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 1-202-982-3002



### Foreign Supplier Verification Programs (FSVP) Support/End-to-end Services Action Items

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	
		Verify	
§ 1.501 To what foods do the requirements in this subpart apply?	Importer's Qualification	Collect/Provide Records	
		Assess	
		Verify	
§ 1.502 What foreign supplier verification program (FSVP) must I have?	FSVP Requirement Program	Collect/Provide Records	
		Assess	
		Draft	
		Review	
		Approve	
		Implement	
		Verify	
		Validate	
		Labeling Requirements per Regulations (if applicable)	Implement
			Verify
	Validate		
	Food Defense Plan	Collect/Provide Records	
		Assess	
		Draft	
		Review	
		Approve	
		Implement	
		Verify	
		Validate	
		Key Activity Type Vulnerability Assessment	Collect/Provide Records
			Assess
	Draft		
	Review		
	Approve		
	Implement		
	Verify		
	Validate		
	Management of Suppliers of Raw Materials and Packaging	Collect/Provide Records	
		Assess	
		Draft	
Review			
Approve			
Implement			
Verify			
Validate			
Temporary FSVP Policy for Emergency Suppliers	Collect/Provide Records		
	Assess		
	Draft		
	Review		
	Approve		



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Requirements	Scope	Action Items		
		Implement		
		Verify		
		Validate		
		Ingredients, Raw Materials, Products Foreign Supplier Importer Evaluation	Collect/Provide Records	
			Assess	
			Draft	
			Review	
			Approve	
			Implement	
			Verify	
Validate				
1.503 - Who must develop my FSVP and perform FSVP activities?			FSVP Personnel Qualifications Program	Collect/Provide Records
				Assess
	Draft			
	Review			
	Approve			
	Implement			
	Verify			
	Validate			
	FSVP Qualified Individual Checklist	Collect/Provide Records		
		Assess		
		Draft		
		Review		
		Approve		
		Implement		
		Verify		
		Validate		
	Job Description	Collect/Provide Records		
		Assess		
		Draft		
		Review		
		Approve		
		Implement		
		Verify		
		Validate		
	FSVP Audit Program	Collect/Provide Records		
		Assess		
		Draft		
		Review		
Approve				
Implement				
Verify				
Validate				
FSVP Qualified Auditor Registry	Collect/Provide Records			
	Assess			
	Draft			



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Requirements	Scope	Action Items			
		Review			
		Approve			
		Implement			
		Verify			
		Validate			
	FSVP Audit Schedule		Collect/Provide Records		
			Assess		
			Draft		
			Review		
			Approve		
			Implement		
			Verify		
			Validate		
			FSVP Audit Plan		Collect/Provide Records
					Assess
	Draft				
	Review				
	Approve				
	Implement				
	Verify				
	Validate				
FSVP Audit Checklist		Collect/Provide Records			
		Assess			
		Draft			
		Review			
		Approve			
		Implement			
		Verify			
		Validate			
		1.504 - What hazard analysis must be conducted?	Hazard Analysis	Collect/Provide Records	
				Assess	
Draft					
Review					
Approve					
Implement					
Verify					
Validate					
HACCP Plan				Collect/Provide Records	
				Assess	
			Review		
			Implement		
			Verify		
			Validate		
Transportation Agreement			Collect/Provide Records		
			Assess		
			Draft		



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Requirements	Scope	Action Items		
1.505 - What evaluation and approval of Foreign suppliers must be conducted		Review		
		Approve		
		Implement		
		Verify		
		Validate		
	Supply Chain Risks	Foreign Supplier Evaluation	Collect/Provide Records	
			Assess	
		Foreign Supplier Evaluation	Collect/Provide Records	
			Assess	
			Draft	
			Review	
			Approve	
			Implement	
			Verify	
		Validate		
		FDA Food Safety Regulations	FDA Food Safety Regulations	Assess
				Review
				Implement
				Verify
				Validate
FSVP Products Description	FSVP Products Description	Collect/Provide Records		
		Assess		
		Draft		
		Review		
		Approve		
		Implement		
		Verify		
Validate				
Product/Service Specifications	Product/Service Specifications	Collect/Provide Records		
		Assess		
		Draft		
		Review		
		Approve		
		Implement		
		Verify		
Validate				
FSVP Team Roster	FSVP Team Roster	Collect/Provide Records		
		Assess		
		Draft		
		Review		
		Approve		
		Implement		
		Verify		
Validate				
Foreign Supplier Verification Activity(ies) Worksheet	Foreign Supplier Verification Activity(ies) Worksheet	Collect/Provide Records		
		Assess		



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Requirements	Scope	Action Items
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	Supplier Requirements Letter	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
1.506 - What Foreign Supplier Verification must be conducted?	Foreign Supplier Verification and related activities Program	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	Finished Product COA	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	Mock Recall and Traceability	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	Mock Recall and Traceability Exercise	Collect/Provide Records
		Assess
		Review
		Approve
Implement		
Verify		
Allergen Policy Statement	Collect/Provide Records	



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Requirements	Scope	Action Items
		Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	California Transparency in Supply Chain Act of 2010 Statement (if applicable)	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
		Verify
	California Proposition 65 Warranty (if applicable)	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
		Verify
	Details of Coding, Traceability & Recall Systems	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
		Verify
FSMA Compliance Statement-Supplier	Collect/Provide Records	
	Assess	
	Draft	
	Review	
	Approve	
	Implement	
	Verify	
FSVP Compliance Statement	Collect/Provide Records	
	Assess	
	Draft	
	Review	
	Approve	
	Verify	



