FSMA Overview: FDA’s goals for the law and the broad effects it has on food and supplement brands

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About CPC

Specialized in regulatory compliance, safety and quality systems, product development, and project management in the food, dietary supplements, and cosmetics and personal care industries, helping domestic and international clients to market their products in the United States, and stay complaint and competitive.

Founded in 2007
Agenda

► FSMA Overview
► Significant Effects on Food and Supplement Brands
► Highlights of FSMA Rules Mostly Applied to Food and Supplement Brands
  ► Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (PCHF) (CFR 117)
  ► Foreign Supplier Verification Programs (FSVP) (CFR 1, Subpart L)
  ► Mitigation Strategies to Protect Food Against Intentional Adulteration (IA) (CFR 121)
► Dietary Supplements and FSMA
► Compliance/Enforcement Status
FSMA Overview

Food Safety Modernization Act (FSMA)

- Signed into law by President Barack Obama on January 4, 2011.
- Comprehensive and systematic overhaul of the nation food safety regulations in over 70 years
- Transforming the nation’s food safety system by shifting the focus from responding to foodborne illness to preventing it.
- Grants the FDA new authorities to regulate the way foods are grown, harvested and processed.
- The FDA published 8 fundamental regulations
FSMA Rules and Programs

- **Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (PCHF) (CFR 117)**
- **Foreign Supplier Verification Programs (FSVP) (CFR 1, Subpart L)**
- **Mitigation Strategies to Protect Food Against Intentional Adulteration (IA) (CFR 121)**
- **Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (PCAF) (CFR 507)**
- **Sanitary Transportation of Human and Animal Food (ST) (CFR 1, Subpart O)**
- **Accredited Third-Party Certification**
- **Voluntary Qualified Importer Program (VQIP)**
- **Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (PS) (CFR 112)**
FSMA’s Broad Effects on Food and Supplement brands

**Prevention & Risk-Based**

- Domestic and foreign companies mandated to have comprehensive, prevention-based controls across the supply chain:
  - Mandatory produce safety standards (CFR112)
  - Mandatory prevention against intentional adulteration (CFR121)
  - Mandatory inspection frequency based on risks
  - Record access
  - Testing by accredited laboratories
- Close the gap between dietary supplement and dietary supplement ingredients
FSMA’s Broad Effects on Food and Supplement brands

More Authorities Allow FDA Reacts to Food Safety Problems Faster

- Mandatory recall (when a company fails to voluntarily recall unsafe food)
- Expanded administrative detention
- Suspension of registration
- Additional Recordkeeping for high risk foods
FSMA’s Broad Effects on Food and Supplement Brands

Import Requirements

- **Importer accountability (FSVP):** For the first time, importers are held responsible to verify their foreign suppliers produce products meet the U.S. food safety standards through FSVP.

- **Third party certification:** Qualified third parties can certify that foreign food facilities comply with U.S. food safety standards.

- **Certification for high risk foods:** High-risk imported foods are required to be certified by a credible third party or to be assured compliance as a condition of entry into the U.S.

- **Voluntary qualified importer program (VQIP):** A voluntary program that participating importers are provided for expedited review of imported food.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (21CFR117)

Key Requirements

► cGMP Updates (21CFR110)
  ► Binding provisions of education, training, and qualified personnel
  ► Requirements for allergen cross-contact
  ► Provision for holding and distribution of human food by-products for animal food

► FOOD SAFETY PLAN
  ► Hazard analysis
    ► Identify reasonably foreseeable, unintentionally/intentionally introduced hazards (biological, chemical/radiological, and physical)
    ► Must have and implement written preventive controls for the identified hazards.
  ► Preventive controls Must be written and implemented to ensure hazards requiring a preventive control to be significantly minimized or prevented
    ► Process controls
    ► Food allergen controls
    ► Sanitation controls
    ► Other Controls
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (21CFR117)

Key Requirements

- Oversight and management of preventive controls must make sure that the controls are being met
  - Monitoring: Ensure that preventive controls are consistently and appropriately performed.
  - Corrections: Timely steps taken to identify and correct a minor, isolated problem that occurs during food production.

- Corrective actions:
  - Identify and correct a problem implementing a PC
  - Reduce the likelihood the problem recurring
  - Evaluate effects on food safety
  - Prevent food that cannot be ensured safe from entering commerce
  - Must be documented with records.

- Verification:
  - Ensure that preventive controls are consistently implemented and effective in minimizing hazards
  - Must be documented
  - Includes product testing and environmental monitoring.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (21CFR117)

Key Requirements

▶ Supply chain program  Must have and implement a risk-based supply chain program if the hazard analysis identifies a hazard that (1) requires a preventive control and (2) the control will be applied in the facility’s supply chain.
  ▶ Use approved suppliers
  ▶ Determine appropriate supplier verification activities and frequency
    ▶ On-site audit
    ▶ Sampling and testing of raw material
    ▶ Review relevant food safety records
    ▶ Other appropriate verification activities
  ▶ Conduct supplier verification activities
  ▶ Document supplier verification activities

▶ Recall plan

▶ Compliance Dates
  ▶ Very small business (< $1 M Sales) - September 17, 2018
  ▶ Small business (< 500 employees) - September 18, 2017
  ▶ Large business - September 19, 2016
Foreign Supplier Verification Programs (FSVP) (CFR 1, Subpart L)

