Appendix 2: Food Safety Plan Worksheets

General Information

Worksheets are recommended to document the product description, hazard analysis and preventive controls. The Hazard Analysis form should contain information to justify the identification of the hazards requiring preventive controls and the types of preventive controls applied. The information in the Food Safety Plan must explain the details for each preventive control.

There is no standardized or mandated format for documenting the Food Safety Plan. It is recommended that the information be arranged in the Food Safety Plan in a progressive manner that clearly explains the thought process for the hazard analysis and the individual steps in the Food Safety Plan. For example, the hazard analysis should contain information to justify the identification of each hazard requiring a preventive control and the types of preventive controls applied. Details should be explained for each preventive control form used for process preventive controls, which may also be adapted for allergen preventive controls. However, other formats are entirely acceptable if the other formats work for the organization and contain all the required information.

The following worksheets are provided as examples. The information is arranged in a similar manner, but the layouts are in either a landscape or a portrait form to suit individual preferences.

Special Note: These worksheets can be used for training purposes as is, but if they are used for official use, they must include details that identify the commercial firm and related information. The additional information must include:

- Firm name and location;
- Date and, when appropriate, the time of the activity documented;
- Where appropriate, product identification and lot code, if any; and
- The signatures or initials of the person performing the activity.

Forms: The following example forms have been provided as samples for use:

- Product Description, Distribution, Consumers, and Intended Use
- Hazard Analysis
- Process Preventive Controls (Landscape Layout)
- Process Preventive Controls (Portrait Layout)
- Food Allergen Preventive Controls
- Ingredient Food Allergen Identification
- Finished Product Food Allergen Label Declaration Criteria
- Production Line Food Allergen Assessment
- Sanitation Preventive Controls
- Corrective Action Form
- Supply-Chain Preventive Controls Determination of Verification Procedures and Corrective Actions
- Ingredient Receiving Procedures
- Food Safety Plan Reanalysis Checklist

> All forms can be adapted or modified as needed. There is NO required form.

Form Name: Product Description, Distribution, Consumers, and Intended Use

FACILITY NAME:		ISSUE DATE:	PAGE OF
ADDRESS:		SUPERSEDES:	PRODUCT CODE:

Product Name(s)	
Product Description, (including important food safety characteristics)	
Ingredients	
Packaging Used	
Intended Use	
Intended Consumers	
Shelf Life	
Labeling Instructions (related to safety)	
Storage and Distribution	

Approved by*:	*Date Approved:*
Print Name:	
Signature or Initials:	

*Signature or initials may just be on plan or may be on each page.

Form Name: Hazard Analysis

FACILITY NAME:		ISSUE DATE:	PAGE OF
ADDRESS:		SUPERSEDES:	PRODUCT CODE:

Hazard identification (Column 2) considers those hazards that may be present in the food. Because the hazard occurs naturally, the hazard may be unintentionally introduced, or the hazard may be intentionally introduced for economic gain.

    B = Biological hazards including bacteria, viruses, parasites, and environmental pathogens

    C = Chemical (including radiological) hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives

    P = Physical hazards include potentially harmful extraneous matter that may cause choking, injury, or other adverse health effects.

(1) Ingredient / Processing Step	(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
	B							
	C							
	P							
	B							
	C							
	P							
	B							
	C							
	P							

(1) Ingredient / Processing Step	(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
	B							
	C							
	P							
	B							
	C							
	P							
	B							
	C							
	P							
	B							
	C							
	P							
	B							
	C							
	P							

(1) Ingredient / Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled, or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply- chain, other preventive control*	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
	B						
	C						
	P						
	B						
	C						
	P						
	B						
	C						
	P						
	B						
	C						
	P						
	B						
	C						
	P						

Form Name: Process Preventive Controls (Landscape Layout)

FACILITY NAME:			ISSUE DATE:		PAGE OF	
ADDRESS:			SUPERSEDES:		PRODUCT CODE:	

Process Preventive Controls									
Process Control/CCP	**Hazard(s)**	**Parameters, Values, or Critical Limits**	**Monitoring**				**Corrective Action**	**Verification**	**Records**
			What	**How**	**Frequency**	**Who**			

Form Name: Process Preventive Controls (Portrait Layout)

FACILITY NAME:		ISSUE DATE:	PAGE OF
ADDRESS:		SUPERSEDES:	PRODUCT CODE:

Process Preventive Controls

[This is an alternate layout for process preventive controls.]

