

# **Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry<sup>1</sup>**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration's (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting the form available at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>.

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<sup>1</sup> This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

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## **Introduction**

We recommend that you use worksheets to document the:

- Product description;
- Hazard analysis;
- Process controls;
- Sanitation controls; and
- Food allergen controls.

There is no standardized or mandated format for documenting the food safety plan. However, in this appendix we refer you to worksheets that were developed by Food Safety Preventive Controls Alliance (FSPCA). We recommend that you use forms such as these for documenting your food safety plan for two reasons: (1) These worksheets are used in training by the FSPCA and, thus, you will be familiar with these forms if you take this training; and (2) these worksheets are similar to forms used in documenting Hazard Analysis and Critical Control Point (HACCP) plans and prerequisite programs and, thus, these worksheets may be similar to forms you are already using.

The FSPCA makes these forms available on its website at [http://www.iit.edu/ifsh/alliance/resources/fspca\\_materials](http://www.iit.edu/ifsh/alliance/resources/fspca_materials). In this Appendix, we have modified the format of FSPCA's forms for consistency with the formats we use for making documents accessible for persons using assistive technology such as a screen reader. You may obtain the current copy of FSPCA's forms from its website.

In general, regardless of whether you use these worksheets, we recommend that you arrange the information in your 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:

- Your hazard analysis should contain information to justify:
  - Your identification of each hazard requiring a preventive control; and
  - The types of preventive controls applied;
- You should explain the details for each preventive control.

Other formats are entirely acceptable if they work for your organization. If you use another format, you should ensure that your format provides all of the information that the preventive controls rule requires for each required component of the food safety plan. See 21 CFR 117.126, 117.305, and 117.310.

Each FSPCA form has a form name, but does not have an identifying number. In this Appendix, we number each FSPCA form (Form 2-A, Form 2-B, etc.) to have a concise identifier for each form.

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## **Form 2-A: FSPCA Form for Product Description**

In Chapter 2 of this guidance, we recommend that you conduct certain preliminary steps before conducting your hazard analysis. One of these preliminary steps is to describe the product, its distribution, intended use, and consumer or end user of the product. The product description form that is commonly used in the development of HACCP plans can be used to do so. See Form 2-A.

Below, we list the information that you will see on Form 2-A. When appropriate for clarity, we explain what type of information you would include for the listed information. Regardless of whether you use Form 2-A, we recommend that you include such information in any product description that you develop.

- General information such as the name and address of the plant, the issue date of the form and the old version (“supersedes”), the page number (often “Page X of Y”).
- Product Name: i.e., the full name of the finished product.
- Product Description, including Important food safety characteristics – i.e., descriptors such as ready-to-eat (RTE), frozen; factors that can influence growth of pathogens, such as whether the food has a low pH or  $a_w$  or contains preservatives.
- Ingredients.
- Packaging Used: e.g., type (bottle, box, can); material (plastic, glass, cardboard with liner); reduced oxygen packaging.
- Intended Use: e.g., intended for retail, foodservice, or further processing; whether the food is ready-to-eat or ready-to-cook by the consumers; and what the potential is for mishandling or unintended use.
- Intended Consumers: usually the general public; however, if a food product is intended specifically for susceptible populations such as hospitals, you should say so.
- Shelf Life.
- Labeling Instructions Related to Safety: e.g., “keep refrigerated” or cooking instructions.
- Storage and Distribution: e.g., whether the food is stored and/or distributed refrigerated, frozen or at ambient temperatures.

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**FORM 2-A PRODUCT DESCRIPTION**

PAGE \_\_\_\_\_

**PRODUCTS:** \_\_\_\_\_  
**PLANT NAME:** \_\_\_\_\_  
**ADDRESS:** \_\_\_\_\_  
**ISSUE DATE:** (mm/dd/yy) \_\_\_\_\_  
**SUPERSEDES:** (mm/dd/yy) \_\_\_\_\_

<b>Product Name(s)</b>	
<b>Product Description, including Important Food Safety Characteristics</b>	
<b>Ingredients</b>	
<b>Packaging Used</b>	
<b>Intended Use</b>	
<b>Intended Consumers</b>	
<b>Shelf Life</b>	
<b>Labeling Instructions related to Safety</b>	
<b>Storage and Distribution</b>	

**Approved:** (signature or initials) \_\_\_\_\_

**Date:** \_\_\_\_\_

## **Form 2-B: FSPCA Form for Hazard Analysis**

In Chapter 2 of this guidance, we explain how to set up an adaptation of the “Hazard Analysis Worksheet” used in HACCP systems to organize your hazard analysis. See Form 2-B. Note that for brevity Form 2-B uses the term “potential hazard” rather than “known or reasonably foreseeable hazard.”

