2020 edition

FSMA / PREVENTIVE CONTROLS
FOOD SAFTEY SYSTEM

A.B.C. Food Manufacturing, Inc.
101 Food Production Blvd.
Yourtown, ZZ 00000

WORKBOOK

CONTENTS

Part 1. General Company Information

Company Name

HACCP/PC Leader Name Contact Info.
Location
Brief Description of Facility:

Quality and Safety Commitment

As a company, _____ has set the following goals and commitments:

- To offer for sale products which in use consistently satisfy the consumer and our business partners
- To provide outstanding service and products to meet customer expectations and are significantly better than any competitive alternative
- To produce products that are safe, legally compliant and meet all our customers' requirements.

In this effort, we have chosen to operate under a HACCP/PC Program and we are fully committed to its implementation and maintenance.

_____ _____

Company Officer Signatures Company Officer Signatures

HACCP/PC Team

Name	Affiliation	Expertise or Certifications

Part 2. Preliminary Information and Hazard Analyses

Product Descriptions	
1. Product name(s) Description	
2. Ingredients, product properties (a_w, pH, preservatives)	
3. Intended use? Intended consumer?	
4. Type of packaging	
5. Shelf life	
6. Where will the product be sold?	
7. Labeling instructions	
8. Special distribution control	

List of Prerequisite Programs (*across all products*)

The HACCP/PC Program for A.B.C., Inc. contains Prerequisite Programs that help maintain safe food production on a daily basis. Our Prerequisite Programs consist of both Good Manufacturing Practice Policies, Operating Prerequisites (identified in the Hazard Analysis) with corresponding Standard Operating Procedures (SOPs) that help achieve these GMPs and oPRPs.

