Contains Non-binding Recommendations

Draft-Not for Implementation

Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic.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/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan.

Introduction and General Information Applicable to This Guidance

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[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.

I. Introduction

In part 117 of 21 CFR, we have established our regulation titled "*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 includes current good manufacturing practice (CGMP) requirements (primarily in subpart B, with associated requirements in subparts A and F) that generally apply to manufacturing, processing, packing, and holding human food. Part 117 also includes requirements (primarily in subparts C and G, with associated requirements in subparts A, D, E, and F) to establish and implement preventive controls for human food.

The preventive controls for human foods (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). The PCHF requirements generally apply to those domestic and foreign facilities that manufacture, process, pack, or hold human food and are required to register under section 415 of the FD&C Act (21 U.S.C. 350d; 21 CFR part 1, subpart H). This registration requirement applies to facilities engaged in the manufacturing/processing, packing, or holding of food for consumption in the United States. (See the definition of "facility" in 21 CFR 1.227 and the registration requirement in 21 CFR 1.225(a).) The PCHF requirements apply to the owner, operator, or agent in charge of a facility.

See Table 1 for a list of the subparts established in part 117.

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

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. See 21 CFR 117.7 for the applicability of subparts C, D, and G to a facility solely engaged in the storage of unexposed packaged food, including the applicability of 21 CFR 117.206 (in subpart D) to unexposed packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

This document is directed to those persons (you) who are subject to the PCHF requirements of part 117. This guidance is not directed to persons who are exempt from PCHF requirements under 21 CFR 117.5 or are subject to the modified requirements in 21 CFR 117.206 for any unexposed packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens. However, such persons may find some of the principles and recommendations in this guidance helpful in manufacturing, processing, packing, and holding human food.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe FDA'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 FDA guidances means that something is suggested or recommended, but not required.

II. Purpose of This Guidance

The purpose of this guidance is 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.

Specifically, this document provides guidance on:

- the components of an FSP and the importance of each component;
- the biological, chemical (including radiological) and physical hazards that are most relevant to manufacturing, processing, packing, and holding FDA-regulated human food products;
- how to conduct a hazard analysis and develop an FSP for the products that you process;

- how to identify preventive controls for common biological (specifically bacterial pathogens), chemical, and physical hazards most relevant to the production of many processed foods so you can apply those preventive controls to the hazards identified in your hazard analysis;
- how to identify and apply the preventive control management components (i.e., monitoring, corrective actions and corrections, verification, and associated records); and
- the recordkeeping requirements associated with the FSP and implementation of the FSP.

We intend this guidance to include multiple chapters. When we develop each chapter, we announce its availability for public comment as the chapter becomes available. In the Table of Contents for this guidance, we list chapters that are not yet available as "coming soon."

We recommend that you consider how this guidance relates to each of your operations and tailor your FSP 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

For the convenience of the reader, we are reproducing the definitions that are codified in 21 CFR 117.3. These definitions were established through rulemaking that culminated in a final rule published on September 17, 2015 (80 FR 55908). They remain current as of the date of this guidance. Because these definitions could change through future rulemaking, you should check for the latest definitions at 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.

Affiliate: Any facility that controls, is controlled by, or is under common control with another facility.

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

Audit: The systematic, independent, and documented examination (through observation, investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis) to assess an audited entity's food safety processes and procedures.

Batter: A semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

Blanching (except for tree nuts and peanuts): A prepackaging heat treatment of foodstuffs for an adequate time and at an adequate temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

Calendar day: Every day shown on the calendar.

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.

Defect action level: A level of a non-hazardous, naturally occurring, unavoidable defect at which FDA may regard a food product "adulterated" and subject to enforcement action under section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act.

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.

Farm: Farm as defined in 21 CFR 1.227.

FDA: Food and Drug Administration.

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.[2]

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

[2] Section 201(qq) of the FD&C Act defines the term ''major food allergen,'' in part, to mean any of the following: 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, soybeans, and sesame or a food ingredient that contains protein derived from one of these foods, with certain exceptions regarding highly refined oils.

during the normal course of operation. "Food contact surfaces" includes utensils and food-contact surfaces of equipment.