See section 2.2.2 in Chapter 2 for an overview of how to set up columns 1-6 of Form 2-B. See the remainder of Chapter 2 for more detail about how to provide information on Form 2-B. Regardless of whether you use Form 2-B, we recommend that you include such information in your hazard analysis.

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**FORM 2-B HAZARD ANALYSIS\***

PAGE \_\_\_\_\_

**PRODUCTS:** \_\_\_\_\_

**PLANT NAME:** \_\_\_\_\_

**ADDRESS:** \_\_\_\_\_

**ISSUE DATE:** (mm/dd/yy) \_\_\_\_\_

**SUPERSEDES:** (mm/dd/yy) \_\_\_\_\_

(1) Ingredient / Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step  B = biological C = chemical, including radiological P = physical	(3) Are any <u>potential</u> food safety hazards requiring preventive control? (Yes/No)	(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? <i>Process including CCPs, Allergen, Sanitation, Supplier, other preventive control</i>	(6) Is the preventive control applied at this step? (Yes/No)

\* The current FSPCA form includes some additional features, such as a separate column for “Yes” and “No” responses and a separate row at each step for biological, chemical, and physical hazards (labeled B, C, and P, respectively).

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## **Form 2-C: FSPCA Form for Process Controls**

Chapter 5 of this guidance provides an overview of the application of preventive controls to significantly minimize or prevent the occurrence of biological, chemical, and physical hazards in finished foods and the food production environment. Chapter 5 also provides an overview of preventive control management components (i.e., monitoring, corrective actions and corrections, and verification activities (and their associated records)). When the preventive control that you identify is a process control, Form 2-C provides a format for you to specify the process control and the associated preventive control management components.

Below, we list the information that you will see on Form 2-C. When appropriate for clarity, we explain what type of information you would include for the listed information. Regardless of whether you use Form 2-C, we recommend that you include such information in your food safety plan when you will implement a process control.

- General information such as the name and address of the plant, the issue date of the form and the old version (“supersedes”), the page number (often “Page X of Y”).
- Process Control: From the Hazard Analysis form, enter the steps identified as requiring a process control
- Hazard(s): From the Hazard Analysis form, enter the hazard requiring a preventive control at each step listed in the “Process Control” column.
- Parameters, values, or critical limits: Enter the parameters, and the associated minimum or maximum value (or critical limits) associated with the parameters.
- Monitoring: In the columns provided, enter what will be monitored, how it will be monitored, the frequency that the monitoring will be done and who will do the monitoring (e.g., the position, such as “operator” or “QA technician”).
- Corrective Actions: Describe the corrective actions that will be taken when deviations from the minimum/maximum values (or critical limits) for a parameter occur.
- Verification: List the ongoing verification activities, including calibration (where appropriate) and records review. Although the form was designed to focus on ongoing verification activities, rather than data and information addressing validation, you also can list information such as a validation study on FSPCA Form 2-C if you find it useful to do so.
- Records: List the names of the records that result from implementation of the process controls (e.g., cook log, cooling records, metal detector check log).

