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Foreign Supplier Verification Programs (FSVP) Setup Services for Food Importers		
Application: U.S.-based food importers		
Requirements	Scope	Action Items
§ 1.500 What definitions apply to this subpart?	Facility/Product Registration and Identification	Collect/Provide Records
		Assess
§ 1.501 To what foods do the requirements in this subpart apply?	Importer's Qualification	Collect/Provide Records
		Assess
§ 1.502 What foreign supplier verification program (FSVP) must I have?	FSVP Requirement Program	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
	Labeling Requirements per Regulations (if applicable)	Implement
	Food Defense Plan	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
	Implement	
	Key Activity Type Vulnerability Assessment	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
	Implement	
	Management of Suppliers of Raw Materials and Packaging	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
Implement		
Temporary FSVP Policy for Emergency Suppliers	Collect/Provide Records	
	Assess	
	Draft	
	Review	
	Approve	
Implement		
Ingredients, Raw Materials, Products Foreign Supplier Importer Evaluation	Collect/Provide Records	
	Assess	
	Draft	
	Review	
	Approve	
Implement		
1.503 - Who must develop my FSVP and perform FSVP activities?	FSVP Personnel Qualifications Program	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
	FSVP Qualified Individual Checklist	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
Job Description	Collect/Provide Records	

		Assess
		Draft
		Review
		Approve
		Implement
	FSVP Audit Program	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
	FSVP Qualified Auditor Registry	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
	FSVP Audit Schedule	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
	FSVP Audit Plan	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
	FSVP Audit Checklist	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
1.504 - What hazard analysis must be conducted?	Hazard Analysis	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
	HACCP Plan	Collect/Provide Records
		Assess
		Review
		Implement
	Transportation Agreement	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
1.505 - What evaluation and approval of Foreign suppliers must be conducted	Supply Chain Risks	Collect/Provide Records
		Assess
	Foreign Supplier Evaluation	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
	FDA Food Safety Regulations	Assess
		Review
		Implement
	FSVP Products Description	Collect/Provide Records

		Assess
		Draft
		Review
		Approve
		Implement
	Product/Service Specifications	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
	FSVP Team Roster	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
	Foreign Supplier Verification Activity(ies) Worksheet	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
	Supplier Requirements Letter	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
1.506 - What Foreign Supplier Verification must be conducted?	Foreign Supplier Verification and related activities Program	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
	Finished Product COA	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
	Mock Recall and Traceability	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
	Mock Recall and Traceability Exercise	Collect/Provide Records
		Assess
		Review
		Approve
		Implement
	Allergen Policy Statement	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
	California Transparency in Supply Chain Act of 2010 Statement (if applicable)	Collect/Provide Records
		Assess
		Draft
		Review
		Approve

	Implement
California Proposition 65 Warranty (if applicable)	Collect/Provide Records
	Assess
	Draft
	Review
	Approve
	Implement
Details of Coding, Traceability & Recall Systems	Collect/Provide Records
	Assess
	Draft
	Review
	Approve
	Implement
FSMA Compliance Statement-Supplier	Collect/Provide Records
	Assess
	Draft
	Review
	Approve
	Implement
FSVP Compliance Statement	Collect/Provide Records
	Assess
	Draft
	Review
	Approve
	Implement
Pallet Requirements	Collect/Provide Records
	Assess
	Draft
	Review
	Approve
	Implement
Policy for Product Events	Collect/Provide Records
	Assess
	Draft
	Review
	Approve
	Implement
Non-GMO Statement, if applicable	Collect/Provide Records
	Assess
	Draft
	Review
	Approve
	Implement
Certificate of Liability Insurance	Collect/Provide Records
	Assess
	Review
	Approve
	Implement
	Product/Service Specifications
Assess	
Draft	
Review	
Approve	
Implement	
FDA Bioterrorism Registration Affidavit/ FDA Food Facility Registration	Collect/Provide Records
	Assess
	Review
	Implement
Country of Origin Certificate	Collect/Provide Records
	Assess
	Draft
	Review
	Approve