Full-time equivalent employee: A term used to represent the number of employees of a business entity for the purpose of determining whether the business qualifies for the small business exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours × 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

Harvesting: Applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (*e.g.*, foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

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.

Holding: storage of food and also includes activities performed incidental to storage of a food (*e.g.*, activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

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.

Lot: The food produced during a period of time and identified by an establishment's specific code.

Manufacturing/processing: Making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

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.

Mixed-type facility: An establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

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

Packing: Placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (*e.g.*, activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pathogen: A microorganism of public health significance.

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

Plant: The building or structure or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

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 auditor: A person who is a qualified individual as defined in this part and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function as required by 21 CFR 117.180(c)(2). Examples of potential qualified auditors include: (1) A government employee, including a foreign government employee; and (2) An audit agent of a certification body that is accredited in accordance with regulations in 21 CFR part 1, subpart M.

Qualified end-user, with respect to a food: The consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in 21 CFR 1.227) that: (1) Is located: (i) In the same State or the same Indian reservation as the qualified facility that sold the food to such restaurant or establishment; or (ii) Not more than 275 miles from such facility; and (2) Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

Qualified facility (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate): A facility that is a very small business as defined in this part, or a facility to which both of the following apply: (1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and (2) The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

Qualified facility exemption: An exemption applicable to a qualified facility under 21 CFR 117.5(a).

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.

Quality control operation: A planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.

Raw agricultural commodity: Has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act[3].

Ready-to-eat (RTE) 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.

Receiving facility: A facility that is subject to subparts C and G of this part and that manufactures/processes a raw material or other ingredient that it receives from a supplier.

Rework: Clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

Safe-moisture level: A level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, processing, packing, and holding. The safe moisture level for a food is related to its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given aw will not support the growth of undesirable microorganisms.

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.

Small business (for purposes of this part): A business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees.

Subsidiary: Any company which is owned or controlled directly or indirectly by another company.

Supplier: The establishment that manufactures/processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature.

Supply-chain-applied control: A preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.

Unexposed packaged food: Packaged food that is not exposed to the environment.

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.

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[3] Any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

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.

Very small business (for purposes of this part): A business (including any subsidiaries and affiliates) averaging less than $1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (*e.g.*, held for a fee).

Water activity (a_w): A measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

Written procedures for receiving raw materials and other ingredients: Written procedures to ensure that raw materials and other ingredients are received only from suppliers approved by the receiving facility (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use).

You, for purposes of this part: The owner, operator, or agent in charge of a facility.

B. Other Terms that FDA Uses in This Guidance

The following definitions in this guidance are intended to help you comply with the PCHF requirements established in subparts C and G of part 117. These terms may be used differently elsewhere.

Adequate cooking instructions: Cooking instructions that are adequate to significantly minimize biological hazards.

Adequately reduce: Capable of reducing the presence of pathogens to an extent sufficient to prevent illness.

Adjustment: An intervention that you take if you determine that there is a deviation from an operating limit, without a deviation from a critical value/critical limit.

Allergen cleaning procedure: Procedures, practices, and processes for cleaning food-contact surfaces of equipment and utensils that are used for foods with different food allergen profiles.

Allergen cross-contact control: Procedures, practices, and processes employed for ensuring protection of food from allergen cross-contact, including during storage, handling, and use.

Allergenic component: A food allergen (i.e., a major food allergen as defined in section 201(qq) of the FD&C Act) that is a component of an ingredient (*e.g.*, the food allergen "milk" in a spice blend).

Allergenic ingredient: A food allergen (i.e., a major food allergen as defined in section 201(qq) of the FD&C Act) that is an ingredient of another food product (*e.g.*, the food allergen "peanuts" added to cookies).

Allergen labeling guidance: Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Guidance for Industry.

Allergen labeling requirements of the FD&C Act: Requirements (in section 403(w) of the FD&C Act (21 U.S.C 343(w))) that apply to certain foods that are, or contain, a major food allergen.

Approved supplier: A supplier that has met the criteria of the receiving facility's supply chain program, is controlling a hazard identified by the receiving facility as requiring a supply-chain-applied control, and has been approved by the receiving facility in accordance with the requirements of part 117, subpart G.

Certificate of analysis: A document, provided by the supplier of a food prior to or upon receipt of the food, that documents the analysis of certain characteristics and attributes of the food.

