

FSMA Webinar How to Use the PCHF Guidance

September 19, 2016

**FDA FOOD SAFETY
MODERNIZATION ACT**

THE FUTURE IS NOW



Objectives

- Purpose and Scope of draft PCHF Guidance
- Describe the structure of the draft PCHF Rule Guidance to Industry document
- Highlight Key Content from Guidance
- Answer Questions

PCHF Guidance Introduction

- **Key Content**

- Summarizes the requirements of the PCHF Rule
- Establishes the purpose of the Guidance is to support compliance to the requirements of Subparts C and G
- Provides a Glossary of Terms Used in the Guidance
- PCHF Guidance Structure

Subparts Established in 21 CFR 117 Requirements

Subpart	Title
A	General Provisions
B	Current Good Manufacturing Practice
C	Hazard Analysis and Risk-Based Preventive Controls
D	Modified Requirements
E	Withdrawal of a Qualified Facility Exemption
F	Requirements Applying to Records That Must be Established and Maintained
G	Supply-Chain Program

Purpose of PCHF Guidance

- To help a facility develop a food safety plan (FSP) in accordance with the requirements of the PCHF Rule (Subpart C and G) of part 117:
 - A written food safety plan (FSP);
 - Hazard analysis;
 - Preventive controls;
 - Monitoring;
 - Corrective actions;
 - Verification; and
 - Associated records.

Guidance Provided on PCHF Rule Subpart C

- Understanding the **biological, chemical (including radiological) and physical hazards** that are commonly of concern in manufacturing, processing, packing, and holding of FDA-regulated food products;
- Understanding the **components of an FSP** and the importance of each component;
- Understanding how to conduct a **hazard analysis and develop an FSP** for the products that you process;
- Understanding how to **identify control measures** for common biological (specifically bacterial pathogens), chemical, and physical hazards associated with many processed foods so you can apply those controls to the hazards identified in your hazard analysis;
- Understanding how to identify and **apply the preventive control management components** (i.e., monitoring, corrective actions and corrections, and verification); and
- Understanding the **recordkeeping requirements** associated with the FSP and implementation of the FSP.



PCHF Guidance Structure

Chapter	Subject	Guidance Page #	Status
1	The Food Safety Plan	11	Draft
2	Conducting a Hazard Analysis	17	Draft
3	Potential Hazards Associated with the Manufacturing, Processing, Packing, and Holding of Human Food	37	Draft
4	Preventive Controls	80	Draft
5	Application of Preventive Controls and Preventive Control Management Components	122	Draft

PCHF Guidance Structure

Chapter	Subject	Status
6	Use of Heat Treatments as a Process Control	Coming soon
7	Use of Time/Temperature Control as a Process Control	Coming soon
8	Use of Formulation as a Process Control	Coming soon
9	Use of Dehydration/Drying as a Process Control	Coming soon
10	Sanitation Controls	Coming soon
11	Food Allergen Controls	Coming soon
12	Preventive Controls for Chemical Hazards	Coming soon
13	Preventive Controls for Physical Hazards	Coming soon
14	Recall Plans	Coming soon

PCHF Guidance Structure

Appendix	Subject	Guidance Page #	Status
1	Potential Hazards for Foods and Processes	140 (<i>see separate document</i>)	Draft
2	Food Safety Plan Forms	142	Draft
3	Bacterial Pathogen Growth and Inactivation	163	Draft
4	Sanitation and Hygienic Zoning	TBD	Coming soon

PCHF Guidance – Chapter 1

Purpose of Chapter

- The guidance provided in this chapter is intended to help facilities that manufacture, process, pack, or hold human food to understand what a food safety plan is and how it differs from a Hazard Analysis and Critical Control Point (HACCP) plan.
- The PCHF Rule requires a facility to prepare, or have prepared, and implement a written food safety plan.