# FORM 2-C PROCESS CONTROLS

PAGE \_\_\_\_\_

PRODUCTS: \_\_\_\_\_  
PLANT NAME: \_\_\_\_\_  
ADDRESS: \_\_\_\_\_  
ISSUE DATE: (mm/dd/yy) \_\_\_\_\_  
SUPERSEDES: (mm/dd/yy) \_\_\_\_\_

Process Control Step	Hazard(s)	Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records



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<b>Process Control Step</b>	<b>Hazard(s)</b>	<b>Critical Limits</b>	<b>What to Monitor</b>	<b>How to Monitor</b>	<b>Frequency of Monitoring</b>	<b>Who Monitors</b>	<b>Corrective Action</b>	<b>Verification</b>	<b>Records</b>

## Form 2-D: FSPCA Form for Sanitation Controls

The forthcoming Chapter 10 of this guidance will address sanitation controls, which can vary substantially from facility to facility. When the preventive control that you identify is a sanitation control, Form 2-D provides a format for you to specify the sanitation control and the associated preventive control management components. Although Form 2-D may not always be the most effective way to describe the many sanitation controls that may be employed, you may find Form 2-D helpful to summarize cleaning and sanitizing of a particular piece of equipment or particular locations in your plant where product is exposed to the environment.

Below, we list the information that you will see on Form 2-D. When appropriate for clarity, we explain what type of information you would include for the listed information.

- General information such as the name and address of the plant, the issue date of the form and the old version (“supersedes”), the page number (often “Page X of Y”).
- Location: Enter the location(s) in the plant where the sanitation control described on Form 2-D will be used.
- Purpose: e.g., to remove food allergens, to reduce contamination with environmental pathogens
- Frequency: How often the procedure is used (e.g., daily; after each production run; weekly;)
- Who: i.e., the position, such as “sanitation technician” or “sanitation supervisor”
- Procedure: You can write the procedure on the form or refer to a specific Standard Operating Procedure (SOP). Procedures can include cleaning procedures and monitoring procedures, such as measuring sanitizer concentration.
- Corrections (Corrective Actions Where Appropriate) - e.g., recleaning equipment that is not visibly clean prior to production. In most cases, corrections are appropriate. However, you may want to include circumstances that would trigger corrective actions.
- Records: the type of records you will maintain.
- Verification activities (such as records review) and the type of records maintained are listed.

## FORM 2-D SANITATION CONTROLS

PAGE \_\_\_\_\_

PRODUCTS: \_\_\_\_\_  
PLANT NAME: \_\_\_\_\_  
ADDRESS: \_\_\_\_\_  
ISSUE DATE: (mm/dd/yy) \_\_\_\_\_  
SUPERSEDES: (mm/dd/yy) \_\_\_\_\_

<b>Location</b>	
<b>Purpose</b>	
<b>Frequency</b>	
<b>Who</b>	
<b>Procedure</b>	
<b>Monitoring</b>	
<b>Corrections (Corrective actions where necessary)</b>	
<b>Records</b>	

Verification: (signature or initials) \_\_\_\_\_

Date: \_\_\_\_\_

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## **FSPCA Food Allergen Control Forms**

Chapter 5 of this guidance provides an overview of the application of preventive controls to significantly minimize or prevent the occurrence of biological, chemical, and physical hazards in finished foods and the food production environment. Chapter 5 also provides an overview of preventive control management components (i.e., monitoring, corrective actions and corrections, and verification activities (and their associated records)). Our forthcoming Chapter 11 - Food Allergen Controls will provide a comprehensive guide to food allergen control.

When the preventive control that you identify is an allergen control, the FSPCA forms that we identify as Forms 2-E, 2-F, 2-G, and 2-H provide a format for you to specify the allergen control and the associated preventive control management components.

- Form 2-E: FSPCA form for Food Allergen Ingredient Analysis. Use for conducting an allergen-specific hazard analysis of food ingredients.
- Form 2-F: FSPCA form for Food Allergen Label Verification List. Use to list the specific allergens to be listed in the “Contains” declaration on the product label.
- Form 2-G: FSPCA form for Production Line Food Allergen Assessment. Use to identify common and unique food allergens for products produced on a production line for the purpose of making decisions on scheduling (e.g., run unique allergens last) and allergen cleaning information (e.g., conduct a full allergen cleaning before running products without the allergen)
- Form 2-H: FSPCA form for Food Allergen Controls. Use to describe any food allergen controls and associated preventive control management components.

Regardless of whether you use these FSPCA Food Allergen forms, we recommend that you conduct a food allergen ingredient analysis and include information such as you see in Form 2-E in your food safety plan. If your food allergen ingredient analysis identifies food allergens that will be (or may be) in your products, we recommend that you include information such as you see in the remaining FSPCA forms in your food safety plan.