Key Requirements

1. Scope

- Who is covered by the rule?
  - An importer - the U.S. owner/consignee of a food offered for import into the United States.
  - If no U.S. owner/consignee, the importer – the U.S. agency or representative of the foreign owner/consignee at the time of entry, as confirmed in a signed statement of consent.
  - Exemptions

- What is an FSVP? An importer must verify that its foreign suppliers to ensure that the food they produce meet the U.S. food safety standards

- Responsibilities of FSVP Importers
  - Determine known or reasonably foreseeable hazards with each food
  - Evaluate the hazard risks and the foreign supplier’s performance
  - Determine appropriate supplier verification activities
  - Conduct supplier verification activities
  - Conduct corrective actions

- Must import food only from approved foreign suppliers or temporarily from unapproved suppliers whose foods have been verified safe before being imported.
Foreign Supplier Verification Programs (FSVP) (CFR 1, Subpart L)

Key Requirements

1. Scope

- FSVP is required for each food from its foreign supplier
  - If the importer obtains a certain food from a few different suppliers, a separate FSVP would be required for each of those suppliers.
  - If the importer obtains many different foods from a single supplier, a separate FSVP would be required for each food from the same supplier.

- Certain importers that are also manufacturers/processors are deemed in compliance with most FSVP requirements if:
  - in compliance with the supply-chain program under the PC rules;
  - implement PCs for the hazards in the food in accordance with PC rules;
  - not required to implement PCs in certain specified circumstances (e.g. coffee beans)

- Re-evaluate the supplier’s performance at least every three years, or when new information occurs about a potential hazard or the foreign supplier’s performance.

- Not required to evaluate the food and supplier or conduct supplier verification activities if they receive adequate assurances that a subsequent entity in the distribution chain is processing the food to meet applicable food safety requirements.
Foreign Supplier Verification Programs (FSVP) (CFR 1, Subpart L)

Key Requirements

2. Hazard Analysis

- Identify and evaluate the known or reasonably foreseeable hazards (incl. intentionally/unintentionally introduced hazards) for each type of food and determine if any control is required.
- Assess the probability that the hazards occur if controls are absent and the severity of the illness or injury the hazards could cause.
- Factors to consider: 1) Formulation 2) Condition/Function/Design of the facility/equipment 3) Materials/Ingredients 4) Transportation practices 5) Harvesting/Raising/Manufacturing/Processing/Packing procedures 6) Packaging and labeling activities 6) Storage and distribution 7) Intended or reasonably foreseeable use 8) Sanitation and hygiene
- Can rely on a third party’s hazard analysis and must review and assess the relevant documentation.

3. Evaluation of Food Risk and Supplier Performance

Must evaluate:
- The hazard analysis
- Risks/hazards significantly minimized or prevented
Foreign Supplier Verification Programs (FSVP) (CFR 1, Subpart L)

Key Requirements

3. Evaluation of Food Risk and Supplier Performance
   Must evaluate:
   ► The foreign supplier’s food safety plan and practices
   ► The foreign supplier’s compliance to applicable FDA food safety regulations
   ► The foreign supplier’s food safety history
   ► Other factors as necessary, including storage and transportation practices.
   Can rely on a third party’s evaluation (not the foreign supplier) and must review and assess the relevant documentation.

4. Supplier Verification
   ► Verification options based on the food risks and the supplier performance: 1) Annual on-site audit 2) Sampling and testing 3) Review relevant food safety records
   ► Can rely on a third party’s verification (not the foreign supplier) and must review and assess the relevant documentation.

5. Corrective Actions
   Must promptly take appropriate corrective actions if the food is determined adulterated or misbranded
Foreign Supplier Verification Programs (FSVP) (CFR 1, Subpart L)

Key Requirements

6. Exemptions and Modified Standards
  ▶ Dietary Supplement
    ▶ Importers who are required to establish and verify components specifications under 21CFR111 are not required to comply with most of the standard FSVP requirements.
    ▶ Importers whose customers are required to establish and verify components specifications under 21CFR111 would have to obtain written assurance from its customers assuring that they are complying with those requirements.
    ▶ Importers of finished products required to comply with most of the standard FSVP requirements (except the hazard analysis requirement), but focus on verification requirements under 21CFR111
  ▶ Very Small Importers and importers of food from certain small suppliers
  ▶ Modified requirements for certain foods from country with food safety system equivalent of the United States’ system (New Zealand and Canada)
  ▶ Certain categories of imported food are not covered by FSVP

7. Unique Facility Identifier (Duns)
Foreign Supplier Verification Programs (FSVP) (CFR 1, Subpart L)

Key Requirements

8. Compliance Dates:
   ▶ Very complicated, check FSMA Compliance Dates published on FDA website

Update

FDA Published List of Records Required Under FSVP on October 7, 2019
Mitigation Strategies to Protect Food Against Intentional Adulteration (IA) (CFR 121)

**Purpose**
Protect the food supply against intentional contamination due to sabotage, terrorism, counterfeiting, or other illegal, intentionally harmful means.

