HACCP Manual

_____

(Company Name)

_____

(Company Location)

COMPANY INFORMATION

Company Name:
Company Address:

Contact Person Name, Title:
Contact Phone Number:
Contact Fax Number:
Contact Email:

Brief Company History:

Types of Products Produced/ Type of Manufacturing:

Quality Policy:

Mission Statement:

Vision Statement:

(insert Organizational chart)

HACCP Team

	Name	Position
Coordinator:		
Other Team Members:		

HACCP Training of Coordinator:

Program Title: **SANITATION PROGRAM**

Person Responsible: Sanitation Manager

Where Located: Sanitation Manager's Office

Revision Approval Authority: Sanitation Manager

Revision Timing: Reviews occur annually and if there are any significant changes in equipment, cleaning chemicals or methods, or if there is a program failure.

Program Description:

Goal: Maintain a sanitary environment, necessary for the production of safe and legal products. Ensure sanitation activities do not pose a risk to product.

Scope: All areas, including processing, product storage areas, support areas, and grounds.

Content:

- Cleaning Schedule
  - Master Cleaning Schedule
  - Daily Cleaning Schedule
- Cleaning Procedures
  - Personal Protection Equipment
  - Sanitation Chemical Information
    - Chemical Identification
    - Concentration
- Individual Cleaning Procedures
- Monitoring/Verification Activities Identified
  - Post Cleaning
  - Pre-operational
  - Post Maintenance
- Validation Procedures

Program Title: **SANITATION PROGRAM (Cont.)**

Training: **Who:** Sanitation, maintenance, production

What: Review of cleaning procedures
- Designated tools
- Safety requirements
- Chemical handling
- Documentation requirements

Schedule: Before starting work and annual renewal

Assessment: All training documented

Program Title: **INTEGRATED PEST MANAGEMENT**

Person Responsible: Sanitation Manager

Where Located: Sanitation Manager's Office

Revision Approval Authority: Sanitation Manager

Revision Timing: Reviews occur annually and if there are any significant changes in control methods or if there is a program failure.

Program Description:

Goal: Manage pest population to minimize its potential for product adulteration and/or contamination.

Scope: All areas, including processing, product storage areas, support areas, and grounds.

Content:

Contracted Services
- License
- Insurance
- Contract

Contracted or Internal
- Pest Control Device map
  - Bait stations
  - Traps
  - Insect light traps
  - Pheromone traps
- Inspection Reports
  - Findings
  - Corrective action/follow-up
  - Trend Analysis
- Approved pest control chemical list
  - Labels
  - MSDS forms

Program Title: **INTEGRATED PEST MANAGEMENT (Cont.)**

Contracted or Internal (Cont.)

Pest chemical usage records/log

- Chemical
- EPA Number
- Target pest
- Method of application
- Quantity used
- Concentration
- Area treated (residual chemical only)
- Date and Time of usage
- Signed (applicator signature)

Training: **Who:** All plant personnel

What: Identifying potential pest issues

Issues supporting exclusion

Open doors

Windows without screens

Etc.

Schedule: Prior to starting work and annual renewal

Assessment: Competency testing

Observation

All training documented

Program Title: **CHEMICAL CONTROL PROGRAM**

Person Responsible: Environmental and Safety Manager

Where Located: Environmental and Safety Manager's Office

Revision Approval Authority: Environmental and Safety Manager

Revision Timing: Reviews occur annually and if there are any significant changes in chemical usage or if there is a program failure.

Program Description:

Goal: Protect the product and process environment from possible chemical contamination.

Scope: All non-ingredient chemicals, such as: sanitation, pest control (if applicable), contractor, maintenance, boiler, and laboratory.

Content:

- Chemical approval procedure
- Approved chemical log/list
- Label and MSDS for each chemical
- Controlled storage (locked or limited access)
- Separation of chemicals
  - Type
  - Chemical toxicity (most toxic on bottom)
- Chemical inventory and usage records
- Contractor chemicals
  - Approval
  - MSDS
  - Storage
- Spill procedures
- Disposal procedures
  - Obsolete chemicals
  - Empty containers

Program Title: **CHEMICAL CONTROL PROGRAM (Cont.)**

Training: **Who:** All plant personnel

What: Chemical handling
- Approval procedure
- Safe chemical handling
- MSDS
- Storage

Schedule: Prior to starting work and annual renewal

Assessment: Competency testing
All training documented

Program Title: **ALLERGEN CONTROL PROGRAM**

Person Responsible: Production Manager

Where Located: Production Manager's Office

Revision Approval Authority: Production Manager

Revision Timing: Reviews occur annually and if there is any removal or addition of allergens to the program, any change in point of allergen addition, or if there is a program failure.