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**Form 2-E: FSPCA Form for Food Allergen Ingredient Analysis**

Below, we list the information that you will see on Form 2-E. When appropriate for clarity, we explain what type of information you would include for the listed information.

- General information such as the name and address of the plant, the issue date of the form and the old version (“supersedes”), the page number (often “Page X of Y”).
- Raw Material Name: List all raw materials received in the facility
- Supplier: Identify the supplier for each raw material
- Food Allergens in Ingredient Formulation: Identify any food allergens in each listed raw material – e.g., by reviewing ingredient labels or contacting the manufacturer
- Food Allergens in Precautionary Labeling: List any allergens listed in precautionary labeling (such as a “May Contain” statement) in raw materials that you receive

## FORM 2-E FOOD ALLERGEN INGREDIENT ANALYSIS

PAGE \_\_\_\_\_

PRODUCTS: \_\_\_\_\_

PLANT NAME: \_\_\_\_\_

ADDRESS: \_\_\_\_\_

ISSUE DATE: (mm/dd/yy) \_\_\_\_\_

SUPERSEDES: (mm/dd/yy) \_\_\_\_\_

### Food Allergens in Ingredient Formulation or in Precautionary Labeling

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

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**Form 2-F: FSPCA Form for Food Allergen Label Verification List**

Below, we list the information that you will see on Form 2-F. When appropriate for clarity, we explain what type of information you would include for the listed information.

- General information such as the name and address of the plant, the issue date of the form and the old version (“supersedes”), the page number (often “Page X of Y”).
- Product: List each product that will contain (or may contain) a major food allergen
- Allergen Statement: Specify the “Contains” statement that you will include on the product label for that product.

**FORM 2-F FOOD ALLERGEN LABEL VERIFICATION LIST**

**PAGE** \_\_\_\_\_

**PRODUCTS:** \_\_\_\_\_  
**PLANT NAME:** \_\_\_\_\_  
**ADDRESS:** \_\_\_\_\_  
**ISSUE DATE:** (mm/dd/yy) \_\_\_\_\_  
**SUPERSEDES:** (mm/dd/yy) \_\_\_\_\_

<b>Product</b>	<b>Allergen Statement</b>
	<b>Contains:</b>
	<b>Contains:</b>
	<b>Contains:</b>
	<b>Contains:</b>

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**Form 2-G: FSPCA Form for Production Line Food Allergen Assessment**

Below, we list the information that you will see on Form 2-G. When appropriate for clarity, we explain what type of information you would include for the listed information.

- General information such as the name and address of the plant, the issue date of the form and the old version (“supersedes”), the page number (often “Page X of Y”).
- Product Name: List each product made in the plant
- Production Line: Identify the production line used for each listed product
- List the allergens that you will add to the listed product, including any allergens listed in precautionary labeling if you determine there is the potential for these to contaminate the line.

**FORM 2-G PRODUCTION LINE FOOD ALLERGEN ASSESSMENT**

PAGE \_\_\_\_\_

**PRODUCTS:** \_\_\_\_\_

**PLANT NAME:** \_\_\_\_\_

**ADDRESS:** \_\_\_\_\_

**ISSUE DATE:** (mm/dd/yy) \_\_\_\_\_

**SUPERSEDES:** (mm/dd/yy) \_\_\_\_\_

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



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**Form 2-H: FSPCA Form for Food Allergen Controls**

The FSPCA Food Allergen Control Form (Form 2-H) is modeled after the FSPCA Process Controls Form (Form 2-C). Below, we list the information that you will see on Form 2-H. When appropriate for clarity, we explain what type of information you would include for the listed information.