**Who is covered?**
- Domestic/foreign companies who are required to register with the FDA as food facilities.
- Some exemptions

**Key Provisions**
Each covered facility is required to prepare and implement a food defense plan, which includes
- Vulnerability assessment
- Mitigation strategy must have monitoring, corrective actions and verification procedures
- Training and recordkeeping

**Compliance Dates**
- Large business (≥ $10 M sales or ≥ 500 employees) July 26, 2019
- Small business (< 500 employees) July 27, 2020
- Very small business (< $10 M Sales) July 26, 2021
## Dietary Supplement (DS) and FSMA

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<tr>
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1. DS is subject to Subpart A, B, and F
2. Depending on the types of operation, DS is subjected to various parts of FSVP
3. Not required by law, could be required by customers, retailers, or third-party certifications
Dietary Supplement (DS) and 21CFR117 (PCHF)

Subject to:
▶ Subpart A – General Provisions: PCQI Training Requirement
▶ Subpart B – Current Good Manufacture Practice: Allergen Cross-Contact
▶ Subpart F – Requirements Applying to Records That Must Be Established and Maintained

Exempted from:
▶ Subpart C – Hazard Analysis and Risk-Based Preventive Controls
▶ Subpart G – Supply-Chain Program

Must Verify/Qualify Suppliers:
▶ DS Suppliers based on 21CFR111
▶ Ingredient Suppliers based on 21CFR117
# Dietary Supplement (DS) and FSVP

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<tr>
<th>Section</th>
<th>Requirement</th>
<th>§1.511(a) Importer - DS GMP Manufacturer&lt;sup&gt;1&lt;/sup&gt;</th>
<th>§1.511(b) Importers' Customer - DS GMP Manufacturer&lt;sup&gt;1,2&lt;/sup&gt;</th>
<th>§1.511(c) Foreign Supplier - DS GMP Manufacturer&lt;sup&gt;3&lt;/sup&gt;</th>
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<td>Maintenance of Records</td>
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<sup>1</sup> Subject to certain dietary supplement cGMP regulations who is required to establish and verify component specifications (21 CFR 111.70(b) (s) or (d), 111.73 and 111.75

<sup>2</sup> Obtain written assurance from customer ensuring compliance applicable sections of 21 CFR part 111 annually (FDA clarification not available yet)

<sup>3</sup> Neither §1.511(a) nor §1.511(b)

<sup>4</sup> Subject to 1.505(a)(1)(ii) through (iv), (a)(2), and (b) through (d)
Compliance and Enforcement Status

FDA Inspection Citation Details on FDA Data Dashboard (as of July 17, 2019)

- FSMA referenced inspection and enforcement started in 2017
- 764 citations referenced to 21CFR1 Subpart L FSVP
  - 532 companies (about 70% of total citations) “fail to develop a written FSVP”, among them were well known nation-wide retailers, distributors, and brands.
- 4084 citations referenced CFR117
  - 875 citations related to Hazard Analysis and Risk-based Preventive Controls and Supply-Chain Program (Subpart C-G)
  - The data indicated that FSVP and Preventive Control are the two main observations during FDA inspections

- Significant Observations in FSVP and PCHF

First Two FSVP Warning Letters

- Agroson's LLC August 26, 2019 - multistate outbreaks of *Salmonella* involving whole, fresh papayas
- Brodt Zenatti Holdings LLC July 30, 2019 - Salmonella Concord multi-state outbreak from imported tahini from West Bank
FSMA Compliance Capability in Food and Supplement Brands

► A Long Way To Go

► Education through training
  - Understand which regulations apply to your business - multiple new regulations in FSMA covering food safety system across the entire supply chain “from farm to table”
  - Ultimately responsible for getting trained
  - Top management’s commitment to FSMA compliance is critical
  - Training throughout the operation

► Determine the most effective approach
  - Internal Capability
  - Outsourced Capability
  - Combination
FSMA Compliance Resources

Food Safety Plan Builder
https://www.cfsanappsexternal.fda.gov/scripts/foodSafetyPlanBuilder/

FSMA Rules & Guidance for Industry

FSVP Fact Sheet:

FSMA TAN POPULAR TOPICS
https://www.fda.gov/media/119823/download

Technical Assistance Network (TAN)

Training & Materials on Preventive Controls for Human Food (FSPCA)
https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-human-food
Questions?

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FSMA Violations and Changing Expectations with FDA

Presented by Coley Anderson
Registrar Corp
Brief Overview

• FDA and FSMA Enforcement
• Common Citations for FSMA Violations
• Understanding What is Expected
• Preventive Controls
• FSVP
• Summary / Questions & Answers
Let’s Begin...

FDA and FSMA Enforcement
FDA FSMA Enforcement

- Food Safety and Modernization Act (FSMA) aims to shift the focus of food safety from reacting to prevention.
- FSMA requires most food facilities to have a Food Safety Plan, Supplier Verification, and Monitoring of Preventive Controls.
- FDA is beginning to enforce FSMA now that most compliance dates have passed.
Compliance deadlines for all covered human food facilities have passed.