Program Description:

Goal: Control the possibility of cross-contamination with allergenic materials and ensure proper labeling of allergens.

Scope: All raw materials, work-in-progress and finished product, as well as employee welfare areas (cafeteria, locker rooms [lunches], vending machines, etc.)

Content:

Allergen identification
- Peanuts, Tree Nuts, Milk (whey, casein), Eggs, Soybean products (protein), Wheat, Fish, Shell Fish
- Sesame seeds (Canada, rest of world)
- Sulfites (Canada, Europe. Not a true allergen)

Receiving
- Allergen inspection part of truck inspection

Storage
- Like over like
- Bottom layer

Production
- Formula identification
- Ingredient lot identification
- Rework
- Scheduling

Personnel practices

Scheduling

Cleaning (changeover checklists, dedicated tools, compressed air usage, verification, validation)

Label verification

Supplier control

Program Title: **ALLERGEN CONTROL PROGRAM (Cont.)**

Training: **Who:** Receiving, Warehousing, Scheduling, Sanitation, Production

What: Allergen Handling
Identification, cleaning procedures, storage, rework, labeling

Schedule: Prior to starting work
Annual renewal training

Assessment: Competency testing
All training documented

Program Title: **GOOD MANUFACTURING PRACTICES**

Person Responsible: Quality Assurance Manager

Where Located: Quality Assurance Manager's Office

Revision Approval Authority: Quality Assurance Manager

Revision Timing: Reviews occur annually and if there are any significant changes in equipment, personnel, or if there is a program failure.

Program Description:

Goal: Maintain an environment and encourage practices that minimize the potential for product adulteration.

Scope: Personnel Practices
Water Quality Program
Plant Maintenance
Building and Grounds
Body Fluids Program
Transportation & Storage

Content:

Personnel Practices:

Jewelry	Hand washing/hand sanitizing
Hair restraint	Locker rooms/lunch rooms/restrooms
Glove policy	Employee health
Food and drink restrictions	Cosmetics
Storage of personal items	
Uniforms/Shoes	Employee Handbook

Program Title: **GOOD MANUFACTURING PRACTICES (Cont.)**

Water Quality:	Incoming water testing for potability - Annual water quality report for municipal water - Potability scan for well water Point of use water testing, includes ice machine Backflow prevention Waste water disposal Plumbing design (CAD Drawing)
Plant Maintenance:	All food-contact surfaces are identified Corrective/unscheduled maintenance - Post-maintenance sanitation Preventive maintenance Equipment design and approved materials Glass, brittle plastics, and ceramics program
Building & Grounds:	Design and construction standards Review and approval of modifications Adequate lighting Traffic patterns (people, product, lifts) Air handling Vegetation control
Body Fluids:	Basic first aid provided by First Responders Clean-up procedures for area and equipment Exposed product disposal Handling of existing sores and wounds Body Fluid Clean-up Kit
Receiving, Transportation and Storage:	Truck inspections - Driver identification - Seals Bulk Vehicles - Cleaning schedule - Wash tickets Inventory control and rotation (FIFO) Temperature control Storage area spacing

Program Title: **GOOD MANUFACTURING PRACTICES (Cont.)**

Training:

Who: All plant personnel, including temporary workers, visitors, contractors

What: General GMP training for everyone
Training is provided for quality technicians regarding water sampling and results interpretation.
Training for maintenance and engineering personnel regarding plant maintenance, building, and grounds issues.
General body fluids training is provided to all personnel
Detailed training is provided for First Responders

Schedule: Prior to starting work in the plant
Upon entry to the plant
Annual renewal

Assessment: Competency testing
All training is documented

Program Title: **SUPPLIER CONTROL PROGRAM**

Person Responsible: Purchasing Manager

Where Located: Purchasing Manager's Office

Revision Approval Authority: Purchasing Manager

Revision Timing: Reviews occur annually and if there is any removal or addition of allergens to the program, any change in point of allergen addition, or if there is a program failure.

Program Description:

Goal: Control of incoming materials through Contract Agreement, Letter of Continuing Guarantee, COA's Specification, etc.

Scope: All raw materials, including packaging material, coming to the plant.

