

COMPANY NAME

Title: Food Safety Plan
Document:
Effective Date:
Supersedes Date:
Reason For Revision:

FSMA Subpart C: §117.126
Version #:
Prepared By:
Approved By:

Page 1 of 7

1. PURPOSE

1.1 To create an organized **FSMA PC Rule risked-base Food Safety Plan** for **Company Name** ensuring all Food Safety Plan Hazards are identified and Preventive Controls are maintained, executed and continuously improved through a formal review process.

2. §117.126 Food Safety Plan Requirements

2.1 Requirement for a food safety plan.

- 2.1.1** **Company Name** will prepare, or have prepared, and implement a written food safety plan.
- 2.1.2** The food safety plan will be prepared, or its preparation overseen, by one or more **Preventive Controls Qualified Individuals**.
- 2.1.3** Contents of a food safety plan. The written food safety plan must include:
- 2.1.4** The written hazard analysis as required by § 117.130(a)(2);
- 2.1.5** The written preventive controls as required by § 117.135(b);
- 2.1.6** The written supply-chain program as required by subpart G of this part;
- 2.1.7** The written recall plan as required by § 117.139(a); and
- 2.1.8** The written procedures for monitoring the implementation of the preventive controls as required by § 117.145(a)(1);
- 2.1.9** The written corrective action procedures as required by § 117.150(a)(1); and
- 2.1.10** The written verification procedures as required by § 117.165(b).
- 2.1.11 Records.** The food safety plan required by this section is a record that is subject to the requirements of subpart F of the PC Rule. (see Records SOP)

2.2 The **Preventive Controls Qualified Individual** at Company Name is: **NAME**

2.3 *The following are members of the **Company Name**. 'Food Safety Plan Team': (name your team)*

- 2.3.1** **Name**
- 2.3.2** **Name**
- 2.3.3** **Name**
- 2.3.4** **Name**

3. §117.126 REQUIREMENTS for HAZARD ANALYSIS

3.1 Hazard Analysis: **Company Name** will conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control.

Approved By: PCQI	Signature	Date
Insert PCQI Name		

COMPANY NAME

Title: Food Safety Plan
Document:
Effective Date:
Supersedes Date:
Reason For Revision:

FSMA Subpart C: §117.126
Version #:
Prepared By:
Approved By:

3.2 The hazard analysis will be written regardless of its outcome.

3.3 Hazard identification: The hazard identification must consider:

3.3.1 Known or reasonably foreseeable hazards that include:

3.3.1.1 Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;

3.3.1.2 Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and

3.3.1.3 Physical hazards (such as stones, glass, and metal fragments); and

3.3.1.4 Known or reasonably foreseeable hazards that may be present in the food for any of the following reasons:

3.3.1.5 The hazard occurs naturally;

3.3.1.6 The hazard may be unintentionally introduced; or

3.3.1.7 The hazard may be intentionally introduced for purposes of economic gain.

3.4 Hazard Evaluation:

3.5 (1)(i) The hazard analysis will include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

3.6 (ii) The hazard evaluation required by paragraph (c)(1)(i) of this section will include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.

3.7 The hazard evaluation will consider the effect of the following on the safety of the finished food for the intended consumer:

3.7.1 The formulation of the food;

3.7.2 The condition, function, and design of the facility and equipment;

3.7.3 Raw materials and other ingredients;

3.7.4 Transportation practices;

3.7.5 Manufacturing/processing procedures;

3.7.6 Packaging activities and labeling activities;

3.7.7 Storage and distribution;

3.7.8 Intended or reasonably foreseeable use;

3.7.9 Sanitation, including employee hygiene; and

3.7.10 Any other relevant factors, such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of some natural toxins).

Approved By: PCQI	Signature	Date
Insert PCQI Name		

COMPANY NAME

Title: Food Safety Plan
Document:
Effective Date:
Supersedes Date:
Reason For Revision:

FSMA Subpart C: §117.126
Version #:
Prepared By:
Approved By:

4. §117.135 REQUIREMENTS for PREVENTIVE CONTROLS

4.1 Company Name will identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

- 4.1.1** Preventive controls required by paragraph (a)(1) of this section include:
- 4.1.2** Controls at critical control points (CCPs), if there are any CCPs; and
- 4.1.3** Controls, other than those at CCPs, that are also appropriate for food safety.

