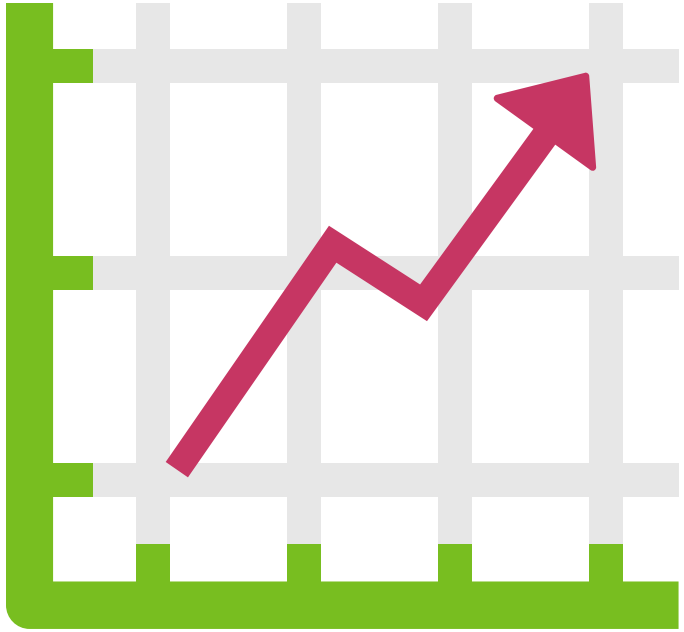
What is a Record?

- Record
  - An account of something, preserved in a lasting form
  - Typically made as the activity occurs
  - Functions as evidence of activities performed
  - Proves you did what you said you were going to do
  - Required by regulation(s)
  - ***Paints a picture of the product, process, plant, and culture***

Required Documents



- Hazard analysis
- Risk evaluation
  - Approve the supplier
- ***Verification activities***
- Corrective action(s)
- Reassessment
- Recordkeeping

Who owns it?

- Designate someone at your facility who has responsibility for:
  - Updating
  - Maintaining
  - Reviewing
  - Filing

- Keep an ongoing history of every change to every document!

Designate a Subject Matter Expert

- Have a robust procedure
- Assign accountabilities
- Update often
- Train on all changes
- Review when received
- Organize / file
- Store effectively

- Ensure ease of retrieval
- Purge expired documents

The law has changed:
Review company policies and FOLLOW THEM!

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Reassess and Update Forms

- When?
  - Initially
  - Regular frequency
  - Changes
- Ensure ease of use
  - Complete data collection
  - Meet regulatory and customer requirements
  - Include implementation dates on all forms
- Include confidentiality statement
- Include work instructions
- Train regularly

Don't collect data just to collect data

Demand Perfection, No Exceptions

Do	Don't
 Use ink	 Use pencil – can be erased
 Fill out in real time	 Fill out in advance
 Use exact time	 Estimate time
 Fill in all information as required	 Leave blank spaces – use N/A or other
 Fill out initials, date and time	 Use hash marks, lines, ditto
 Write clearly – use best penmanship	 Use markers or pastel ink – can run or fade
 Review document before submitting	 Use cheat sheets

Control and Storage of Records

- A fully developed and implemented document control system:
  - Track changes
  - Maintain security
  - Control access
  - Clear retention timelines
  - Review upon completion
  - Storage requirements
- Storage requirements:
  - Industry leading practice is to keep food safety documents separate from other records
  - Determine your recordkeeping system (paper, electronic)
  - Determine who has access and who owns it (have several back up people with access)
  - Create or review record retention policy

Test Procedures

- Pull records from several months ago for review with management team
  - Can you find the document?
  - How long did it take to retrieve?
  - Is it complete?
  - Does it paint a accurate picture?
  - Are you following your procedure?
  - Is record review a part of mock exercises?

