

# FSVP Exposure: The Risk You May Already Own

## The Issue

Retailers and distributors frequently unknowingly assume FSVP liability when importing food. The FDA does not rely on contracts or supplier intent – it determines responsibility based on who owns the product at entry and who is listed in import filings.

## Why This Matters Now

- FSVP enforcement is increasing
- ~ 50% fail inspections
- “No FSVP program” = most common violation

## FDA Expectations

### (If the Importer)

- Hazard analysis
- Supplier verification
- Approved supplier program
- Corrective actions
- Qualified oversight
- Full recordkeeping

**No program = automatic violation**

## What To Do Now

1. Determine Exposure
  - SKUs + importer of record
2. Close Gaps
  - If importer → build FSVP program
  - If not → document and get assurance
3. Operationalize Controls
  - Require importer designation
  - Centralize documentation

## The Core Risk

You may already be the Importer if you:

- Buy direct from foreign suppliers
- Take title before entry
- Appear on import filings

**Even if you don't intend to be.**

## What Happens

### If You Get It Wrong

- FDA inspection → Form 483 warning letter
- Fast remediation ~15 days
- Shipments /DWPE
- Delays, losses, potential seizure

## Bottom Line

FSVP is binary:

- You're Compliant
- Or you are exposed

**The biggest risk is not knowing you are the importer.**



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# FSVP Exposure Assessment

Use this as a rapid internal diagnostic. If you answer “Yes” to any item in Sections A–C, you likely have FSVP exposure and should escalate.

## A. Import Ownership & Control (Primary Trigger)

- Do we purchase food directly from a foreign supplier?
- Do we take title to the product before or at U.S. entry?
- Are we listed as Importer of Record (IOR) or Consignee on customs filings?
- Do we control or arrange the import process (broker, logistics, customs clearance)?

If YES to any above → HIGH likelihood you are the FSVP Importer

## B. Entry Filing Visibility (Regulatory Determination Layer)

- Is our company name listed on import forms and/or is your DUNS used for identification at entry?
- Do we know who is declared as the FSVP Importer for every SKU?

If UNKNOWN → You have exposure risk (FDA decides based on filings, not assumptions)

## C. Contract vs. Reality Gap (Common Failure Point)

- Do suppliers claim they are the importer, but we appear on entry docs?
- Do we rely on verbal or contractual statements instead of entry verification?

If YES → You are at high risk of being deemed the importer regardless of contracts

## D. If We ARE the Importer – (Answering “No” to any = compliance gap)

- Written FSVP plan per food/supplier
- Documented hazard analysis
- Defined verification activities (audit/testing/records review)
- Corrective action procedures
- Assigned FSVP Qualified Individual (QI)
- Reassessment process (< 3 years or trigger-based)

Any “No” → Likely inspection finding (Form 483)

## E. If We Are NOT the Importer (Answering “No” to any = exposure)

- Identified FSVP Importer (name, address, UFI/DUNS)
- Written assurance importer is performing FSVP
- Documentation tied to specific products/suppliers
- Internal record of who is responsible per import flow

If missing → FDA may still hold you accountable

## F. Red Flags (Immediate Escalation)

- “We’ve never been inspected, so we’re fine”
- “Our supplier handles that” (without documentation)
- No FSVP Program

### Bottom-Line Scoring

0–2 Yes answers: Low exposure

3–5 Yes answers: Moderate exposure (needs validation)

6+ Yes answers: High probability you are the FSVP Importer



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