- General information such as the name and address of the plant, the issue date of the form and the old version (“supersedes”), the page number (often “Page X of Y”).
- Allergen Control Step: Describe the step at which the allergen control is being applied e.g., at label receipt or label application for label controls; at post-production sanitation for equipment cleaning.
- Hazard: e.g., undeclared allergen due to incorrect label; undeclared allergen due to cross-contact.
- Criterion: Specify the criterion you are trying to meet, e.g., all finished product labels declare the allergens in the product.
- Monitoring; In the columns provided, enter what will be monitored (e.g., the label ingredient declaration), how it will be monitored (e.g., the label will be visually checked and compared to the product formulation), the frequency that the monitoring will be done (e.g., each new order of labels before they are released to production), and who will do the monitoring (e.g., label coordinator).
- Corrective Actions: In some cases, corrections will be appropriate. However, you should include circumstances that would trigger corrective actions.
- Verification: List the verification activities, such as records review.
- Records: List the names of the records that result from implementation of the food allergen controls (e.g., label review log).

# FORM 2-H FOOD ALLERGEN CONTROLS

PAGE \_\_\_\_\_

**PRODUCTS:** \_\_\_\_\_  
**PLANT NAME:** \_\_\_\_\_  
**ADDRESS:** \_\_\_\_\_  
**ISSUE DATE:** (mm/dd/yy) \_\_\_\_\_  
**SUPERSEDES:** (mm/dd/yy) \_\_\_\_\_

Allergen Control Step	Hazard(s)	Criterion	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records

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<b>Allergen Control Step</b>	<b>Hazard(s)</b>	<b>Criterion</b>	<b>What to Monitor</b>	<b>How to Monitor</b>	<b>Frequency of Monitoring</b>	<b>Who Monitors</b>	<b>Corrective Action</b>	<b>Verification</b>	<b>Records</b>

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## **Form 2-I: FSPCA Form for Supply-chain-applied Preventive Controls Program**

Chapter 5 of this guidance provides an overview of the application of preventive controls to significantly minimize or prevent the occurrence of biological, chemical, and physical hazards in finished foods and the food production environment. Chapter 5 also provides an overview of preventive control management components (i.e., monitoring, corrective actions and corrections, and verification activities (and their associated records)). Our forthcoming Guidance for Industry, Supply-Chain Programs, Draft Guidance, will provide a comprehensive guide to supply-chain controls.

When the preventive control that you identify is a supply-chain control, Form 2-I provides a format for you to specify the preventive control and the associated preventive control management components appropriate for a supply-chain program. You would use a separate form for each ingredient that would have a supply-chain program control. Below, we list the information that you will see on Form 2-I. When appropriate for clarity, we explain what type of information you would include for the listed information. Regardless of whether you use Form 2-I, we recommend that you include such information in your food safety plan when you will implement a supplier control.

- General information such as the name and address of the plant, the issue date of the form and the old version (“supersedes”), the page number (often “Page X of Y”).
- Hazards requiring a supply-chain-applied control: List each hazard requiring a preventive control
- Preventive controls applied by the supplier: When applicable, list any preventive controls applied by the supplier
- Verification activities: List the verification activities you will conduct – i.e., onsite audits; sampling and testing of the raw material or other ingredient; review of the supplier’s relevant food safety records; and other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient.
- Verification procedures: e.g., procedures for receiving raw materials and other ingredients; audit procedures
- Records: e.g., records documenting receipt from an approved supplier, records documenting review of supplier verification activities

## Form 2-I: Supply-chain-applied Preventive Controls Program

PAGE \_\_\_\_\_

**PRODUCTS:** \_\_\_\_\_  
**PLANT NAME:** \_\_\_\_\_  
**ADDRESS:** \_\_\_\_\_  
**ISSUE DATE:** (mm/dd/yy) \_\_\_\_\_  
**SUPERSEDES:** (mm/dd/yy) \_\_\_\_\_

***Determination of Verification Procedures***

Ingredient:

<b>Hazards requiring a supply-chain-applied control</b>	
<b>Preventive controls applied by the supplier</b>	
<b>Verification activities</b>	
<b>Verification procedures</b>	
<b>Records</b>	

***Approved Suppliers for Ingredients Requiring a Supply-chain-applied Control***

Ingredient (requiring supply-chain-applied control)	Approved Supplier	Hazard(s) requiring supply-chain-applied control	Date of Approval	Verification method	Verification records

***Receiving Procedure for Ingredients Requiring a Supply-chain-applied Control***

*[Document procedures used for receiving ingredients requiring a supply-chain-applied control.]*