Certificate of Conformance: A document, provided by the supplier of a food prior to or upon receipt of the food, that states that the processing of the food and/or the food itself conform to certain specifications.

Changeover: Procedures used to prepare the processing line when different products are produced on the same processing line.

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

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 method (*e.g.*, using cleaning tanks) used to clean equipment parts, and ancillary items including piping and valves after disassembly by taking them from the production area to a designated cleaning area.

Codex validation guidelines: Codex publication titled "Guidelines for the Validation of Food Safety Control Measures (CXG 69-2008)."

Commercial entity provisions: Provisions of 21 CFR 117.136.

Compositing: Combining analytical portions from more than one collected sample into a mixture in preparation for analytical testing of the mixture.

Consignee: The term defined in 21 CFR part 7 to mean anyone who received, purchased, or used the product being recalled. (See 21 CFR 7.3(n).)

Controlled wet cleaning: The removal of soil, including food residues, dirt, grease, or other objectionable matter, from a surface, using a limited amount of water and detergents and controlling the spread of the water used.

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

Cooking instructions: Instructions to heat-process food using a kill step (*e.g.*, by baking, boiling, or microwave cooking).

Corrective action: An action to identify and correct a food safety 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).

Covered produce: Produce, listed in 21 CFR 112.1(b), that is subject to the standards for growing, harvesting, packing, and holding of produce for human consumption in the produce safety regulation.

Critical parameter/critical factor: A parameter that could, if varied, affect the adequacy of a preventive control to significantly minimize or prevent a hazard requiring a preventive control.

Critical value/critical limit: A maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a preventive control.

Deviation: Failure to meet a critical value/critical limit or adhere to a critical parameter/critical factor.

Direct account: The term used in FDA's recall policy in 21 CFR part 7, subpart C to mean the first consignee in a recalling firm's distribution chain.

Direct consignee: The term used in 21 CFR 117.139 to mean the first consignee in a recalling firm's distribution chain. Part 117 uses the term "direct consignee" to have the same meaning as "direct account" in 21 CFR part 7, subpart C.

Draft allergen labeling guidance: Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Guidance for Industry (Draft Guidance).

Dry cleaning: The physical removal of soil, including food residues, dirt, grease, or other objectionable matter, from a surface, by actions such as wiping, sweeping, brushing, scraping, or vacuuming the residues) without water.

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, such as an environmental pathogen or an appropriate indicator organism.

Exception record: A record that is created only when there is loss of control.

Food allergen label specification: All features of the product label that you will use to ensure that the finished food will not be misbranded under section 403(w) of the FD&C Act. Examples of such features are product name; the approach to naming the food source of all allergenic

ingredients (and allergenic components of ingredients) (*e.g.*, within the ingredient statement or in a separate "Contains" statement); and any color coding or other distinctive features that you use to help production personnel select the correct label.

Food allergen profile: The food allergen sources present or absent in a food.

Food safety plan: A set of documents that contain the written hazard analysis, the written preventive controls, the written supply-chain program (when applicable), the written recall plan, and written preventive control management components (i.e., written procedures for monitoring, corrective action, and verification) as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system. See 21 CFR 117.126 and 117.140.

Food Safety System: The outcome of implementing the food safety plan and its supporting elements.

Fully cooked food: Food that a manufacturer/processor has heat-treated using a kill step.

HACCP (Hazard Analysis and Critical Control Point): A systematic approach to the identification, evaluation, and control of food safety hazards.

Hazard analysis: The process of identifying hazards, and evaluating information on those hazards (including the severity of the illness or injury if the hazard were to occur and the conditions that could lead to its presence), to determine which hazards require a preventive control and therefore should be addressed in a HACCP plan or a food safety plan.[4]

Heating instructions: Instructions for consumers to heat-process food without using a kill step (*e.g.*, through warming or through surface heat treatments (such as toasting)).

Import alert: An FDA document that informs FDA's field staff and the public that the agency has enough evidence to allow for Detention Without Physical Examination (DWPE) of products that appear to be in violation of the FDA's laws and regulations. These violations could be related to the product, manufacturer, shipper, importer, and/or other information.

Intrinsic properties: Parameters inherent to a food.