PCHF Guidance - Chapter 1 Highlights the Food Safety Plan (FSP)

- Provides industry some insight as to the difference between a HACCP Plan and an FSP
- Key content:
 - No standard form for an FSP
 - FSP requires a written Hazard Analysis
 - In the event no hazards are identified, the rationale for this finding is still required

PCHF Guidance – Chapter 1

Comparison of Elements Between HACCP Plan and FSP

Element	HACCP Plan	Different in Food Safety Plan
Hazard Analysis	Biological, chemical, physical hazards	Chemical hazards include radiological hazards, consideration of economically motivated adulteration (21 CFR 117.130(b)(1)(ii))
Preventive Controls	CCPs for processes	Process CCPs + controls at other points that are not CCPs (21 CFR 117.135(a)(2))
Parameters and values	Critical limits at CCPs	Parameters and minimum/maximum values (equivalent to critical limits for process controls) (21 CFR 117.135(c)(1))
Monitoring	Required for CCPs	Required as appropriate for preventive controls (21 CFR 117.145)
Corrective actions and Corrections	Corrective actions	Corrective actions or corrections as appropriate (21 CFR 117.150(a))
Verification (including validation)	For process controls	Verification as appropriate for all preventive controls; validation for process controls; supplier verification required when supplier controls a hazard (21 CFR 117.155, 117.160)
Records	For process controls	As appropriate for all preventive controls (21 CFR 117.190)
Recall plan	Not required in the plan	Required when a hazard requiring a preventive control is identified (21 CFR 117.139)

PCHF Guidance – Chapter 2

Purpose of Chapter

- The guidance provided in this chapter is intended to help facilities that manufacture, process, pack, or hold human food to conduct a hazard analysis.
- The Preventive Controls for Human Food Rule (PCHF Rule) requires facilities to conduct a hazard analysis.
- The hazard analysis must be written, regardless of the results of the analysis, and must include two elements:
 1. a hazard identification and
 2. a hazard evaluation.



PCHF Guidance – Chapter 2

- A definition for “Hazard Analysis”

Hazard Analysis

The process of collecting and evaluating information on hazards and the conditions leading to their presence to determine which hazards are significant for food safety and therefore should be addressed in a HACCP plan or food safety plan (FSP).

Food Safety Preventive Controls Alliance

PCHF Guidance – Chapter 2

Highlights Conducting a Hazard Analysis

- Focused guidance for use in conducting a hazard analysis
- Key Content:
 - Examples of questions to be considered when identifying potential hazards regarding:
 - Ingredients
 - Product intrinsic factors
 - Processing procedures
 - Microbial content of food
 - Facility / Equipment design
 - Packaging / Storage conditions

PCHF Guidance – Chapter 2

- Sources of Data about Outbreaks

Food and Drug Administration (FDA)

- Outbreak investigations – reports for FDA regulated foods

Centers for Disease Control and Prevention (CDC)

- Foodborne Outbreaks (including links to the List of Selected Multistate Foodborne Outbreak Investigations (see below) and Morbidity and Mortality Weekly Report reports on foodborne outbreaks)
- List of Selected Multistate Foodborne Outbreak Investigations - searchable database for selected U.S. outbreaks by year and by pathogen
- Attribution of Foodborne Illness – reports on foods associated with illness

Center for Science in the Public Interest (CSPI)

- Outbreaks & Recalls

PCHF Guidance – Chapter 3

Purpose of Chapter

- The guidance in this chapter is intended to help facilities that manufacture, process, pack, or hold human food consider the biological, chemical, and physical hazards that are commonly of concern in food plants and that should be addressed in a hazard analysis.
- It addresses ingredient-related hazards, process-related hazards, and hazards that may be introduced from the food-production environment (facility-related hazards).