Preventive Controls:
- Facilities with >500 full-time equivalent employees: September 19th, 2016
- Small businesses (<500 employees): September 18th, 2017
- Very small businesses/qualified facilities: September 17, 2018

FSVP Importer Rule:
- Supplier is a large business: May 30, 2017
- Supplier is a small business: March 19, 2018
- Supplier is a very small business/qualified facility: March 18, 2019

Expect more enforcement now that these dates have passed!
What is FDA doing now?

Common FSMA Violations
How does FDA enforce FSMA?

• Facility inspections
• Audit of importers
• Failure to comply may result in one or more of the following:
  – FDA Warning Letters
  – Recalls
  – Detentions and Refusals in Port
  – Import Alerts
  – Suspension of registration
  – Civil and criminal charges
  – Collateral damage to company image
FDA Inspections

• Under FSMA, FDA is increasing the total number of inspections annually
• Foreign facilities and their U.S. Agents will receive a **Notice of Inspection** via email
• Domestic facilities receive **no advanced notice** of inspection
FDA Inspections

- Inspections typically last 2 days
- Day 1:
  - Opening meeting
  - Quick tour
  - Document Review (includes Food Safety Plan)
- Day 2:
  - Factory inspection
  - Closing meeting
  - Delivery of form 483 “Inspectional Observations”
FSMA Foreign Facility Inspection Schedule

- 2011- 600 Foreign Inspections
- 2012- 1,200 Foreign Inspections
- 2013- 2,400 Foreign Inspections
- 2014- 4,800 Foreign Inspections (only completed 1,327 total in 2014)
- 2015- 9,600 Foreign Inspections
- 2016- 19,200 Foreign Inspections

NOTE: FDA is increasing the number of inspections globally. No one country, region, or company is being targeted for inspection.
Common FSMA Violations

• In FY 2018, FDA issued 2583 citations during inspections
• FDA cited 278 U.S. importers for not developing a FSVP
• Most common FSMA related Violation up from 108 in FY 2017

FSVP Violations more than doubled!
Common FSMA Violations

FDA issued 396 citations during inspections relating to Preventive Controls violations in 2018. These include:

- Not having a HARPC Food Safety Plan
- Not identifying all hazards and establishing controls
- Not having a PCQI
- Not monitoring sanitation/allergen controls
- Improper record-keeping
Common FSMA Violations

¼ of all inspection violations in 2018 are FSMA related!!!

Inspection Violations

- Preventive Controls: 74%
- FSVP: 11%
- Other: 15%
Warning Letters

• As recently as August 2019, FDA is issuing warning letters for FSMA violations
• Facilities must respond to warning letters within 15 days or receive other regulatory action (i.e. import alerts, etc.)
• Reasons for receiving warning letters:
  – Failure to develop a HARPC Food Safety Plan
  – Leaving out a component of a Food Safety Plan (i.e. environmental controls, allergen controls, etc.)
  – Not properly implementing the Food Safety Plan at the facility
  – Not having a FSVP
How do I prevent a violation?

Understanding What is Expected
Understanding What is Expected

• FDA believes education is key
• FDA seeks to help a facility understand what is expected of them when issuing a citation
• Many facilities are not used to the new rules
• Many importers do not realize they are under the new rule or fail to develop a new program
Exemptions

• Exemptions and modified requirements:
  – Retail establishments (restaurants and stores)
  – Qualified facilities (less than $1 million annually)
  – Juice and Seafood HACCP
  – Alcoholic beverages
  – Dietary supplements
  – USDA products
  – Farms
  – Unexposed, packaged food in warehouses

If you do not fall under these, you need a Food Safety Plan and Supplier Verification!
Avoiding inspection citations

Preventive Controls Rules
Many manufacturers have BRC, ISO 22000, GFSI, HACCP, etc. HARPC is a new standard- none of these auditing schemes cover Food Safety Plans

• **HACCP**
  - Preventive controls to ‘Critical Control Points’

• **HARPC**
  - Allergen controls
  - Sanitation controls
  - Supply chain controls
HARPC Food Safety Plan Components
Every Component is required for a complete Food Safety Plan!

- Hazard Analysis
- Preventive Controls
- Supply Chain Program
- Recall Plan
- Monitoring Procedures
- Verification
- Corrective Action
- Record-keeping

Food Safety Plan Components
Preventive Controls

• Food Safety Plan must be written by a “Preventive Controls Qualified Individual” (PCQI)
  – Must receive training or be otherwise qualified through job experience to develop and apply a Food Safety Plan
• Plan must be signed by the owner or managing agent of the facility
Preventive Controls

• Risk Analysis
  – Identify and evaluate the risks associated with a certain food
    • Naturally occurring
    • Unintentionally introduced
    • Adulteration for economic gain
  – Biological, chemical (including radiological), and physical
    • You must identify all hazards for a complete Food Safety Plan; consider all possibilities
Preventive Controls

- **Biological Hazards** - harmful microorganisms (bacteria, viruses, parasites) from environment or inadequate sanitation; be aware of cross contamination
- **Chemical/Radiological Hazards** - pesticides, chemicals introduced during manufacturing, unapproved food additives
- **Physical Hazards** - extraneous materials (metals, plastic, wood chips, glass, etc.)
Preventive Controls