Good Manufacturing Practice Policies

GMP 1	*examples*	
GMP 2		
GMP 3		
GMP 4		
GMP 5		
GMP 6		

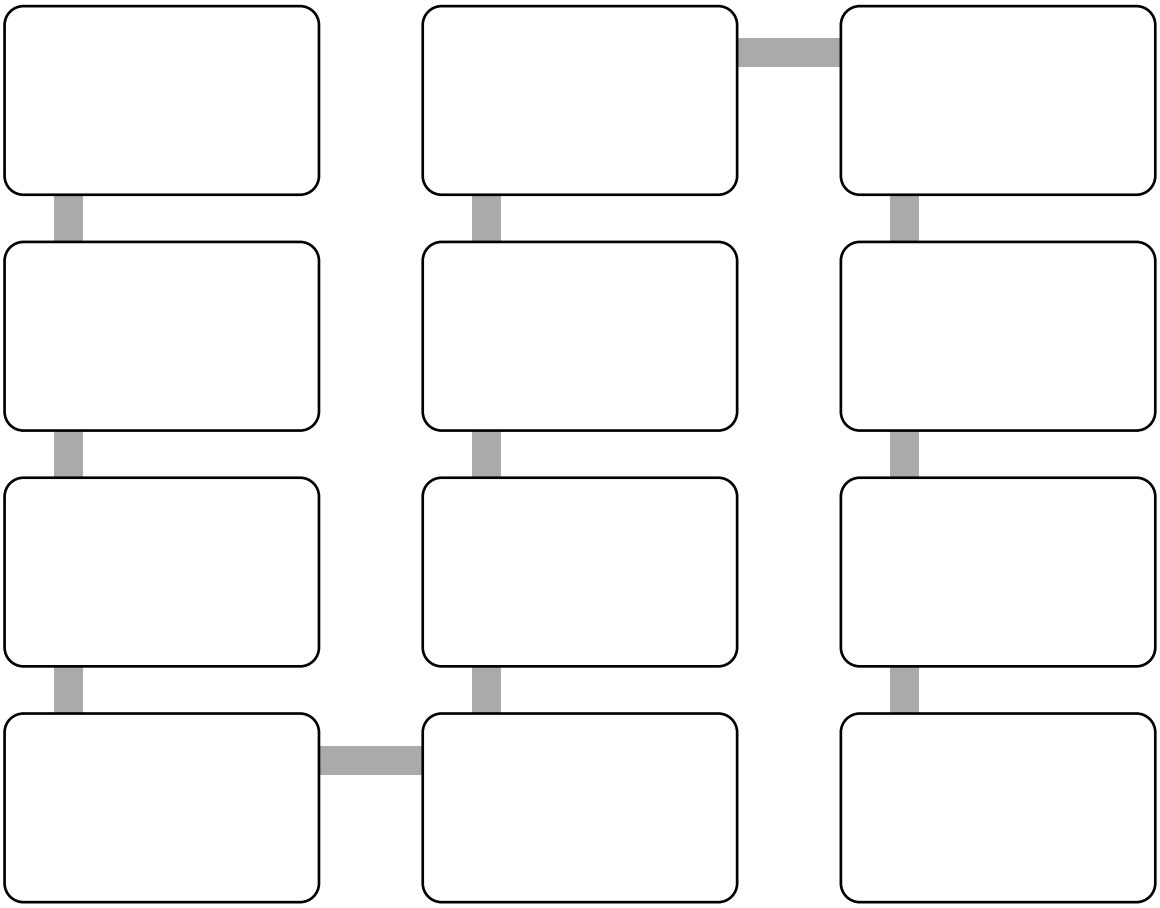
Operational Prerequisite Programs

oPRP 9	*examples*	
oPRP 10		
oPRP 11		
oPRP 12		
oPRP 13		
oPRP 14		

Standard Operating Procedures

SOP 1	*examples*	
SOP 2		
SOP 3		

Flow Chart(s) *Product(s)*_____



Narrative (Optional)

HAZARD ANALYSIS (Ingredients)				
Ingredients and Packaging (FCS)	**Potential Hazards Introduced, Controlled, Enhanced or Reduced**	**Does Hazard Require Control?**	**Justification for Significance**	**Control Measure(s)** PC, oPRP, or GMP
	B- P – C –	B- P – C –		
	B- P – C –	B- P – C –		
	B- P – C –	B- P – C –		
	B- P – C –	B- P – C –		

HAZARD ANALYSIS (Process)				
Process Step	**Potential Hazards Introduced, Controlled, Enhanced or Reduced**	**Does Hazard Require Control?**	**Justification for Significance**	**Control Measure(s)** PC, oPRP, or GMP
	B- P – C –	B- P – C –		
	B- P – C –	B- P – C –		
	B- P – C –	B- P – C –		
	B- P – C –	B- P – C –		

HAZARD ANALYSIS (Process)				
Process Step	**Potential Hazards Introduced, Controlled, Enhanced or Reduced**	**Does Hazard Require Control?**	**Justification for Significance**	**Control Measure(s)** PC, oPRP, or GMP
	B- P – C –	B- P – C –		
	B- P – C –	B- P – C –		
	B- P – C –	B- P – C –		
	B- P – C –	B- P – C –		

Part 3a. Process Preventive Control Summary					
CCP No.	**Critical Limits**	**Monitoring**	**Corrective Actions**	**REC**	**VER**
		What, How, Frequency, Who		Moved to worksheet next page	Moved to worksheet next page
			Identify & eliminate cause of deviation *Bring CCP under control after cor. action is taken* *Measures to prevent recurrence are established.* *No product that is injurious to health or adulterated enters commerce.*		

Records and Verification (worksheet)			
CCP	**Records (who & how often)**	**Responsibility**	**CCP Verification (who & how often)**
	Receiving Log (Form X), Daily Production Log (Form X), Thermometer Calibration Log (Form X)	Processor	1) Process Supervisor will observe Processor in monitoring CCP's for accuracy and review all records weekly. 2) Processor will calibrate thermometers twice weekly.
	Daily Production Log (Form X)	Processor	1) Processor will calibrate metal detection equipment daily and record results into Logbook. 2) Process Supervisor will review log book weekly.
	Daily Production Log (Form X)	Processor	1) Process Supervisor will observe Processor in monitoring CCP's for accuracy and review all records weekly. 2) Processor will calibrate water activity meter once weekly. 3) Process Supervisor will send a representative sample for microbial testing once per every six months.

	Allergen Preventive Control Program | Allergens present in facility *Alternatively create an Excel Spreadsheet*									
Raw Material Name	Supplier	E	D	S	W	TN	GN	F	SH	Comments
		Egg, dairy, soy, wheat, tree nuts, grd nuts, fish, shellfish								
Finished Product Name		E	D	S	W	TN	GN	F	SH	Comments