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Requirements	Scope	Action Items
	Pallet Requirements	Validate
		Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
		Policy for Product Events
	Assess	
	Draft	
	Review	
	Approve	
	Implement	
	Verify	
	Validate	
	Non-GMO Statement, if applicable	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
		Verify
	Validate	
	Certificate of Liability Insurance	Collect/Provide Records
		Assess
		Review
		Approve
		Implement
		Verify
	Validate	
	Product/Service Specifications	Collect/Provide Records
Assess		
Draft		
Review		
Approve		
Implement		
Verify		
Validate		
FDA Bioterrorism Registration Affidavit/ FDA Food Facility Registration	Collect/Provide Records	
	Assess	
	Review	
	Implement	
	Verify	
Validate		



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Requirements	Scope	Action Items
	Country of Origin Certificate	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	Bill of Lading	Collect/Provide Records
		Review
		Approve
		Implement
		Verify
	SDS/MSDS (if applicable)	Collect/Provide Records
		Review
		Implement
		Verify
	Quality Agreement	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
		Verify
Validate		
Authenticity Validation test results	Collect/Provide Records	
	Review	
	Implement	
	Verify	
Hold Harmless Agreement, Guaranty-Warranty of Product (Supplier)	Collect/Provide Records	
	Assess	
	Draft	
	Review	
	Approve	
	Implement	
	Verify	
	Validate	
§ 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
		Verify
	FSVP Import Foods Hazard Program	Collect/Provide Records
		Assess
		Draft





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Requirements	Scope	Action Items
		Review
		Approve
		Implement
		Verify
		Validate
	Hazard Analysis	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	Compliance Statement	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
	Customer Written Assurance - Applicable Food Safety Requirements	Collect/Provide Records
		Assess
		Review
		Verify
Customer Written Assurance	Collect/Provide Records	
	Assess	
	Draft	
	Review	
	Approve	
	Implement	
	Verify	
FSVP Requirement Program	Collect/Provide Records	
	Assess	
	Draft	
	Review	
	Approve	
	Implement	
	Verify	
	Validate	
§ 1.508 - What corrective actions must I take under my FSVP?	FSVP Corrective Action Program	Collect/Provide Records
		Assess
		Draft
		Review
		Approve



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Application: U.S.-based food importers

Requirements	Scope	Action Items	
		Implement	
		Verify	
		Validate	
	Corrective Action Report (CAPA Report)		Collect/Provide Records
			Assess
			Draft
			Review
			Approve
			Implement
			Verify
Validate			
1.509 - How must the importer be identified at entry?	Qualified Individual Checklist	Collect/Provide Records	
		Assess	
		Draft	
		Review	
		Approve	
		Implement	
		Verify	
		Validate	
	FSVP CBP Filing Form		Collect/Provide Records
			Assess
			Draft
			Review
			Approve
			Implement
			Verify
			Validate
	FSVP Ingredient Product Register		Collect/Provide Records
			Assess
			Draft
			Review
			Approve
			Implement
			Verify
			Validate
	Importer Information Form		Collect/Provide Records
			Assess
			Draft
			Review
Approve			
Implement			
Verify			
Validate			
Data Universal Numbering System (DUNS) number - UFI		Collect/Provide Records	
		Assess	
FDA Bioterrorism Registration Affidavit/FDA		Collect/Provide Records	



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Requirements	Scope	Action Items
	Food Facility Registration	Assess Draft Review Approve Implement Verify Validate
1.510 - How must I maintain records of my FSVP?	Document Control Program	Collect/Provide Records Assess Draft Review Approve Implement Verify Validate
	Document Change History	Collect/Provide Records Assess Draft Review Approve Implement Verify Validate
	Master Document Register	Collect/Provide Records Assess Draft Review Approve Implement Verify Validate
	Document Destruction Record-Form	Collect/Provide Records Assess Draft Review Approve Implement Verify Validate
	Records Program	Collect/Provide Records Assess Draft Review Approve Implement Verify



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Requirements	Scope	Action Items
§ 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)	Validate
		Provide Records
		Collect Records
		Assess
		Review
		Verify
	Imported Goods Subjected to Dietary Supplement Regulation Program, (if applicable)	Validate
		Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
		Verify
§ 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	Validate
		Collect/Provide Records
		Assess
		Draft
		Review
		Approve
	FSVP Imported Goods from Small Foreign Supplier Program	Implement
		Verify
		Validate
		Collect/Provide Records
		Assess
		Draft
		Review
		Approve
§ 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)	Implement
		Verify
		Validate
		Collect/Provide Records
		Assess
		Draft
	Import Food from Equivalent Food Safety System Program (if applicable)	Review
		Approve
		Implement
		Verify
		Validate
		Collect/Provide Records
		Assess
		Draft



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Requirements	Scope	Action Items
	Exemptions	Validate
		Collect/Provide Records
		Assess
		Verify
§ 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
		Verify
		Validate
	U.S. Agent or Representative Designation	Identify
		Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
		Verify
	FSVP Requirements - Compliance	Implement
		Verify
		Validate
	Consequences of Non-Compliance Program	Collect/Provide Records
		Assess
Draft		
Review		
Approve		
Implement		
Verify		
Validate		
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
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
		21 CFR 121.130
Assess		
Draft		
Review		
Approve		
Implement		
Verify		



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Requirements	Scope	Action Items
		Validate
	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
		Verify
		Validate
117.435 Onsite audit.	Internal Audit Checklist for Foreign Suppliers	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
21 CFR 117.410(e) General requirements applicable to a supply-chain program.	Customer Complaint Program	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
21 CFR 101.3 Identity labeling of food in packaged form.	Label Management/Product Identification	Collect/Provide Records
		Assess
		Draft
		Review
		Approve
		Implement
		Verify
		Validate
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
		Verify
		Validate

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