		Implement
	Bill of Lading	Collect/Provide Records
		Review
		Approve
		Implement
	SDS/MSDS (if applicable)	Collect/Provide Records
		Review
		Implement
	Quality Agreement	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
Authenticity Validation test results	Collect/Provide Records	
	Review	
	Implement	
Hold Harmless Agreement, Guaranty-Warranty of Product (Supplier)	Collect/Provide Records	
	Assess	
	Draft	
	Review	
	Approve	
§ 1.507- What requirements apply when I import a food that cannot be consumed without the hazards being controlled or for which the hazards are controlled after importation?	Exemption from § 1.505 and § 1.506	Collect/Provide Records
		Assess
	FSVP Import Foods Hazard Program	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
	Hazard Analysis	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
Compliance Statement	Collect/Provide Records	
	Assess	
	Draft	
	Review	
	Approve	
Customer Written Assurance - Applicable Food Safety Requirements	Collect/Provide Records	
	Assess	
	Review	
Customer Written Assurance	Collect/Provide Records	
	Assess	
	Draft	
	Review	
	Approve	
FSVP Requirement Program	Collect/Provide Records	
	Assess	
	Draft	
	Review	
	Approve	
§ 1.508 - What corrective actions must I take under my FSVP?	FSVP Corrective Action Program	Collect/Provide Records
		Assess
		Draft
		Review
		Approve

		Implement
	Corrective Action Report (CAPA Report)	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
1.509 - How must the importer be identified at entry?	Qualified Individual Checklist	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
	FSVP CBP Filing Form	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
	FSVP Ingredient Product Register	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
	Importer Information Form	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
	Data Universal Numbering System (DUNS) number - UFI	Collect/Provide Records
		Assess
	FDA Bioterrorism Registration Affidavit/FDA Food Facility Registration	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
1.510 - How must I maintain records of my FSVP?	Document Control Program	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
	Document Change History	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
	Master Document Register	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
	Document Destruction Record-Form	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement

	Records Program	Collect/Provide Records Assess Draft Review Approve Implement
§ 1.511 What FSVP must I have if I am importing a food subject to certain requirements in the dietary supplement current good manufacturing practice regulation?	21 CFR Part 111 - Current Good Manufacturing Practice In Manufacturing, Packaging, Labeling, Or Holding Operations For Dietary Supplements Requirements (if applicable)	Provide Records Collect Records Assess Review
	Imported Goods Subjected to Dietary Supplement Regulation Program, (if applicable)	Collect/Provide Records Assess Draft Review Approve Implement
§ 1.512 What FSVP may I have if I am a very small importer or I am importing certain food from certain small foreign suppliers?	Very Small Importer/Small Foreign Supplier	Collect/Provide Records Assess Draft Review Approve Implement
	FSVP Imported Goods from Small Foreign Supplier Program	Collect/Provide Records Assess Draft Review Approve Implement
§ 1.513 What FSVP may I have if I am importing certain food from a country with an officially recognized or equivalent food safety system?	Countries with FDA Officially Recognized or Equivalent Food Safety System (if applicable)	Collect/Provide Records Assess Draft Review Approve Implement
	Import Food from Equivalent Food Safety System Program (if applicable)	Collect/Provide Records Assess Draft Review Approve Implement
	Exemptions	Collect/Provide Records Assess
§ 1.514 - What are some consequences of failing to comply with the requirements of this subpart?	U.S. Owner or Consignee	Identify Collect/Provide Records Assess Review Implement
	U.S. Agent or Representative Designation	Identify Collect/Provide Records Assess Draft Review Approve Implement
	FSVP Requirements - Compliance	Implement
	Consequences of Non-Compliance Program	Collect/Provide Records Assess Draft Review Approve Implement
21 CFR 117 Subpart G - Supply Chain Program 117.410 General requirements applicable to a supply-chain program.	Approved Supplier Program	Collect/Provide Records Assess

program.		Draft
		Review
		Approve
		Implement
21 CFR 121.130	Food Fraud Vulnerability Assessment (Supplier and Ingredient) Program	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
	FFVA Ingredient and Supplier	Collect/Provide Records
		Assess
21 CFR 117.139 Recall plan	Product Withdrawal and Recall Program	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
117.435 Onsite audit.	Internal Audit Checklist for Foreign Suppliers	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
21 CFR 117.410(e) General requirements applicable to a supply-chain program.	Customer Complaint Program	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
21 CFR 101.3 Identity labeling of food in packaged form.	Label Management/Product Identification	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
1.1315 Traceability Plan, FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods	Traceability Program	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement

To avail of our professional services kindly contact hello@consultareinc.com or call 1-202-982-3002.