• Preventive Controls
  – Steps to ensure food is handled in a sanitary manner
  – Eliminate or reduce the hazards associated with the foods
  – Examples
    • Sanitation Controls
    • Process Controls
    • Allergen Controls
    • Recall Plan
    • Supply Chain Program

• Sanitation Controls and Allergen Controls are common violations; be aware
Preventive Controls

- **Process Controls**- any procedure at the facility, e.g. making sure temperatures are maintained or properly acidifying or irradiating a product

- **Food Allergen Controls**- preventing allergen cross-contact during storage, handling; having proper allergen warnings on label

- **Sanitation Controls**- maintain cleanliness of any food contact surface, equipment, or utensils

- **Other Controls**- consider all procedures and practices, e.g. hygiene training, etc.
Preventive Controls

• Supply Chain Program
  – Verify controls applied by your suppliers
  – Put controls in place for uncontrolled hazards
  – Only use approved suppliers
  – Determine adequate supplier verification activities
  – Documentation
Preventive Controls

• PC Management Components
  – Verification
    • Validate controls
    • Verify monitoring and corrective actions
    • Calibrate instruments
    • Product sampling and testing
    • Record review
Preventive Controls

• PC Management Components
  – Monitoring
    • Procedures to monitor the preventive controls
    • Performed with adequate frequency
    • Recordkeeping
    • Reassess after any production change
Preventive Controls

Monitoring depends on the product at the facility. Examples of monitoring:

• Temperature during heat/cooling processes
• pH levels
• Moisture levels
• Pressure levels or flow rates
Preventive Controls

• PC Management Components
  – Corrective actions
    • What to do in case of a non-compliance
  – Recordkeeping
    • Maintain records for at least two years after their creation
Preventive Controls

Documentation required for:

• Basis for not establishing a control for an identified hazard
• Monitoring preventive controls
• Any corrective actions taken
• All verification activities including reanalysis of the Food Safety Plan
• All relevant training for employees and PCQIs
Follow Your Food Safety Plan

• Once you have developed your Food Safety Plan, it is important to continually follow it
• Incorporate your Preventive Controls into your company’s SOPs
• Failing to do so could result in FDA action, such as warning letters

Example from FDA Warning Letter:

4. You did not implement a preventive control, as required by 21 CFR 117.135(a). Specifically, your food safety plan dated [redacted], contains the preventive control of “run order of allergenic materials” for the food safety hazard of “food allergens from other products.” However, during the inspection, our investigators did not observe this control, and their review of your records indicated you do not have a schedule in place to run a specific order of allergenic materials.
Avoiding inspection citations

Foreign Supplier Verification Program (FSVP)
• Persons who import food into the U.S. are required to perform risk-based foreign supplier verification activities to verify that:
  – Food is produced in compliance with the applicable FDA regulations (e.g. Preventive Controls rules and Current Good Manufacturing Practices)
  – Food is not adulterated
  – Food is labeled properly with respect to allergens
FSVP

• FSVP Rule defines importer as the U.S. owner or consignee of an article of food at time of entry
  – If there is no U.S. owner or consignee, the importer is the U.S. agent or representative of the foreign owner or consignee, as confirmed in a signed statement of consent.
  – FSVP Importer must be in the United States
  – Different than the importer of record
    • Same person may act as both but not necessarily
FSVP

• Importers must establish and follow written procedures to only import food from their approved suppliers
• Need to develop and maintain an FSVP for each food brought into the U.S.
• Evaluation of risk and supplier’s performance must be reevaluated every 3 years
• Examples of verification:
  – On-site audits of the supplier’s facility
  – Sampling and testing
  – Review of the supplier’s food safety records
Each Component is required for a complete FSVP!
Summary

• FDA beginning to more strictly enforce FSMA rules
• Knowing what to do is key to avoiding a citation
• Can be involved, but essential to a successful business
Registrar Corp’s Solutions

- Registrar Corp provides a full range of fixed-fee compliance services:
  - Registration & U.S. Agent Service
  - Prior Notice Filings
  - Label, Ingredient, and Product Review
  - FSMA Compliance Services
  - Mock Inspection Service
  - Detention Assistance
  - DWPE Petition Submissions
  - FDA Compliance Monitor (Verify your suppliers)
Let us be your resource on FDA regulation.

Questions & Answers
Contact Us

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SUPPLY SIDE WEST – FSMA COMPLIANCE

October 16, 2019
Who is Kestrel

- Consulting and Advisory Firm
  - Focus on Food Safety
    - Compliance, FSMA, FSVP, IA, Food Defense, GFSI, audit readiness, Supply Chain, Internal Audits, Supply Chain and Supplier audits, Label Review, Training, programs development, etc.
    - Dietary Supplements experience with multiple manufacturers, branded products, distributors, ingredients, flavors, packaging for FDA compliance, Certificates of Free Sale, Plant Commissioning, training
  - Environmental, Health & Safety
  - Data Management
FSMA Issues and Impacts

- Presents Program Decision Challenges
- Food Compliance to FSMA Section 117 and/or Dietary Supplements Section 111
- FSMA Section 111 GMP’s for Dietary Supplements Only Facilities
- Dual Jurisdiction for Food and Dietary Supplement Facilities
- All other FSMA Requirements Must be Met
Definitions Dietary Supplement/Food