4.2 Preventive controls must be written.

4.3 Preventive controls include, as appropriate to the facility and the food:

4.3.1 Process controls. Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, acidifying, irradiating, and refrigerating foods. Process controls must include, as appropriate to the nature of the applicable control and its role in the facility’s food safety system:

- 4.3.1.1** Parameters associated with the control of the hazard; and
- 4.3.1.2** The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.

4.3.2 Food allergen controls. Food allergen controls include procedures, practices, and processes to control food allergens. Food allergen controls must include those procedures, practices, and processes employed for:

- 4.3.2.1** Ensuring protection of food from allergen cross-contact, including during storage, handling, and use; and
- 4.3.2.2** Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

4.4 Sanitation controls. Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards. Sanitation controls must include, as appropriate to the facility and the food, procedures, practices, and processes for the:

- 4.4.1.1** Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment;

Approved By: PCQI	Signature	Date
Insert PCQI Name		

COMPANY NAME

Title: Food Safety Plan
Document:
Effective Date:
Supersedes Date:
Reason For Revision:

FSMA Subpart C: §117.126
Version #:
Prepared By:
Approved By:

4.4.1.2 Prevention of allergen cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product.

4.4.2 Supply-chain controls. Supply-chain controls include the supply-chain program as required by subpart G of this part.

4.4.3 Recall plan. Recall plan as required by § 117.139.

4.4.4 Other controls. Preventive controls include any other procedures, practices, and processes necessary to satisfy the requirements of paragraph (a) of this section. Examples of other controls include hygiene training and other current good manufacturing practices.

4.5 § 117.136 Circumstances in which the owner, operator, or agent in charge of a manufacturing/processing facility is not required to implement a preventive control. (if applicable)

4.5.1 Circumstances. If you are a manufacturer/processor, you are not required to implement a preventive control when you identify a hazard requiring a preventive control (identified hazard) and any of the following circumstances apply:

4.5.2 You determine and document that the type of food (e.g., raw agricultural commodities such as cocoa beans, coffee beans, and grains) could not be consumed without application of an appropriate control.

4.5.3 You rely on your customer who is subject to the requirements for hazard analysis and risk-based preventive controls in this subpart to ensure that the identified hazard will be significantly minimized or prevented and you:

4.5.4 Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

4.5.5 Annually obtain from your customer written assurance, subject to the requirements of § 117.137, that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the identified hazard.

4.5.6 You rely on your customer who is not subject to the requirements for hazard analysis and risk-based preventive controls in this subpart to provide assurance it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements and you:

4.5.7 Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

4.5.8 Annually obtain from your customer written assurance that it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements.

Approved By: PCQI	Signature	Date
Insert PCQI Name		

COMPANY NAME

Title: Food Safety Plan
Document:
Effective Date:
Supersedes Date:
Reason For Revision:

FSMA Subpart C: §117.126
Version #:
Prepared By:
Approved By:

- 4.5.9 You rely on your customer to provide assurance that the food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and you:
- 4.5.10 Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and
- 4.5.11 Annually obtain from your customer written assurance, subject to the requirements of § 117.137, that your customer:
- 4.5.12 Will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and
- 4.5.13 Will only sell to another entity that agrees, in writing, it will:
- 4.5.14 Follow procedures (identified in a written assurance) that will significantly minimize or prevent the identified hazard (if the entity is subject to the requirements for hazard analysis and risk-based preventive controls in this subpart) or manufacture, process, or prepare the food in accordance with applicable food safety requirements (if the entity is not subject to the requirements for hazard analysis and risk-based preventive controls in this subpart); or
- 4.5.15 Obtain a similar written assurance from the entity’s customer, subject to the requirements of § 117.137, as in paragraphs (a)(4)(ii)(A) and (B) of this section, as appropriate; or
- 4.5.16 You have established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the food you distribute and you document the implementation of that system.
- 4.5.17 Records. You must document any circumstance, specified in paragraph (a) of this section, that applies to you, including:
- 4.5.18 A determination, in accordance with paragraph (a) of this section, that the type of food could not be consumed without application of an appropriate control;
- 4.5.19 The annual written assurance from your customer in accordance with paragraph (a)(2) of this section;
- 4.5.20 The annual written assurance from your customer in accordance with paragraph (a)(3) of this section;
- 4.5.21 The annual written assurance from your customer in accordance with paragraph (a)(4) of this section; and
- 4.5.22 Your system, in accordance with paragraph (a)(5) of this section, that ensures control, at a subsequent distribution step, of the hazards in the food you distribute.

