Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic.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 your question at https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm.

Introduction and Purpose

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I. Introduction

In 21 Code of Federal Regulations (CFR) part 117 (part 117), we have established our regulation entitled "*Current Good Manufacturing Practice, Hazard Analysis, and Risk Based Preventive Controls for Human Food*." We published the final rule establishing part 117 in the *Federal Register* of September 17, 2015 (80 FR 55908). Part 117 establishes requirements for current good manufacturing practice for human food (CGMPs), for hazard analysis and risk-

[1] 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. Underlined text in yellow highlights represents a correction from the draft "Introduction and Purpose" that we issued for public comment in August 2016.

based preventive controls for human food (PCHF), and related requirements as shown in Table 1.

Table 1. Subparts Established in 21 CFR Part 117

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

The PCHF requirements implement the provisions of the FDA Food Safety Modernization Act (FSMA), established in section 418 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350g). Part 117 includes several complete or partial exemptions from the PCHF requirements. See 21 CFR 117.5 for a list and description of these exemptions.

This document is directed to those persons (you) who are subject to the PCHF requirements of part 117). Establishing risk-based preventive controls enables you to apply a proactive and systematic approach to your food safety program through the establishment of preventive controls designed to protect your food, and the consumer, from biological, chemical (including radiological), and physical hazards. Risk-based preventive controls will not give you a "zero-risk" system for manufacturing, processing, packing, and holding food; rather, risk-based preventive controls are designed to minimize the risk of known or reasonably foreseeable food safety hazards that may cause illness or injury if they are present in the products you produce.

This guidance is intended to help you comply with the following specific PCHF requirements established in subparts C and G of part 117:

- A written food safety plan (FSP);
- Hazard analysis;
- Preventive controls;
- Monitoring;
- Corrective actions;
- Verification; and
- Associated records.

You only need to apply preventive controls if, after conducting a hazard analysis of the products and processes conducted at your facilities, you identify known or reasonably foreseeable biological, chemical, or physical hazards that require a preventive control. (Known or reasonably foreseeable hazards are the potential hazards to be evaluated by the facility to determine whether any require a preventive control in that facility.) We do not expect that known or reasonably foreseeable hazards for a food require a preventive control in all facilities. We also do not expect that all possible preventive measures and verification procedures apply to all foods produced in your facility. For example, we would not expect you to have sanitation controls to prevent food allergen cross-contact for a processing line that is dedicated to foods containing only that food allergen.

It is important for you to be aware of the potential hazards that may be associated with your food process and products. When you understand the potential hazards, it is easier to design and implement an FSP designed to control all identified food safety hazards that may cause illness or injury if they are present in the products you produce.

This guidance is not directed to persons who are exempt under 21 CFR 117.5. However, such persons may find some of the principles and recommendations in this guidance helpful in manufacturing, processing, packing, and holding human food.

We intend this draft guidance to include the 16 chapters listed in the Table of Contents. We will announce the availability of each draft chapter for public comment as the chapter becomes available, rather than delaying release of individual draft chapters until all the draft chapters are available. Those chapters that you see listed in the Table of Contents as "coming soon" are not yet available.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance describes the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Purpose of this Guidance

The purpose of this guidance is to help you develop an FSP in accordance with the PCHF requirements. Specifically, this document provides guidance on:

- 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.

We recommend that you consider how this guidance relates to each of your operations and tailor your control strategies to the specific circumstances for the foods you process.

III. Glossary of Terms Used in This Guidance

A. Definitions Established in 21 CFR 117.3

Acid foods or **Acidified foods:** Foods that have an equilibrium pH of 4.6 or below.

Adequate: That which is needed to accomplish the intended purpose in keeping with good public health practice.

Allergen cross-contact: The unintentional incorporation of a food allergen into a food.

Correction: An action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).

Critical control point (CCP): A point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

Environmental pathogen: A pathogen capable of surviving and persisting with the manufacturing processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Examples of environmental pathogens include *Listeria monocytogenes* and *Salmonella* spp. but do not include the spores of pathogenic sporeforming bacteria.

Facility: A domestic facility or foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of 21 CFR part 1, subpart H.

Food: Includes (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article and includes raw materials and ingredients.

Food allergen: A major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act (e.g., any of the following: (1) Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans. (2) A food ingredient that contains protein derived from a food specified in paragraph (1), except any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.)

Food-contact surfaces: Those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operation. “Food contact surfaces” includes utensils and food-contact surfaces of equipment.