ALLERGEN PREVENTIVE CONTROL ANALYSIS

	Allergen Hazards	Control Programs
IDENTIFY	Are there allergens present in the facility (ingredients, product, elsewhere)?	(Yes) Master Allergen List
	Can allergens be minimized in formulations?	SOP _____
	Are Suppliers vetted for their allergen programs? COA/LOG/records	SOP _____
	Is there a need for allergen receiving controls? Can unapproved supplies be received?	SOP _____
	Where are allergens stored? How will staff recognize allergen foods in storage?	SOP _____
	Are allergens present elsewhere? Research. Staff use.	SOP _____
PREVENT	Is there a need for allergen storage controls to minimize X-contact?	SOP _____
	Is there a need for dedicated allergen processing /scheduling controls to minimize X-contact? Location - time? Consider dust, overspray?	SOP _____
	IS there a need to control staff movement in allergen areas?	SOP _____
	Is there a need for allergen cleaning controls to minimize X-contact?	SOP _____
	Are there rework allergen concerns?	SOP _____
DECLARE	Are all applicable allergens on the label for each batch? Who checks?	SOP _____
	Who approves labels? Internal and external (regulatory – USDA / FDA)?	SOP _____
	Are the correct labels being used? Are outdated labels present?	SOP _____
	Can a “made in a facility that contains: (-)” be used?	SOP _____
	Is there traceability from ingredient to product? Is this a verification activity?	SOP _____
	What about retail/foodservice packaging?	SOP _____

NOTES

Part 3b. ALLERGEN PC					
Process Step	**Allergen Parameters**	**Monitoring**	**Corrective Actions**	**REC**	**VER**

SANITATION (detailed) HAZARD ANALYSIS			
Product _____			
STEP	**Potential allergen or environmental hazard**	**Control measures (PC, oPRP, or GMP)**	**Justification**

Part 3c. SANITATION PC						
Process Step	**Allergen or Pathogen**	**Parameters**	**Monitoring**	**Corrective Actions**	**REC**	**VER**

Cleaning and Sanitizing FCS SOP	
Purpose **Scope**	This SOP is required to support the Sanitation Preventive Control Program to control cross contact of allergens and cross contamination of environmental pathogens.
Background	Food contact surfaces must be both visually clean and verified clean using an ATP indicator. Monitoring, Corrective Actions, and Records are required.
Management Procedures	Management shall:
Staff Procedures including monitoring	Staff shall:
Corrective Actions	
Verification	
Records	The visual clean status, ATP RLUs, and any applied corrective actions will be indicated on the batch log when applicable.

21 CFR 117 Subpart G--Supply-Chain Program

117.405 - Requirement to establish and implement a supply-chain program.
A facility must establish (document) and implement (monitor, verify, and record) a risk-based supply-chain program –*only*--for those raw materials /ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control.

117.410 - General requirements applicable to a supply-chain program.
Suppliers of controlled ingredients must be approved and verified. Verification of control can include (a) onsite audits (2nd or 3rd party), sampling and testing of the applicable raw material, and/or a review of the supplier's relevant food safety records.

117.415 - Responsibilities of the receiving facility.
In addition to Supplier Approval; the (receiving) facility must establish written procedures for receiving controlled raw materials, then document both implementation and verification activities that those procedures are followed. At no time may Supplier (1st party) activities be permitted for verification of control.
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117.420 - Using approved suppliers.
PRE-approval of controlled raw materials' suppliers is required. Corrective actions would permit holding those raw materials until approval is completed.

117.425 - Determining appropriate supplier verification activities (including frequency).
"Controlled ingredient" Supplier verification activities must be predetermined, including the frequency of those verification activities.

117.430 - Conducting supplier verification activities for raw materials.
"Controlled ingredient" Supplier verification activities must be implemented before first use and then periodically.
--If verification is an onsite audit, perform initially then at least annually thereafter.
--If verification is an LOG (letter of guarantee) obtain written assurance, at least every 2 years, that the supplier is producing the *controlled* raw material in compliance with applicable FDA food safety regulations. The Controlled Ingredient Supplier will also provide a brief description of the preventive controls being implemented.

117.435 - Onsite audit.
Performed by a "qualified" auditor. Controls must be documented and implemented at the same levels as expected of the facility under FDA. State, federal, or international (equivalent food safety nations) regulatory audits are acceptable. Third party auditors must be qualified as described in Part M of 21 CFRR 117.

117.475 - Records documenting the supply-chain program.
These include (a) Supplier preapproval, (b) Receiving procedures, and (c) verification activities. *Review the CFR for this section*.

Supplier Applied Preventive Controls	
Raw materials and product	
Supplier-applied Controls	
Supplier Pre-approval	Supplier Preapproval SOP: Form(s) and Record(s): --completed supplier form
Receiving Procedures (Corrective Actions)	Purchasing SOP: Receiving SOP: Form(s) and Record(s): --purchasing records --receiving records
Verifications (with records)	Onsite audit specifications SOP: Forms and Records --audit reports
	Testing Specifications SOP: Forms and Records --COAs --in house records --third party lab records
	Food Safety Records Letter of Guarantee (LOG) specifications SOP: Forms and Records --LOGs --Regulatory Audit reports