The Foreign Supplier Verification Program (FSVP) and International Rules for the Supplement Sector

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FSVP Background

- According to FDA, imported food is roughly 19 percent of the U.S. food supply
  - Approximately 52 percent of the fresh fruits and 22 percent of the fresh vegetables consumed by Americans
  - CDC estimates that each year 48 million people get sick from a foodborne illness, 128,000 are hospitalized, and 3,000 die
- FSVP minimizes the risk associated with imported food by requiring importers to verify that foreign suppliers are producing food in a way that provides at least the **same level of public health protection** as U.S. safety standards

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.

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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)

Requirement	Importer of DS components and manufactures/processes in compliance with CGMPs	Company whose customer must establish specifications for DS components under CGMPs	Importer of finished DS products
Written assurance of compliance from customer	No	Yes	No
Use qualified individuals	Yes	Yes	Yes
Identify importer at entry	Yes	Yes	Yes

FSVP Requirements by role (1.511)

Requirement	Importer of DS components and manufactures/processes in compliance with CGMPs	Company whose customer must establish specifications for DS components under CGMPs	Importer of finished DS products
Records requirement	Yes	Yes	Yes
Other	-	-	Must also (1) evaluate the DS and foreign supplier performance, (2) approve foreign supplier ,(3) implement your FSVP, and (4) take corrective actions

FSVP and FDA Enforcement

- 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)

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FSVP and FDA Enforcement

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?

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