- A **dietary supplement** (or **food supplement** or **nutritional supplement**) is anything taken by mouth which helps enhance **food** that a person or animal eats. It can be in pill, powder, or a liquid form. The **supplement** provides nutrients such as vitamins, minerals, fiber, fatty acids, or amino acids.
  - Covered by 21 CFR Section 111 GMPs and FSMA FDA

- **Food** is any substance consumed to provide nutritional support for an organism. It is usually of plant or animal origin, and contains essential nutrients, such as carbohydrates, fats, proteins, vitamins, or minerals.
  - Unless exempt covered under FSMA Section 117 cGMPs
FSMA Issues and Impacts

Requirements

- Food Companies Must Determine What Applies for FSMA
- They Also Must Determine What Does Not Apply
- All Must be Documented and Recorded
- Justification Must Be Established
- FSMA Requires This
- Dietary Supplements Requires the Specifics of Section 111 (Test and Approval of All Stages of Production)
Food Safety Plan

Includes:

- Hazard Analysis and Preventive Controls
- Food Safety Team
- Qualifications
- PCQIs
- Internal Audit Resources
- Qualified Sanitation Management
FSMA Requirements

- Establishing a “fixed” position of a PCQI within the organization of a food processor or distributor
- Oversight of the development of all of the related FSMA requirements of a company or site
- Having proper qualifications, including education and experience along with current certifications
- The role and responsibility of multiple resources to cover operations at all times
- Supported by Audit and Sanitation Resources
HACCP/PCQI Food Safety Plans

- Understanding the relationship between FSMA, Section 111, HACCP and food safety systems
- FSMA Section 117 cGMP’s, and DS Section 111 Applications
- Importance of SOP’s, cGMP’s, and SSOP’s
- PCHF HACCP concepts & hazard categorization
- Seven principles/12 steps required for HACCP
- Flow chart, diagram requirements and critical equipment of process and products
HACCP/PCQI Role

- Proper methods to establish critical limits, preventive measures, validation of critical control points and monitoring requirements.
- Proper methods to establish critical limits, preventive measures, validation of CCP’s and monitoring requirements.
- Process, requirements and importance of effective record keeping.
- Effective HACCP program verification processes and procedures.
PCQI Qualification Requirements

- Training - A **PCQI** is a *qualified* individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by **FDA** or be otherwise *qualified* through job experience to develop and apply a food safety program administration.

- Job and industry experience in food safety that can be demonstrated to be a **PCQI**

- Capability to contribute and oversee the FSMA FSP to Section 117 requirements and Dietary Supplements Section 111

- Capability to oversee the other related FSMA rules like FSV
PCQI Role Validation

- Have you established a program to “vet” and validate your PCQIs under FSMA and Dietary Supplements?
- Does PCQI status include the verification of full qualifications to FSMA and Dietary Supplements as determined?
- Following accepted PCQI training has a process been established to verify the capability of your PCQIs?
- Have you qualified an Audit process and trained auditors to meet these requirements of your FSMA Food Safety Plan?
- Have you determined and documented the specific Food Safety Plan role of your PCQI including decision making?
- How is Internal Audit and Sanitation Addressed?
Foreign Supplier Verification Program (FSVP) QI

- Knowledge to implement the requirements of the ‘Foreign Supplier Verification Program’ for
  - Importers of Food for Humans and Animal regulation of the US Food & Drug Administration
  - Regulation and guidance that implements the provisions of the Food Safety Modernization Act (FSMA)
- Oversees US based importers who meet the definition of ‘importer’ in the FSVP rule.
  - For consignee of food at time of entry or US agent or representative of the foreign owner
Foreign Supplier Verification Program (FSVP) Requirements

- FSMA FSVP requires US food importers to implement plans to ensure compliance of foreign suppliers to FSMA requirements
- Including Registration with FDA to make shipments
- Foreign suppliers must be in good standing
- Importers must ensure that the Foreign Suppliers maintain FSMA compliant food safety plans
- Foreign Suppliers must ensure that the food safety requirements of the customer programs are met
Foreign Supplier Verification Program
Training

- FSMA FSVP that US companies using products from outside the US are trained in the FSMA requirements, including Dietary Supplements
- That US companies using imported food product have been properly educated in management of the import process and importers
- That importers of food may be a third-party supplier, and internal supplier or direct import
- That programs for foreign supplied materials meet or follow the US Domestic food safety plans
Foreign Supplier Verification Programs Qualifications

- Importers and US companies must develop and implement FSV programs for FSMA and DS
- Programs must demonstrate the requirements of importer and foreign supplier qualifications
- Programs must be in-place prior to the scheduling of a foreign supplied material
- Must validate the FSV program, importer programs, foreign supplier and ensure they all meet requirements
- Require documentation requirement for shipments
FSVP Validation

- Audit and implement an assessment, verification and validation process?
- Establish document requirements for each level in the supply chain to qualify working with these entities?
- Importer qualification must include they have established a qualified individual function/role?
- Foreign suppliers are suspended by the US for reasons including lack of site inspection?
- Importers and FS’s must allow shipment inspection?
Additional FSMA Rules