Hazard: Any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.

Hazard requiring a preventive control: A known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food

would, based on the outcome of a hazard analysis (which includes 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) establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification and records) as appropriate to the food, the facility and the nature of the preventive control and its role in the facility's food safety system.

Known or reasonably foreseeable hazard: A potential biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food.

Microorganisms: Yeast, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens. The term "undesirable microorganisms" includes those microorganisms that are pathogens, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Monitor: To conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

Pathogen: A microorganism of public health significance.

Pest: Any objectionable animals or insects including birds, rodents, flies, and larvae.

Preventive controls: Those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packaging, or holding at the time of the analysis.

Preventive controls qualified individual (PCQI): A qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Qualified individual: A person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

RTE (Ready-to-eat) food: Any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

Sanitize: To adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Significantly minimize: To reduce to an acceptable level, including to eliminate.

Validation: Obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

B. Other Terms that FDA Uses in this Guidance

Clean in place (CIP): A system used to clean process piping, bins, tanks, mixing equipment, or larger pieces of equipment without disassembly, where interior product zones are fully exposed and soil can be readily washed away by the flow of the cleaning solution.

Clean out of place (COP): A system (*e.g*. cleaning tanks) used to clean equipment parts, piping, etc. after disassembly.

Control point (CP): Any step at which biological, physical, or chemical factors can be controlled.

Cleaning: The removal of soil, food residue, dirt, grease or other objectionable matter.

Control, Control measure: See Preventive controls.

Corrective action: An action to identify and correct a problem that occurred during the production of food, including actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).

Critical limit (CL): A maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled to prevent, eliminate or reduce to an acceptable level the occurrence of a food-safety hazard.

Deviation: Failure to meet a critical limit.

End-Point Internal Product Temperature (EPIPT): A measurement of the internal temperature of the product at the end of the heat process.

Environmental sample: A sample that is collected from a surface or area of the plant for the purpose of testing the surface or area for the presence of microorganisms, usually environmental pathogens.

Food safety plan: A set of written documents that is based upon food safety principles and incorporates hazard analysis, preventive controls, and delineates monitoring, corrective action, and verification procedures to be followed, including a recall plan.

Food Safety System: The result of the implementation of the Food Safety Plan.

HACCP (Hazard Analysis and Critical Control Point): A system which identifies, evaluates, and controls hazards that are significant for food safety.

Hazard analysis: The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which should be addressed through a preventive control.

Operating limits: Criteria that may be more stringent than critical limits and are established for reasons other than food safety.

Prerequisite programs: Procedures, including Current Good Manufacturing Practices (CGMPs), that provide the basic environmental and operating conditions necessary to support the Food Safety Plan.

Severity: The seriousness of the effects of a hazard.

IV. Table of Abbreviations Used in This Guidance

Abbreviation	What It Means
ABC	Almond Board of California
a_w	Water activity
CCP	Critical control point
CDC	Centers for Disease Control and Prevention
CIP	Clean in place
CFR	Code of Federal Regulations
CGMP	Current good manufacturing practice
CL	Critical limit
Codex	Codex Alimentarius Commission
COP	Clean out of place

Abbreviation	What It Means
CP	Control point
D-value	Decimal reduction time
EPIPT	End-Point Internal Product Temperature
EPA	U.S. Environmental Protection Agency
FALCPA	Food Allergen Labeling and Consumer Protection Act
FDA	U.S. Food and Drug Administration
FSIS	Food Safety and Inspection Service of the U.S. Department of Agriculture
FSMA	FDA Food Safety Modernization Act
FSP	Food safety plan
FSPCA	Food Safety Preventive Controls Alliance
HACCP	Hazard Analysis and Critical Control Point
HPP	High Pressure Processing
LACF	Low-acid canned food
NRTE food	Not ready-to-eat food
Part 117	Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (21 CFR part 117)
PCHF	“Preventive Controls for Human Food” (requirements in 21 CFR part 117 for hazard analysis and risk-based preventive controls for human food in accordance with section 418 of the FD&C Act)
PCQI	Preventive controls qualified individual
PPO	Propylene oxide
ROP	Reduced oxygen packaging
RTE food	Ready-to-eat food
TDT	Thermal Death Time
USDA	U.S. Department of Agriculture

Abbreviation	What It Means
WIP	Work-in-process
z-value	The degrees in Fahrenheit required for the thermal destruction curve to cross one log cycle (i.e., for reducing the D value by a factor of 10)