Process Control/CCP Step				
Hazard(s)				
Parameters, values, or critical limits				
Monitoring	**What**			
	How			
	Frequency			
	Who			
Corrective Action				
Verification				
Records				

Form Name: Food Allergen Preventive Controls

FACILITY NAME:		ISSUE DATE:	PAGE OF		
ADDRESS:		SUPERSEDES:	PRODUCT CODE:		

Food Allergen Preventive Controls

Allergen Controls	Hazard(s)	Criterion	Monitoring				Corrective Action	Verification	Records
			What	**How**	**Frequency**	**Who**			

Form Name: Ingredient Food Allergen Identification

| FACILITY NAME: | | ISSUE DATE: | | PAGE OF | |
| ADDRESS: | | SUPERSEDES: | | PRODUCT CODE: | |

| Raw Material Name | Supplier | Food Allergens in Ingredient Formulation | | | | | | | | | Allergens in Precautionary Labeling |
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)	Sesame	

How to Use the Ingredient Allergen Identification Chart
List all ingredients received in the facility. Identify allergens contained in each ingredient by reviewing ingredient labels or contacting the manufacturer. **Any allergens listed in "May contain" or other precautionary labeling on ingredients should be listed in the last column and reviewed to determine if allergen labeling is needed on the finished product.**

Form Name: Finished Product* Food Allergen Label Declaration Criteria

FACILITY NAME:		ISSUE DATE:	PAGE OF
ADDRESS:		SUPERSEDES:	PRODUCT CODE:

Product	Allergen Statement	Label Number
All finished product labels must declare the allergens present in the formula.		

Form Name: Production Line Food Allergen Assessment

FACILITY NAME:				ISSUE DATE:			PAGE	OF	
ADDRESS:				SUPERSEDES:			PRODUCT CODE:		

Product Name	Production Line	Intentional Allergens								
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)	Sesame

Scheduling Implications:

Allergen Cleaning Implications: (Required)

How to Use the Production Line Food Allergen Assessment Form
Complete for each production line. Identify each allergen contained in each product produced on the line. Identify any allergens unique to a specific product, then indicate scheduling information (i.e., run unique allergens last) and allergen cleaning information.

Form Name: Sanitation Preventive Controls

FACILITY NAME:		ISSUE DATE:	PAGE OF
ADDRESS:		SUPERSEDES:	PRODUCT CODE:

Objective	
Purpose	
Frequency	
Who	
Procedure	
Monitoring	
Corrections or Corrective Actions	
Records	

Form Name: Corrective Action Form

FACILITY NAME:		ISSUE DATE:	PAGE OF
ADDRESS:		SUPERSEDES:	PRODUCT CODE:

Date of Record:	Code or Lot Number:
Date and Time of Deviation:	

Description of Deviation:

Root Cause/Actions Taken to Restore Order to the Process:

Name of Person Taking Action:	Signature of Person Taking Action:

Amount of Product Involved in Deviation:

Evaluation of Product Involved with Deviation:

Final Disposition of Product:

Verification Record	
Reviewer Name:	*Date of Review:*
Reviewer Signature or Initials:	

Form Name: Supply-Chain Preventive Controls Determination of Verification Procedures and Corrective Actions

FACILITY NAME:			ISSUE DATE:		PAGE OF				
ADDRESS:			SUPERSEDES:		PRODUCT CODE:				
Raw Material or Other Ingredient	Approved Supplier Name and Location	Date of Approval	Hazard(s) Requiring a Supply-Chain-Applied Control	Preventive Control Applied by Supplier	Verification Activities	Verification Procedures	Corrective Actions	Records	

Form Name: Ingredient Receiving Procedures

FACILITY NAME:	ISSUE DATE:	PAGE OF
ADDRESS:	SUPERSEDES:	PRODUCT CODE:

[Document procedures used for receiving ingredients requiring a Supply-chain Preventive Control.]:	
Purpose	
Frequency	
Who	
Procedure	
Corrections	
Records	
Verification	

Example: For each shipment received, the receiving clerk uses the receiving database to identify required documentation then:

- Verifies that the product is from an approved supplier and their specific location;

- Verifies that each lot in the shipment is accompanied by a COA, if appropriate;

- Reviews each COA against acceptance criteria above, as appropriate; and

- Documents the above on the Incoming Raw Material Receiving Log.

Form Name: Food Safety Plan Reanalysis Checklist

FACILITY NAME:		ISSUE DATE:	PAGE OF
ADDRESS:		SUPERSEDES:	PRODUCT CODE:

Reason for reanalysis:				
Reanalysis Task	**Date Reviewed and Initials**	**Is Update Needed? (yes/no)**	**Date Task Completed**	**Signature or Initials of Person Completing Task**
List of Food Safety Team with individual responsibilities				
Product Flow Diagrams				
Hazard Analysis				
Process Preventive Controls				
Food Allergen Preventive Controls				
Sanitation Preventive Controls				
Supply-Chain Program				
Recall Plan				
Updated Food Safety Plan Implemented	Not applicable	Not applicable		
Updated Food Safety Plan Signed by Owner or Agent-in-Charge	Not applicable	Not applicable		
Verification Record (this is not required in the regulation but is recommended)				
Reviewer Name:			*Date of Review:*	
Reviewer Signature or Initials:				
Date issued: mm/dd/yyyy		**Supersedes: mm/dd/yyyy**		