- Records are for third party review now
  - Use appropriate terminology
  - Follow your company policy
  - Know when to notify legal counsel
  - Keep a copy for your files
  - Verify they are marked Confidential

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Compliance Dates

- **FSVP importer whose foreign supplier is not subject to the PC or produce safety rules**: **May 30, 2017**
- **FSVP importer whose foreign supplier is required to comply with the PC rule for human food**. Compliance dates when foreign suppliers are in these categories:
  - Small businesses as defined in 21 CFR 117.3: **March 19, 2018**
  - Qualified Facilities (including Very Small Businesses) as defined in 21 CFR 117.3: **March 18, 2019**
  - Suppliers subject to the Pasteurized Milk Ordinance: **March 18, 2019**
  - "All Other" Businesses Suppliers: **May 30, 2017**
- **FSVP importer of animal food whose foreign supplier is subject to the current good manufacturing practices ("CGMP") requirements in subpart B of 21 CFR part 507 in the PC rule for animal food**. Compliance dates when foreign suppliers are in these categories:
  - Small Businesses as defined in 21 CFR 507.3: **March 19, 2018**
  - Qualified Facilities (including Very Small Businesses) as defined in 21 CFR 507.3: **March 18, 2019**
  - "All Other" Businesses: **May 30, 2017**
- **FSVP importer whose foreign supplier is required to comply with the animal food preventive controls requirements in subpart C of part 507 of the PC rule for animal food, but that is not required to comply with the CGMP requirements in subpart B of 21 CFR part 507.** Compliance dates when foreign suppliers are in these categories:
  - Small Businesses as defined in 21 CFR 507: **March 18, 2019**
  - Qualified Facilities (including Very Small Businesses) as defined in 21 CFR 507.3: **March 17, 2020**
  - "All Other" Businesses: **March 19, 2018**

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Compliance Dates

- **FSVP importer whose foreign supplier is required to comply with the produce safety rule**, except for the requirements applicable to sprouts in subpart M of 21 CFR part 112. Compliance dates when foreign suppliers are in these categories:
  - Small Businesses as defined in 21 CFR 112.3: **July 29, 2019**
  - Very Small Businesses as defined in as defined in 21 CFR 112.3: **July 27, 2020**
  - "All Other" Businesses: **July 26, 2018**
- **FSVP importer whose foreign supplier is required to comply with the requirements in the produce safety rule applicable to sprouts in subpart M of 21 CFR part 112**. Compliance dates when foreign suppliers are in these categories:
  - Small Businesses as defined in 21 CFR 112.3: **July 26, 2018**
  - Very Small Businesses as defined in 21 CFR 112.3: **July 29, 2019**
  - "All Other" Businesses: **July 26, 2017**
- **FSVP importer whose foreign supplier is subject to the produce safety rule and eligible for a qualified exemption** (other than when the foreign supplier is a farm producing sprouts). Compliance dates when foreign suppliers are in these categories:
  - Small Businesses as defined in21 CFR 112.3: **July 29, 2019**
  - Very Small Businesses as defined in 21 CFR 112.3: **July 27, 2020**
- **FSVP importer whose foreign supplier is a farm producing sprouts that is eligible for a qualified exemption under the produce safety rule**. Compliance dates when foreign suppliers are in these categories:
  - Small Businesses as defined in21 CFR 112.3: **July 26, 2018**
  - Very Small Businesses as defined in 21 CFR 112.3: **July 26, 2019**

A Picture Paints a Thousand Words

Resources

Manage Recordkeeping & Documentation with Ease

- Digitized Records:
  - Store records in a secure cloud for access in minutes
- Secure Documentation:
  - Protected electronic records that meet requirements for electronic records
- Employee Training:
  - Qualified Individual training in one system
- Documentation Review:
  - Expert industry consulting for gap analysis, practice audits, etc.

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Upcoming Webinars

November 30

10 AM Pacific | 12 PM Central | 1 PM Eastern

Waste Not, Want Not: Strategies to Reduce Waste for Increased Profitability

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across the country

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Q & A

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THANK YOU

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