Foreign Supplier Verification Program (FSVP) Considerations

What the FDA requires **retailers/distributors who *might* be the Importer of Record (IOR) or FSVP Importer** to have in place under the **Foreign Supplier Verification Program (FSVP)**.

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1. First Principle: When a Retailer *Becomes* the FSVP Importer

The FDA does **not** rely on contracts or supplier statements. It uses **objective criteria tied to import ownership and entry filings**.

You are the FSVP Importer if:

- You are the **U.S. owner or consignee at time of entry**
- You **purchase directly from a foreign supplier**
- You **take title before or at U.S. entry**
- You are listed on **customs entry (IOR or consignee)**

Critical implication:

If FDA sees you as the owner/consignee on entry, **you are accountable for FSVP — whether you intended to be or not**

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2. What FDA Requires IF You Are the FSVP Importer

If a retailer is (or may be) the importer, the FDA expects a **complete, documented FSVP program**.

A. Formal FSVP Program (Core Requirement)

You must develop, maintain, and follow a **written FSVP plan for each food and each foreign supplier**.

Must include:

- Hazard analysis (known or reasonably foreseeable hazards)
- Evaluation of supplier performance and risk
- Supplier verification activities
- Corrective action procedures
- Reassessment procedures (at least every 3 years or when risk changes)

B. Hazard Analysis

You must determine:

- Biological hazards (e.g., pathogens)
- Chemical hazards (e.g., allergens, residues)
- Physical hazards

And document:

- Whether hazards require a control
- Who controls them (supplier vs. you)

C. Supplier Evaluation & Approval

You must evaluate:

- Supplier's food safety performance
- Compliance history (FDA warning letters, import alerts)
- Nature of the food and its risk

Output required:

- Approved supplier determination (documented)

D. Supplier Verification Activities

Based on risk, FDA expects one or more:

- Onsite audits (required for serious hazards unless justified otherwise)
- Sampling and testing
- Review of supplier records (COAs, process controls)
- Other verification activities as appropriate

E. Corrective Actions

You must define and execute actions when:

- Supplier is out of compliance
- Product may be adulterated or misbranded

F. FSVP Qualified Individual (QI)

You must designate a person who:

- Has training or experience in food safety
- Develops and oversees the FSVP

G. Import Entry Requirement (Often Missed)

At time of import, you must provide:

- **FSVP Importer name**
- **Address**
- **UFI (DUNS number)**

This is how FDA identifies responsibility.

H. Recordkeeping (Critical for Inspections)

You must maintain:

- FSVP plan
- Hazard analyses
- Supplier evaluations
- Verification records
- Corrective action records

Records must be:

- Available promptly (typically within 24 hours)
- Retained for at least 2 years

3. What FDA Requires IF You Are *NOT* the FSVP Importer

If a retailer/distributor is **not the importer**, obligations shift from execution → **verification of responsibility**.

Minimum FDA Expectation:

A. Identify the FSVP Importer

You must maintain:

- Name
- Address
- UFI/DUNS

B. Written Assurance FSVP Is Being Performed

Typically:

- Letter stating compliance with **21 CFR Part 1 Subpart L**
- Confirmation of hazard analysis + verification activities

C. Maintain Basic Supplier Documentation (Best Practice)

Not strictly FSVP, but expected operationally:

- Food safety certifications (e.g., GFSI)
- COAs
- Recall plans
- Product specs

Key distinction:

If you are NOT the importer, you **do not need**:

- Hazard analysis
- FSVP plan
- Supplier verification program
- Qualified individual

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4. FDA Enforcement Reality (Highly Material)

Your notes correctly highlight how FDA actually enforces:

Common Violations:

- No FSVP program at all (most frequent)
- Incomplete hazard analysis

- Failure to verify suppliers

Consequences:

- **Form 483 observations**
- **Warning letters (public)**
- **Import refusal / DWPE**
- **Product seizure or destruction**

Critical Insight:

FDA determines responsibility based on **entry documentation**, not internal assumptions or supplier agreements

This is where many retailers get exposed.

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5. What Retailers Who "MIGHT" Be Importers Should Have (Practical Standard)

Given ambiguity risk, sophisticated retailers maintain **defensive compliance posture**:

Minimum Defensive Set:

- Determination framework (are we importer?)
- Documentation of importer for every imported SKU
- Importer UFI/DUNS records
- FSVP assurance letters
- Supplier documentation repository

If risk exists of being importer:

They also prepare:

- Draft or active FSVP programs
- Hazard analysis templates
- Supplier verification protocols

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6. Simple Executive-Level Rule

- **If you touch import ownership → assume FSVP responsibility until proven otherwise**
- **If you rely on someone else → document it rigorously**

7. Bottom Line (What FDA Actually Cares About)

FDA is not evaluating intent — they are evaluating:

1. **Who owned the food at entry**
2. **Who is declared in import filings**
3. **Whether that entity has a complete FSVP program**

If those don't align:
→ **You will be cited**