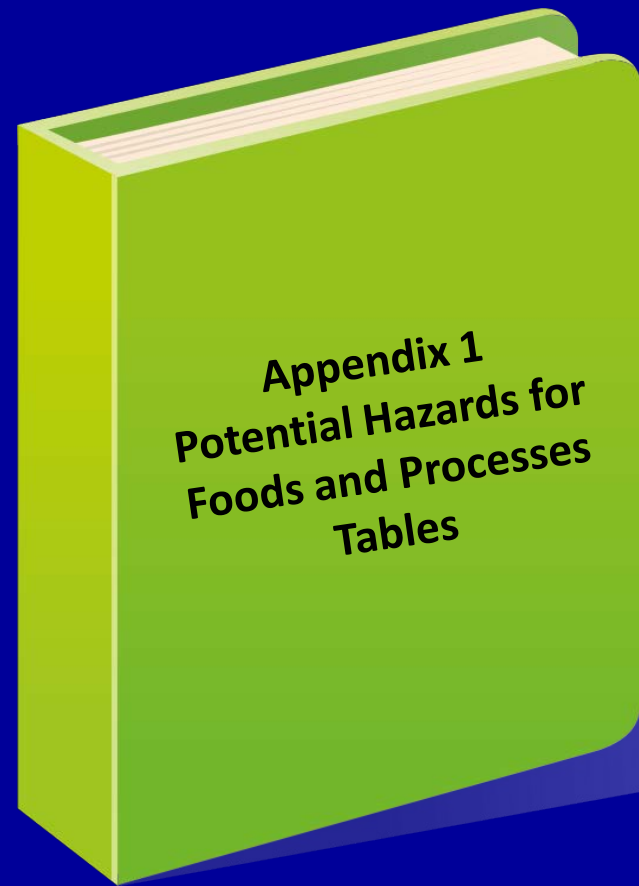
PCHF Guidance – Chapter 3

Highlights Potential Hazards Associated with the Manufacturing, Processing, Packing, and Holding of Human Food

- It does not provide an exhaustive compendium of hazards or details about each hazard.

PCHF Guidance – Chapter 3

- **Key Content:**
 - Where possible, scientific literature, regulations, and/or guidance (issued by FDA or our food safety regulatory partners) is referenced
 - Hazards Tables found in Appendix 1



PCHF Guidance – Chapter 3

Key Content:

- Scientific Literature and Data
 - Information provided for background and basis for hazard identification.

PCHF Guidance – Chapter 3

- **Hazards Tables Content**
 - Provided data based on scientific literature, FDA / CDC / USDA data, industry data and experience, etc.
 - The tables found in Appendix 1 are intended for use in considering potential hazards
- **Hazards Tables Review**
 - Understand the structure of the hazards tables
 - Understanding how to access the information contained in the tables



PCHF Guidance – Chapter 3

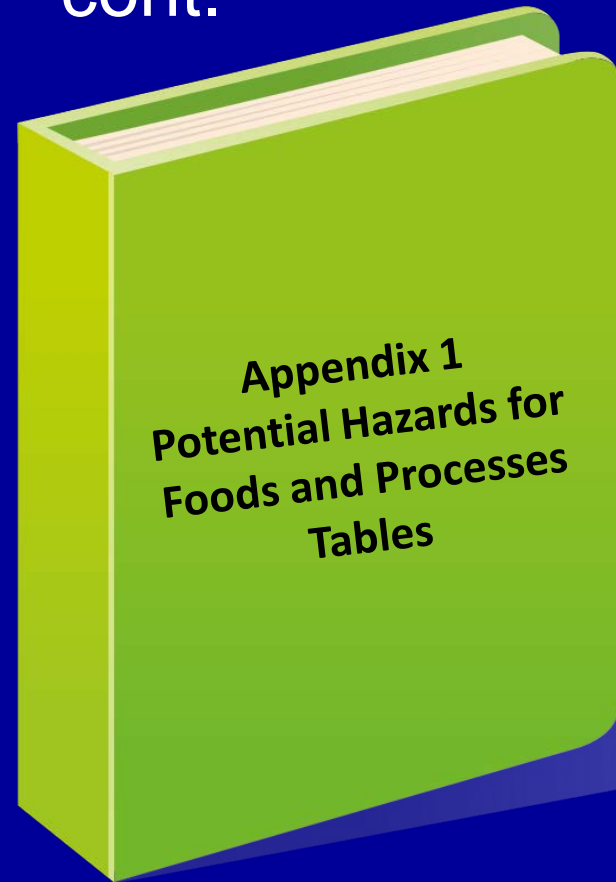
Appendix 1

- Bakery
- Beverage
- Chocolate and Candy
- Dairy
- Dressings and Condiments
- Egg
- Food Additives
- Fruits and Vegetables
- Game Meat
- Grains
- Multi-Component Foods (such as a refrigerated entrée or a sandwich)
- Nuts
- Oil
- Snack Foods
- Soups
- Spice
- Sweeteners

PCHF Guidance – Chapter 3

Appendix 1 – cont.