- Food Defense Assessment and Controls
  - 2019 Instatement & 2020 Enforcement
- International Adulteration Vulnerability and Plan
  - 2019 Instatement & 2020 Enforcement
- Environmental Monitoring Program
  - Current Requirements
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The Foreign Supplier Verification Program (FSVP) and International Rules for the Supplement Sector

Claudia Lewis
Partner, Venable LLP
202.344.4359
CALewis@Venable.com
General FSVP Requirements

- A written hazard analysis evaluating the risks posed by a food and the foreign supplier’s performance
- Supplier verification activities to allow the importer to approve the foreign supplier
- Corrective actions and recordkeeping
- Must be implemented by a qualified individual who has appropriate training and experience
Exemptions

**EXEMPTIONS INCLUDE:**

- Qualified facilities (small importers) - subject to modified requirements
- Activities subject to seafood, juice, and LACF HACCP requirements
- **GMP-compliant dietary supplement facilities**
- Farms; low-risk activity/food combinations performed by farm mixed-type
- Alcohol beverage facilities
- Food imported from a country with an officially recognized U.S.-equivalent safety system (e.g., New Zealand)
What is a dietary supplement for the purposes of FSVP?

FD&C Act Section 201(ff): A food intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

- A vitamin
- A mineral
- An herb or other botanical
- An amino acid
- A dietary substance for use by people to supplement the diet by increasing the total dietary intake, or
- A concentrate, metabolite, constituent, extract, or combination of the above

Also, under FSVP definition (21 CFR 1.500), a dietary supplement component is any substance intended for use in the manufacture of a dietary supplement, including dietary ingredients.
Why are dietary supplements treated differently than foods by FSVP?

Supplements in compliance with CGMP (Part 111) already meet many FSVP requirements. Under the CGMP, manufacturers of supplements are required to:

- Establish specifications for each component used in manufacturing to ensure identity, purity, strength, composition, and freedom from contamination (111.70(b))
- Establish specifications for labels and packaging that may come into contact with supplements to ensure that such packaging is safe and suitable for intended use (111.70(d))
- Ensure that the above requirements are met (111.73)
- Take steps to ensure that the requirements are met (111.75)
Why are dietary supplements treated differently than foods by FSVP?

Therefore, FDA believes that “compliance by the importer (or its customer) with these specification and verification provisions in the dietary supplement CGMP regulation provides adequate assurances that foreign supplier of the dietary supplement or dietary supplement component produced it in compliance with the FD&C Act” and “[t]herefore, imposing additional supplier verification requirements…would be redundant and unnecessary”

- FSVP Draft Guidance For Industry
### FSVP Requirements by role (1.511)

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Importer of DS components and manufactures/processes in compliance with CGMPs</th>
<th>Company whose customer must establish specifications for DS components under CGMPs</th>
<th>Importer of finished DS products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Written assurance of compliance from customer</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Use qualified individuals</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Identify importer at entry</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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## FSVP Requirements by role (1.511)

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<td>Records requirement</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Other</td>
<td>-</td>
<td>-</td>
<td>Must also (1) evaluate the DS and foreign supplier performance, (2) approve foreign supplier, (3) implement your FSVP, and (4) take corrective actions</td>
</tr>
</tbody>
</table>
General Statistics

For FY 2018 (most current data on FDA website), FDA noted the following number of inspection observations:

- Failure to develop an FSVP (278 citations)
- Failure to develop an FSVP - very small importer or importer from small supplier (11 citations)
- Did not keep required FSVP record (4 citations)
- Did not make record available (2 citations)
- Did not maintain/follow FSVP (2 citations)
- Did not sign/date FSVP (2 citations)
- Did not provide English translation of FSVP record (1 citation)
- Did not provide adequate assurances that foreign supplier is producing food in compliance with processes and procedures that provide required level of public health protection (1 citation)
Only 1 FSVP Warning Letter to Date: Brodt Zenatti Holdings LLZ (7/30/19)

- Firm was involved in the multi-state outbreak of *Salmonella* Concord in tahini
  - FDA identified Karawan brand tahini as the likely source of the outbreak
- Did not develop an FSVP as required by section 805 of the FD&C Act and 21 CFR part 1 subpart L
  - Specifically, did not develop an FSVP for sesame paste tahini manufactured by Karawan Tahini and Halva in the West Bank
- FDA issued a Form FDA 483a to the firm at the close of the inspection
  - Note: FDA issues Form 483a (“FSVP Observations”) for FSVP inspection violations instead of the normal Form 483
Best Practices

- Identify the right people:
  - FSVP Importer
  - Qualified individual

- Maintain the right documentation
  - Written assurance (if necessary)
  - Required records

- Continue compliance with applicable CGMPs for dietary supplements
Conclusion

QUESTIONS?
FDA Audit Focus, Mock Audit, and Qualified Individual Importance

By Earl Arnold, AIB International
Global Manager Food Defense/FSMA
Agenda

- FDA Inspections
  - High risk
  - FSMA focus
- Qualified Individual’s Roles in FDA inspections
  - Preventive Controls Qualified Individual (PCQI)
  - Qualified Individuals
  - Qualified Auditors
- Mock Audits
  - Regulatory inspection policy
  - Photos
  - Samples
  - Interviews
FDA’s Goal and Objective