Content:
All suppliers identified
Raw materials supplied identified
Specification requirements
Shipping requirements
COA requirements
Prerequisite Program requirements
Supplier Evaluation

Training: **Who:** Receiving and Quality Personnel

What: Product information
Approved Suppliers
Receiving Requirements

Schedule: Prior to starting work and annual renewal

Assessment: Competency testing
All training is documented

Program Title: **CUSTOMER COMPLAINT PROGRAM**

Person Responsible: Quality Assurance Manager

Where Located: Quality Assurance Manager's Office

Revision Approval Authority: Quality Assurance Manager

Revision Timing: Reviews occur annually and if there is a program failure.

Program Description:

Goal: Identification and resolution of complaints.

Scope: All complaints from customers and consumers, including quality, service, and food safety issues.

Content: Separation of food safety and other complaints
Investigation of complaints
Root-cause, corrective action, and preventive action
Trend analysis
Annual review of food safety complaints by HACCP Team

Training: All personnel responsible for customer communications (phones, email, face-to-face) are trained in obtaining complaint information and dealing with potentially disgruntled customers.

The QA Manager and Plant Management Team are provided training in root-cause analysis, trend analysis, and effective follow-up.

Program Title: **TRACEABILITY PROGRAM**

Person Responsible: Quality Assurance Manager

Where Located: Laboratory

Revision Approval Authority: Quality Assurance Manager

Revision Timing: Reviews occur semi-annually (trace exercises); if there are any significant changes in non-bulk to bulk items; if there is a program failure.

Program Description:

Goal: Identify and trace materials from receipt through production to first point of distribution.

Scope: All raw materials, packaging material, processing aides, work-in-progress, rework and finished product.

Content:
Identification of suppliers
Identification of transport vehicles and drivers
(Possibly part of Transportation Program)
Identification of incoming material by lot code and quantity
Raw material inventory control (WIP, finished product) in storage
Formula control/usage records including rework
Finished product lot code identification
Finished goods inventory control
Shipping/distribution records by quantity and lot code
Traceability exercises

Training:

Who: Receiving, warehouse, production, shipping personnel and management staff

What: Lot number identification for raw material (receipt and usage)
Finished product quantity and lot numbers
Shipping quantity and lot numbers

Schedule: Annually

Assessment: Traceability exercises
Documented results

Program Title: **RECALL PROGRAM**

Person Responsible: Plant Manager

Where Located: Plant Manager's Office

Revision Approval Authority: Plant Manager

Revision Timing: Reviews occur semi-annually (recall drills) and if there are any significant changes in non-bulk to bulk items, or if there is a program failure.

Program Description:

Goal: Removal of suspect product, that is in violation of a regulatory requirement, from the market in a timely and effective manner.

Scope: All product potentially accessible to consumers.

Content: Recall Team
- Name
- Contact information
- Alternates identified

Responsibilities of Team members
Name and location of records used for traceability
Customer (first external customer)
- Name
- Emergency contact information

Lot Code information/identification
Regulatory contact information
Letters of notification
Reportable Food Registry
- FDAAA 2007 – Section 417 FDCA

Recall exercises

Program Title: **RECALL PROGRAM (Cont.)**

Training: **Who:** The Recall Team and alternates

What: Recall knowledge
- Criteria
- Legal responsibility
- Record location
- Individual and Team responsibilities

Schedule: Annual

Assessment: Recall exercises
Documented results

RAW MATERIAL HAZARD ANALYSIS

List all raw materials used in the facility	Identify known hazards	Risk Assessment		Does this material contain a potential significant hazard?[1] (Yes/No)
		Likelihood	Severity	
	B			
	C			
	P			
	B			
	C			
	P			
	B			
	C			
	P			
	B			
	C			
	P			

RAW MATERIAL HAZARD ANALYSIS

Hazards: B = Biological, C = Chemical, P = Physical,
Risk Assessment: VL = Very Low / L = Low / M=Medium / H = High

[1]Significant Hazard: Please refer to the Risk Assessment grid. Any hazard having High Risk must be considered a significant hazard.