- Information provided in each the table is organized to describe:
 - Food Categories
 - Food Subcategories
 - Hazards
 - Example Products



PCHF Guidance – Appendix 1

Biological Hazards Tables

Table 1A: Information that you should consider for potential ingredient or other food-related biological hazards for Bakery Items

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Unbaked Bakery Items - Ready-To-Bake (RTB)	1a	Bread, Biscuits, Rolls, Cookie Dough, Pizza/Pie Crust	Refrigerated						X	X	X					Buttermilk biscuits, Cinnamon rolls, Croissants, Pizza Crust, Chocolate Chip Cookie Dough, Puff Pastry, <u>Phyllo</u>
Unbaked Bakery Items - Ready-To-Bake (RTB)	1b	Bread, Biscuits, Rolls, Cookie Dough, Pizza/Pie Crust	Frozen						X	X	X					Buttermilk biscuits, Cinnamon rolls, Croissants, Pizza Crust, Chocolate Chip Cookie Dough, Puff Pastry, <u>Phyllo</u>
Unbaked Bakery Items - Ready-To-Bake (RTB)	2a	<u>Parbaked/ParBoiled</u> Bread, Biscuits, Rolls, Pizza/Pie Crust	Refrigerated						X	X	X					Artisan breads, Bagels, Biscuits, Rolls, Croissant, Pizza Crust

PCHF Guidance – Appendix 1

Chemical Hazards Tables

Table 2A: Information that you should consider for potential ingredient or other food-related chemical hazards for Bakery Items

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Unbaked Bakery Items - Ready-To-Bake (RTB)	1a	Bread, Biscuits, Rolls, Cookie Dough, Pizza/Pie Crust	Refrigerated					X				Buttermilk biscuits, Cinnamon rolls, Croissants, Pizza Crust, Chocolate Chip Cookie Dough, Puff Pastry, Phyllo
Unbaked Bakery Items - Ready-To-Bake (RTB)	1b	Bread, Biscuits, Rolls, Cookie Dough, Pizza/Pie Crust	Frozen					X				Buttermilk biscuits, Cinnamon rolls, Croissants, Pizza Crust, Chocolate Chip Cookie Dough, Puff Pastry, Phyllo
Unbaked Bakery Items - Ready-To-Bake (RTB)	2a	Parbaked/ParBoiled Bread, Biscuits, Rolls, Pizza/Pie Crust	Refrigerated					X				Artisan breads, Bagels, Biscuits, Rolls, Croissant, Pizza Crust
Unbaked Bakery		Parbaked/ParBoiled										

PCHF Guidance – Appendix 1

Process Related Hazards Tables

Table 3A: Information that you should consider for potential process-related biological, chemical, and physical hazards for Bakery Items

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	formation due to poor formulation control	formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Unbaked Bakery Items - Ready-To-Bake (RTB)	1a	Bread, Biscuits, Rolls, Cookie Dough, Pizza/Pie Crust	Refrigerated		X			X		X	X	X	X		Buttermilk biscuits, Cinnamon rolls, Croissants, Pizza Crust, Chocolate Chip Cookie Dough, Puff Pastry, Phyllo
Unbaked Bakery Items - Ready-To-Bake (RTB)	1b	Bread, Biscuits, Rolls, Cookie Dough, Pizza/Pie Crust	Frozen		X			X		X	X	X	X		Buttermilk biscuits, Cinnamon rolls, Croissants, Pizza Crust, Chocolate Chip Cookie Dough, Puff Pastry, Phyllo
Unbaked Bakery Items - Ready-To-Bake (RTB)	2a	<u>Parbaked/ParBoiled</u> Bread, Biscuits, Rolls, Cookie Dough, Pizza/Pie Crust	Refrigerated		X			X		X	X	X	X		Artisan breads, Bagels, Biscuits, Rolls, Croissant, Pizza Crust

PCHF Guidance – Chapter 4

Purpose of Chapter

- The guidance provided in this chapter is intended to help facilities that manufacture, process, pack, or hold human food to identify and implement preventive controls.