- Reduce the risk of illness or injury attributed to food manufactured and distributed from facilities subject to FSMA
  - Domestic
  - Imported
- FDA’s implementation mantra: “to educate before it regulates”
FDA Inspections

- Inspections performed by:
  - FDA personnel
  - State personnel
  - Accredited third parties
  - Individual inspector
  - Large team of inspectors
Question

- When is an Inspection Required?
Answer

- Routine Basis
  - Increased frequencies
  - Frequency determined by risk
- For Cause
  - Lower threshold
  - Used to require “credible evidence”
  - Now only needs “reason to believe”
High Risk Foods

FDA Class 1 & 2 Recalls

Severe Adverse Health Consequence or Death in Humans or Animals (SAHCODHA)

- Salmonella, 50 (25%)
- Listeria monocytogenes, 38 (19%)
- Undeclared Allergens, 95 (47%)
- Nutrient Imbalance, 8 (4%)
- Undeclared Sulfites, 5 (2.5%)
- E. coli, 2 (1%)
- Drug Contamination, 2 (1%)
- Lead, 1 (0.5%)
What Happens in an Inspection?

- Inspector has authority to
  - Inspect during normal business hours
  - Take samples
  - Take photos
- Inspector must present
  - Credentials
  - Form 482
- Facility provides
  - Designated, trained escorts
  - Overview of policies and GMPs
What Happens in an Inspection?

- More assertive and comprehensive
  - Prior to FSMA, FDA was insistent on accessing records
  - FDA is asserting “right” to take photographs and review records
  - Inspections becoming more detailed, emphasizing:
    - Basic sanitation
    - Allergen control
    - Personnel adherence to GMPs
Regulatory Expectations

- FSMA audits are more in-depth
  - Hazard analysis conclusions
  - Allergen controls
  - Environmental monitoring
  - Qualified individuals
  - Following your plan

- Includes all FSMA regulations
  - Preventive Controls
  - Sanitary Transportation Act
  - Foreign Supplier Verification Act
  - Intentional Adulteration Regulation
Qualified Individuals

- A person who has the education, training, or experience (or combination) necessary to perform an activity required under the specific regulation, as appropriate to the individual’s assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.
Qualified Auditors

May be important to consider if you have a supply-chain preventive control.

- A person who is a qualified individual and has technical expertise obtained through education, training, or experience (or a combination) necessary to perform the auditing function.

- Examples of potential qualified auditors include:
  - A government employee, including a foreign government employee; and
  - An audit agent of a certification body that is accredited in accordance with regulations.
Leaders of Your Programs

- Preventive Controls Regulation
  - Preventive Controls Qualified Individual
    - An individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

- Intentional Adulteration
  - Food Defense Qualified Individual—successfully completed training for the specific function at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to conduct the activities.
  - One or more qualified individuals must do or oversee:
    - The preparation of the food defense plan
    - Conduct of a vulnerability assessment
    - Develop mitigation strategies
    - Conduct reanalysis as required
Determination of Qualified Individuals

FDA is not establishing minimum standards for competency and do not intend routinely to directly assess the qualifications of persons who function as qualified individuals, whether by their training or by their job experience. Instead, FDA intends to focus inspections on the adequacy of the regulatory plans. As necessary and appropriate, they may consider whether deficiencies identified in the regulatory plans suggest that the qualified individuals may not have adequate training or experience to carry out their assigned functions.
How Are They Doing it Now?

- Reviewing Regulatory Plans for Compliance
  - Food Safety Plans
  - Food Defense Plans
  - Foreign Supplier Verification Program
  - Sanitary Transport Regulation
- Interviewing personnel
- Observing monitoring, corrective actions, and verification activities
- Reviewing training records
- Swabathons
Four Levels of Training

- PCQI or FDQI
- Supervisors and or managers
- Individuals doing a task related to compliance
- General awareness training
Preparation for FDA Audits

- Well developed regulatory inspection procedure
  - Designated trained individuals (all shifts)
  - Questions to ask
  - Interviewing employees
  - Photo requests
  - Samples and swabbing requests
  - Document submission
  - Control information
- Be aware of Forms 482, 483, 484
Developing Mock Audit Program

Conducted by someone that will not be recognized

- Designated trained employees
  - Representative on all shifts
  - Only provide what is asked for
  - Do not volunteer or add information that is not requested
  - Ask the right questions to FDA
Developing Mock Audit Program

Conducted by someone that will not be recognized

- Challenge personnel
  - Photo requests or challenges
  - Sample and swabbing procedures
  - Interview “qualified individuals”
- Witness activities
  - Are all written procedures followed?
  - GMPs followed?
  - Information controlled?
Resources

- www.FDA.gov
  - Notifications
- www.aibinternational.com
  - Additional courses
  - FDA Preparedness Assessments
- Industry publications
- Food Safety Magazine
- Quality Assurance Magazine
Summary

- FDA Inspections
  - High risk
  - FSMA focus
- Qualified Individuals Roles in FDA Inspections
  - Preventive Controls Qualified Individual (PCQI)
  - Qualified Individuals
  - Qualified Auditors
- Mock Audits
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Questions