Any raw material with a significant hazard must be carried over to the Process Hazard Analysis form for further analysis. Non-significant hazards are not transferred to the Process Hazard Analysis

List all raw materials used in the facility	Identify known hazards	Risk Assessment		Does this material contain a potential significant hazard?[1] (Yes/No)
		Likelihood	Severity	
	B			
	C			
	P			
	B			
	C			
	P			
	B			
	C			
	P			
	B			
	C			
	P			

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HACCP FINISHED PRODUCT PROFILE

General Product Information:

Description of Product(s):	
Intended Use and Consumer/ Customer:	
Method of Storage and Distribution:	
Shelf-life/ Traceability information:	

Technical Product Information:

Preservative(s):	
Water activity (a_w):	
pH/ titratable acidity:	
Packaging requirements:	

Food Safety Information:

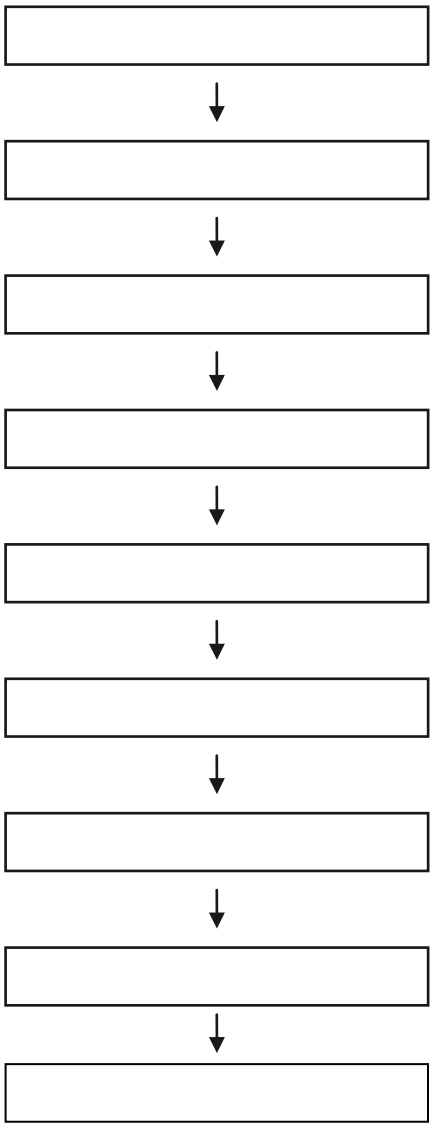
Potential for consumer/ customer misuse:	
Describe the potential food safety issues associated with this product/ process And (if applicable) Key controls, such as CCP identification	

Signature of Company Official: _____

Title: _____ **Date:** _____

PROCESS FLOW DIAGRAM

Guidance: Accurate flow-charting is critical to ensure that raw material transfers, process steps, and distribution are analyzed for potential hazards. Typically, flow charts include receiving, warehouse/bulk storage, product manufacturing steps, and finished product storage/shipping. Make your flow charts simple, yet cover all principal process steps. Be sure any potential CCPs are included. Do not include process conditions or proprietary information.



PROCESS HAZARD ANALYSIS

(1)	(2)			(3)	(4)	(5)
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	B					
	C					
	P					
	B					
	C					
	P					
	B					
	C					
	P					
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	C					
	P					
	B					
	C					
	P					
	B					
	C					
	P					
	B					
	C					
	P					

HACCP MASTER PLAN

(1)	(2)	(3)	(4)	(5)	(6)	(7)
CCP	**Significant Hazard**	**Critical Limits**	**Monitoring**	**Corrective Action**	**Verification**	**Records**
			What:			
			How:			
			Frequency:			
			Who:			

Signature of Company Official: _____ **Title:** _____ **Date:** _____

HACCP MASTER PLAN

(1)	(2)	(3)	(4)	(5)	(6)	(7)
CCP	**Significant Hazard**	**Critical Limits**	**Monitoring**	**Corrective Action**	**Verification**	**Records**
			What:			
			How:			
			Frequency:			
			Who:			

Signature of Company Official: _____ **Title:** _____ **Date:** _____

HACCP MASTER PLAN

(1)	(2)	(3)	(4)	(5)	(6)	(7)
CCP	**Significant Hazard**	**Critical Limits**	**Monitoring**	**Corrective Action**	**Verification**	**Records**
			What:			
			How:			
			Frequency:			
			Who:			

Signature of Company Official: _____ **Title:** _____ **Date:** _____

HACCP DEVIATION REPORT

Date: _____ Critical Control Point: _____

Location: _____ Equipment: _____

Specified Range: _____ Actual Reading: _____

Past History: _____

Corrective Action_____

Future Corrective Action Needed: _____

Product Disposition: _____

Attach a copy of all records of the critical control point deviation.

Reviewed By:

_____
Signature of HACCP Coordinator

Date: _____