PCHF Guidance – Chapter 4

Chapter 4 provides general information on preventive control programs that a facility could use to control a hazard. They include:

Preventive Control	Chapter Section
Process Controls	4.3
Sanitation Controls	4.4
Food Allergen Controls	4.5
Supply-chain Controls	4.6
Recall Plans	4.7

PCHF Guidance – Chapter 4

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 do not include** those procedures, practices, and processes that are not applied to the food itself, e.g., controls of personnel or the environment that may be used to significantly minimize or prevent hazards.

PCHF Guidance – Chapter 4

Process Controls

Process Control Subcategory	Hazard Category	Examples	Chapter Section
Lethal Treatments	Biological	Heat treatments (also called thermal treatments) (e.g., cooking, roasting, baking) High Pressure Processing (HPP) Irradiation Antimicrobial fumigation (e.g., with propylene oxide (PPO))	4.3.1
Time/Temperature of Holding	Biological	Refrigeration Freezing	4.3.2
Formulation	Biological	Reducing the water activity Reducing the pH (acidification) Adding preservatives	4.3.3
Dehydration/Drying	Biological	Air-drying (forced air and heating) Freeze drying Spray drying	4.3.4
Recipe Management	Chemical	Controlling the maximum level of food ingredients	4.3.5
Storage Conditions	Chemical	Controlling moisture during storage of raw agricultural commodities	4.3.6
Physical Sorting	Chemical	Reducing mycotoxin content through sorting by color and physical damage in raw agricultural commodities	4.3.7
Exclusion of Metal and Glass	Physical	Using magnets Using metal detectors Using sieves, screens Using X-ray systems	4.3.8

PCHF Guidance – Chapter 4

Sanitation Controls

- Sanitation controls must include, as appropriate to the facility and the food, procedures, practices, and processes for the:
 - Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment; and
 - 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.

PCHF Guidance – Chapter 4

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:
 - Ensuring protection of food from allergen cross-contact, including during storage, handling, and use; and
 - Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the FD&C Act (21 U.S.C. 343(w)).



PCHF Guidance – Chapter 4

Supply-Chain Controls

- In this section of this guidance, we discuss the use of ingredient specifications as a supply-chain control for several chemical hazards –
 - pesticides,
 - drug residues,
 - heavy metals,
 - mycotoxins.
- See our forthcoming draft guidance “Supply-Chain Program for Human Food Products: Guidance for Industry” for in-depth guidance on supply-chain controls.

PCHF Guidance – Chapter 5

Purpose of Chapter

- This chapter 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.
- This chapter also provides an overview of preventive control management components (i.e., monitoring, corrective actions, and corrections, and verification activities (and their associated records)).



PCHF Guidance – Chapter 5

Biological Hazards

- Provides general information about the effects of the listed preventive controls but is not intended to imply that a particular preventive control has been validated for control of specific pathogens in specific foods.
- You are responsible for validating specific preventive controls as appropriate to the nature of the preventive control and its role in your facility's food safety system



PCHF Guidance – Chapter 5

- Examples of the Application of Preventive Controls for Chemical Hazards
- Examples of the Application of Preventive Controls for Food Allergen Hazards
- Examples of Application of Preventive Controls for Physical Hazards

PCHF Guidance – Chapter 5

- **Overview of Preventive Control Management Components**
 - Monitoring;
 - Corrective actions;
 - Corrections, and;
 - Verification activities (and their associated records).

PCHF Guidance Summary

Review:

- Structure of the guidance document
- Key content
- Guidance still to come