

A. Import Activity

- Do we purchase food from suppliers outside the U.S.?
- Are we listed as consignee on imported goods?
- Do we use private label products manufactured overseas?

If YES to any → potential FSVP exposure

B. Legal Responsibility

- Are we identified as FSVP importer in customs filings?
 - Do we know who our FSVP importer is for each product?
 - Is there alignment between Importer of Record and FSVP importer?
-

C. Program Ownership

- Do we have a documented FSVP program?
 - Is a **Qualified Individual (QI)** assigned?
 - Are hazard analyses completed for all imported products?
-

D. Supplier Controls

- Are all foreign suppliers formally approved?
 - Do we have current audit reports or equivalent verification?
 - Are suppliers screened for FDA Import Alerts and Warning Letters?
-

E. Documentation Readiness

- Can we produce FSVP records within 24 hours?
 - Are CoAs, specs, and food safety documents complete and current?
 - Are records centralized and audit-ready?
-

F. Risk Triggers

- Any supplier on Import Alert?
 - Any recent FDA warning letters or refusals?
 - Any gaps in supplier documentation?
-

Scoring

- 0–3 gaps → Low risk
 - 4–7 gaps → Moderate risk
 - 8+ gaps → **High regulatory exposure**
-