Approved By: PCQI	Signature	Date
Insert PCQI Name		

COMPANY NAME

Title: Food Safety Plan
Document:
Effective Date:
Supersedes Date:
Reason For Revision:

FSMA Subpart C: §117.126
Version #:
Prepared By:
Approved By:

5. Food Safety Plan – Activities and Criteria

5.1.1 Food Safety Plan Team meets at a **minimum of once a year** to review the following programs and procedures:

5.1.1.1 Food Safety Plan

5.1.1.2 Preventive Controls

5.1.1.3 Food Safety Plan and PC Supporting Documentation and Logs

5.2 Responsibility: The PCQI is responsible for maintaining the Food Safety Plan and Preventive Controls.

5.3 The Food Safety Plan is required a formal reanalysis once every three (3) years.

5.4 The Food Safety Plan Team will conduct a formal Reanalysis (117.170) review or analysis if any of the below occurs or a minimum of every three (3) years:

5.4.1 Change of Process Flow

5.4.2 Change of Equipment

5.4.3 Addition of new SKU's or products

5.4.4 Incorporation of an allergen

5.4.5 Change of personnel or responsibilities

5.4.6 Change or modification of the building or equipment

5.4.7 Regulatory guidance

5.4.8 Change of Formula or Supplier

5.4.9 Recall with a like product

5.4.10 Industry Trending

5.4.11 Process Authority Communication

5.5 Pre-Requisite Programs at **Company Name:**

5.5.1 Personnel Practices

5.5.2 Personnel Processing Practices

5.5.3 Training of Personnel

5.5.4 Calibration of Equipment

5.5.5 Management of Pests and Vermin

5.5.6 Premises and Equipment Maintenance

5.5.7 Cleaning and Sanitation

5.5.8 Monitoring Water and Microbiology Quality

5.5.9 Control of Physical Contaminants

5.5.10 Supplier Approval

5.5.11 Transport and Delivery

Approved By: PCQI	Signature	Date
Insert PCQI Name		

COMPANY NAME

Title: Food Safety Plan
Document:
Effective Date:
Supersedes Date:
Reason For Revision:

FSMA Subpart C: §117.126
Version #:
Prepared By:
Approved By:

- 5.5.12 Waste Management and Disposal
- 5.5.13 Allergen Control

- 5.6 A minimum of one Food Safety Plan Team Member will be designated a formal Preventive Controls Qualified Individual (PCQI).
- 5.7 The Team will be trained on the Food Safety Plan Principles (Hazards and Preventive Controls) and the FSP content.
- 5.8 Formal Food Safety Plan training will occur a minimum of once a year and/or if the Food Safety Plan is revised.

6. Responsibility

- 6.1 The Preventive Controls Qualified Individual is responsible for creating and maintaining the Food Safety Plan.
- 6.2 All Food Safety Plan Team members are responsible for assisting in maintaining the Food Safety Plan required activities and Preventive Controls.

7. Documentation

- 7.1 Food Safety Plan
- 7.2 PCQI Training Certificate
- 7.3 Preventive Controls Outline and Logs
- 7.4 Food Safety Plan Training Logs
- 7.5 Food Safety Plan Team Meeting Notes
- 7.6 Prerequisite SOP's
- 7.7 Prerequisite Logs
- 7.8 Verification and Validation Schedule
- 7.9 Recall Plan
- 7.10 Supply Chain Program

Approved By: PCQI	Signature	Date
Insert PCQI Name		