



Preventive Controls Inspections from a State Regulator's Perspective

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WSDA Mission Statement



“To support the viability and vitality of agriculture while protecting consumers, public health and the environment.”



Title 21 CFR Part 117



Current Good Manufacturing Practices, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

- [Subpart A--General Provisions](#)
- [Subpart B--Current Good Manufacturing Practice](#)
- **[Subpart C--Hazard Analysis and Risk-Based Preventive Controls](#)**
- [Subpart D--Modified Requirements](#)
- [Subpart E--Withdrawal of a Qualified Facility Exemption](#)
- [Subpart F--Requirements Applying to Records That Must Be Established and Maintained](#)
- **[Subpart G--Supply-Chain Program](#)**

Qualified Facility



“Very small business” means a business (including any subsidiaries and affiliates), averaging less than \$1,000,000, adjusted for inflation, per year, in sales of human food.

Very Small Business



- **EXEMPT** from having a written Food Safety Plan (Subparts C & G) **IF**:
 - Submits a Qualified Facility Attestation to FDA.
- Small Business **IS** subject to the
 - GMP requirements in subpart B
 - the qualified individual training requirements
 - training records.
- If it does **NOT** submit a Qualified Facility Attestation
 - **SUBJECT TO FULL REQUIREMENTS**
 - including the written food safety plan.

Preventive Controls Inspections



WSDA inspectors have been conducting Full Preventive Control inspections since January 2018



Inspection Process



2 WSDA inspectors

- Initial Interview
- Walk through facility
- Develop Hazard Analysis to determine significant hazards requiring preventive controls
- Compare Hazard Analysis to firm's Hazard Analysis



Inspection Process



- Evaluate written preventive control programs for required components
- Determine implementation of written preventive control programs
- Review Records
- Close Out Meeting



Required Written Food Safety Plan Components



- The written hazard analysis
- The written preventive controls
- The written supply-chain program as required by subpart G
- The written recall plan
- The written procedures for monitoring the implementation of the preventive controls
- The written corrective action procedures
- The written verification procedures
- Records

Written Hazard Analysis



FDA's Hazard Analysis and Risk Based Preventive Controls for Human Food: Guidance for Industry

(Draft Guidance)

- Made for Industry to assist in developing Food Safety Plan
- We use Hazard Tables in Appendix 1 to determine potential hazards
 - Biological
 - Chemical
 - Process Related

Written Hazard Analysis



Evaluate Potential Hazards to determine if they are Significant Hazards at that facility based on:

- Specific chapters in the Hazard's Guide
- Past experience
- Scientific reports
- Illness data
- Other information

Hazard Analysis



Significant Hazards require a Preventive Control program to prevent or significantly reduce the hazard

Big Picture Food Safety Plan



1. Identify significant hazards specific to the facility
2. Develop written preventive control procedures to control each identified hazard
 1. Monitoring
 2. Corrective Actions
 3. Verification
 4. Validation for process controls
3. Implement written preventive control programs
4. Keep monitoring / verification records to show written plan is implemented

Food Safety Plans Are Facility Specific



- No one size fits all plan
- No standard type of plan for each food type
- Plan needs to address facility's specific
 - Process Steps
 - Ingredients
 - Finished Product

Food Safety Plans



- No specific forms
- No specific terminology
- May need multiple food safety plans
 - Can group related products into one Food Safety Plan

Nut Butter Example Plant A Process



1. Receives raw nuts
2. Roast nuts on site
3. Grinds nuts with metal on metal contact
4. Packages different kinds of nut butters on shared equipment
5. Product exposed to environment after roasting step before it is packaged
6. Packages product in glass containers
7. Tests finished product for aflatoxin on site

Nut Butter Example Plant B Process



1. Receives previously roasted nuts
2. Nuts come with Certificate of Analysis for aflatoxin
3. Nuts turned into paste without metal on metal contact
4. Only packages one kind on nut butter
5. Product exposed to environment before packaging
6. Packages product into plastic containers

Food Safety Plans



The same hazards can be controlled
by different programs

Significant hazards need to be
controlled before the food reaches
the public.

Supply Chain Programs	
Plant A	Plant B
None	Verifying Supplier
	Controlled Hazards of:
	Aflatoxin
	Salmonella
Process Control Programs	
Plant A	Plant B
Roasting to control Salmonella	None
Aflatoxin testing	
Metal	
Glass	

Sanitation Control Programs	
Plant A	Plant B
Open product exposed to environment - Recontamination with environmental pathogens hazard	Open product exposed to environment - Recontamination with environmental pathogens hazard
Equipment / Facility SSOPs	Equipment / Facility SSOPs
Employee GMPs	Employee GMPs
Verification Step of Environmental Monitoring	Verification step of Environmental monitoring

Allergen Control Programs	
Undeclared Allergen – Labeling Hazard	
Plant A	Plant B
Make sure allergen is declared on label	Make sure allergen is declared on label
Correct label on corresponding container (multiple allergenic products)	
Undeclared Allergen – Cross Contact Hazard	
Plant A	Plant B
Multiple nuts on shared equipment	None
Scheduling / Sanitation	

Preventive Controls Inspections



Food Safety Plans are

- Facility Specific
- Tailored to Facility's
 - Products
 - Ingredients
 - Processes



Significant hazards need to be controlled before the food reaches the public.

Preventive Controls (PC) Related Violations



- No/Incomplete Food Safety Plan (FSP)
- FSP not created by PCQI
- Firm does not have a PCQI
- No Recall Plan/Incomplete Plan
- Failing to identify hazards
- PC's did not include written procedures
- No/Incomplete corrective action procedures
- Inadequate monitoring procedures
- Process not validated

PC Related Violations



- Not implementing controls
- No/untimely review of monitoring records
- No supply chain program established
- Critical limits/parameters inadequate
- Monitoring information not recorded in records
- Records missing other required information
- Undeclared allergens on label as a result of not having/implementing allergen controls

Top Violations Observed



Violation	% of debits
Not identifying a hazard/incomplete HA	50%
Missing/inadequate written procedures for controls	27%
No/inadequate corrective action procedures	23%
Not reviewing monitoring records	13%
Not recording monitoring info on records	10%

In Preparation of Inspection



- Read over Subparts C and G in the regulation 21 CFR Part 117
- Consult the FDA's Hazard Guide and Tables about your products and ingredients when conducting Hazard Analysis
- Have written preventive control procedures that include written
 - Monitoring Procedures
 - Corrective Actions
 - Verification Procedures

In Preparation of Inspection




- Implement written procedures
- Monitor implementation of procedures with record keeping and reviewing
- Train all employees in food safety and food hygiene principles and keep records of training






We are working collaboratively with industry to protect public health







Questions?

Food Safety Program



Thank you!



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