Kill step: Lethal processing to significantly minimize biological hazards.

Knowledgeable person: A person who has knowledge about the safe manufacturing, processing, packing, or holding of food.

Label: A display of written, printed, or graphic matter upon the immediate container of any article. See section 201(k) of the FD&C Act (21 U.S.C. 321(k)).

[4] Adapted from the Food Safety Preventive Controls Alliance (FSPCA) definition of hazard analysis, which is 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.

Labeling: All labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. See section 201(m) of the FD&C Act (21 U.S.C. 321(m)).

Label control: Procedures, practices, and processes employed for labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the FD&C Act.

Lethality treatment: A process that is used to significantly minimize (kill, destroy) viruses, parasites, or the vegetative cells of bacteria or to inactivate spores of sporeforming bacteria.

Microbial challenge study: A study in which a preventive control is "challenged" by a pathogen or surrogate microorganism to determine the impact of the preventive control on the pathogen or its surrogate.

NACMCF guidelines for conducting microbial challenge studies: National Advisory Committee on Microbiological Criteria for Foods publication titled "Parameters for Determining Inoculated Pack/Challenge Study Protocols," J. Food Prot. 73:140-202.

Non-lethality treatment: A process that is used to minimize or prevent the growth of microorganisms (*e.g.*, time/temperature controls, most formulation controls, and dehydration/drying) rather than for the purpose of killing/destroying them.

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

Other risk-based mitigation measure: A measure, other than a "preventive control" as defined in 21 CFR 117.3, to reduce the risk of foodborne illness.

Partially cooked food: Food that a manufacturer/processor has heat-treated without using a kill step.

Pertinent pathogen: A known or reasonably foreseeable pathogen that requires a preventive control and is the most difficult to control by the process (*e.g.*, the pathogen that has the greatest resistance to a lethality treatment or that is least impacted by a non-lethality treatment).

Potential hazard: Synonym for "known or reasonably foreseeable hazard" as defined in 21 CFR 117.3. (See section III.B.)

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

Principal display panel: The part of a food label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale and is often the front panel of a food product. See 21 CFR 101.1.

Process parameter: A measurable or observable factor associated with the delivery of a process.

Produce safety regulation: Our regulation, established in 21 CFR part 112, titled "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption."

Produce that is rarely consumed raw: Produce, listed in 21 CFR 112.2(a)(1), that is exempt from the standards for growing, harvesting, packing, and holding of produce for human consumption in the produce safety regulation.

Recall: A firm's removal or correction of a marketed product that FDA considers to be in violation of the laws it administers and against which the Agency would initiate legal action, *e.g.*, seizure. "Recall" does not include a market withdrawal or a stock recovery. (See 21 CFR 7.3(g).)

Recall classification: The numerical designation (i.e., I, II, or III) assigned by FDA to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled. (1) Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death (21 CFR 7.3(m)(1)); (2) Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious health consequences is remote (21 CFR 7.3(m)(2)); and (3) Class III is a situation in which use of, or exposure to, a violative product is not likely to cause illness or injury (21 CFR 7.3(m)(3)). (See 21 CFR 7.3(m).)

Reduce to an acceptable level: See definition of "adequately reduce."

Relevant hazards: Universe of all hazards that are most relevant to food safety and that are narrowed (through the hazard identification phase of a hazard analysis) to known or reasonably foreseeable ("potential") hazards that are then evaluated (through the hazard evaluation phase of a hazard analysis) to determine the hazards requiring a preventive control.

Risk management strategy: A combination of appropriate, risk-based preventive controls (and associated preventive control management components) and other risk-based mitigation measures that are not preventive controls.

Root cause analysis: A retrospective evaluation of information from a root cause investigation of a contamination event[5] to determine what actions can be taken to eliminate the root cause(s) and prevent a recurrence of the event.

Root cause investigation: A procedure used to attempt to determine the root cause(s) of a contamination event[6] by investigating all aspects of the manufacturing process, including the environment, and provide information for use in determining factors that may have contributed to the event, actions that can be taken to fix the problem that resulted in the event, and actions to prevent the problem from recurring.

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[5] Although most commonly associated with a pathogen contamination event, such evaluation could be adapated to identify and correct a problem related to any adulteration under section 402 or misbranding under section 403(w) of the FD&C Act.

