

CFSRS Checklist of Food Safety Fundamental Programs Including Those Designated Preventive Controls

Written HACCP Program Requirements	FSMA Preventive Controls or Other Regulatory Reference	Written Program		Implemented & Fully Operational		Supporting Records System	
		Yes	No	Yes	No	Yes	No
Food Safety - HACCP - 5 Preliminary Steps & 7 Principles	21 CFR 117.130						
Product Description							
Product Flow Diagrams with Narrative	21 CFR 117.130, 140, 145, 150						
Hazard Analysis for Each or Similar Groups of Products							
HACCP Plan Summary Table for all CCPs	No Specific Requirements						
Food Quality - QACCP - 5 Preliminary Steps & 7 principles							
Enhanced Product Flow Diagrams including key Quality Processing Steps							



Level #1 - Written Food Safety Fundamental Program Requirements

1) Employee, Supervisor, Visitor & Contractor Personnel Hygiene (GMPs)	117.10a & b, 117.135e						
2) Premises Maintenance including PM Program	117.2 & 117.140 a-d						
3) Equipment Maintenance including PM Program	117.35a, 117.37d,e 117.40 a-e						
4) Storage, Cleaning & Sanitization of Equipment - A PREVENTIVE CONTROL!!	117.35 d, e & f 117.80b (10)						
5) Cleaning of Facility - A PREVENTIVE CONTROL	117.110.10c, 117.37f						
6) Integrated Pests Management	117.20b(3ii & 3iii) & b (7), 117.35c						
7) Environmental Monitoring	117.15a (1) (ii) & 117.165 b (3)						
8) Foreign Matter (Metal, Glass, Glass-like & Wood) Contamination Management - A PREVENTIVE CONTROL	117.80c(6), 117.40a, b & d, 117.80a(5), 117.80c(8)						
9) Allergen Management - A PREVENTIVE CONTROL	117.135						
10) Employee & Supervisory Training	117.9						
11) Temperature Management of Raw Materials, In-Process & Finished Products)	117.40e 117.80b (3)						
12) Water & Air Supply Safety	117.37 a & b, 117.40 e, 117.80b(16)						
14) Loading, Unloading, Storage & Transport Management	FSMA Section 111, Sanitary Food Transportation Act of 2005; 117.80a, 117.80b(6), 117.80b (13v)						
15) Chemical Inventory and Proper Storage, Labeling & Use	117.35(b)						
16) Dry & Liquid Waste Disposal	117.37 c,d & f						
17) Calibration of Measuring of Testing, Auditing & Processing Equipment Instruments	117.40f						
18) Multi-tiered Food Defense Program	FSMA Section 106 Bioterrorism Act of 2002						
19) Verification Program	117.155 & 117.165						
20) Validation Program	117.160, 117.180 a (2)						
21) Internal Audits	No Specific Requirements						

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		Yes	No	Yes	No	Yes	No
22) Corrections, Corrective & Preventative Actions (CAPA)	117.150						
23) Traceability of Ingredient, Packaging & Finished Product	Section 204 & 206, Bioterrorism Act of 2002, 21 CFR 7						
24) Recall/Market Withdrawal Program for Finished Products - A PREVENTIVE CONTROL	Section 204 & 206, 21 CFR 117.139, Bioterrorism Act of 2002, 21 CFR 7						
25) Supplier Management Program of Raw Materials, Ingredients, Packaging & Labeling - A PREVENTIVE	117.405 - 117.475						
26) Complaint Management	No Specific Requirements, however implied as part of ReAnalysis 3 year requirement						
27) Document Control of All Written Preventive Controls Programs for: 1. Process Controls 2. Sanitation Controls 3. Allergens 4. Recall programs 5. Supply Chain management 6. Other programs as required to support the food safety plan	117.135, Food Safety Plan Must be Available Immediately if Requested by FDA Investigator						
28) Records Control including the following Preventive Control Records: 1. Monitoring of preventive controls; 2. Corrective actions; 3. Verification of monitoring records, corrective action records, 4. Validation activities 5. Calibration of process monitoring and verification instruments; 6. Product testing; 7. Environmental monitoring; 8. Records review 9. Reanalysis of Food Safety Plan (min.of once every 3 years) 10. Supply- chain programs 11. Qualifications of Preventive Controls Qualified Individual & qualified auditor.	117.190, Records supporting the food safety plan for last 6 months must be retrievable within 24 hours. Records older than 6 months may be stored off-site.						
29) Business Continuity/Crisis Management	No Specific Requirements						
30) Packaging & Labeling Management	21 CFR 101, Food cannot be misbranded or misled the consumer						
31) Senior Management Review of Food Safety Program							
32) Management of Contract Service Providers							