[6] Although most commonly associated with a pathogen contamination event, such procedure could be adapated to identify and correct a problem related to any adulteration under section 402 or misbranding under section 403(w) of the FD&C Act.

Safety factor: An increase in a process parameter so that it exceeds the minimum needed to achieve control.

Sanitation break: Stopping production to clean and sanitize all food-contact surfaces (FCSs) in the production system.

Sanitation cleaning procedures: Procedures, practices, and processes to clean (and, as applicable, sanitize) FCSs and non-FCSs.

Second-party audit: An audit conducted by an employee of a receiving facility.

Serious adverse health consequences or death to humans hazard: A hazard for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans.

Severity: The seriousness of the effects of a hazard.

Surrogate microorganism: A non-pathogenic microorganism that has survival and/or growth capabilities that are similar to, or more robust than, the pertinent pathogen under the conditions being evaluated.

Target microorganism: The pertinent pathogen or its surrogate that will be evaluated in a validation study.

Third-party audit: An audit conducted by a qualified auditor that is not an employee of either the receiving facility or the supplier.

Time/temperature control for safety food (TCS food): A food that requires time/temperature control for safety to limit growth of, or toxin formation by, pathogens.

Unintended allergen presence: The presence of an allergen due to allergen cross-contact.

Visibly clean: Without visibly detectable material such as food residue, film, or protein sheen.

We, our, and us: The U.S. Food and Drug Administration.

Work-in-process (WIP): Partially finished products that are in between different production stages (*e.g.*, batched or pre-processed ingredients that are transferred to totes and held until moved to another processing line to be incorporated into another product).

IV. Abbreviations

Table 2: Abbreviations Used in This Guidance

Abbreviation	What It Means
ABC	Almond Board of California
a_w	Water activity

Abbreviation	What It Means
BHA	Butylated hydroxyanisole
BHT	Butylated hydroxytoluene
CBA	Consumer Brands Association (formerly Grocery Manufacturers Association)
CBA Low-Moisture Foods Guidelines	CBA "Control of *Salmonella* in Low-Moisture Foods Guidance Document"
CCP	Critical control point
CDC	Centers for Disease Control and Prevention
CIP	Clean in place
CFIA	Canadian Food Inspection Agency
CFR	Code of Federal Regulations
CGMP	Current good manufacturing practice
CFSAN	Center for Food Safety and Applied Nutrition
CL	Critical limit
COA	Certificate of Analysis
Codex	Codex Alimentarius Commission
COP	Clean out of place
CP	Control point
CPG	Compliance Policy Guide
D-value	Decimal reduction time
DON	Deoxynivalenol
EDTA	Ethylene-diaminetetraacetate

Abbreviation	What It Means
EMP	Environmental monitoring program
EPIPT	End-Point Internal Product Temperature
EPA	U.S. Environmental Protection Agency
ECDPC	European Centre for Disease Prevention and Control
EFSA	European Food Safety Authority
FALCPA	Food Allergen Labeling and Consumer Protection Act
FAO	Food and Agriculture Organization of the United Nations
FCS	Food-contact surface
FDA	U.S. Food and Drug Administration
FDA's *Listeria* guidance*	Control of *Listeria monocytogenes* in Ready-To-Eat Foods: Guidance for Industry
FD&C Act	Federal Food, Drug, and Cosmetic Act
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
FSVP	Foreign Supplier Verification Programs
GE	Glycidyl Esters
GMA	Grocery Manufacturers Association (now Consumer Brands Association)
HACCP	Hazard Analysis and Critical Control Point
HPP	High Pressure Processing

Abbreviation	What It Means
ICMSF	International Commission on Microbiological Specifications for Foods
IFT	Institute of Food Technologists
ILSI	International Life Sciences Institute
ILSI Europe	International Life Sciences Institute Europe
IQF	Individually quick frozen
IRAC	Interagency Risk Assessment Consortium
ISO	International Organization for Standardization
JECFA	Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives
Juice HACCP guidance	Guidance for Industry: Juice HACCP Hazards and Controls Guidance
LACF	Low-acid canned food
3-MCPD	3-Monochloropropane-1,2-Diol
3-MCPDE	3-Monochloropropane-1,2-Diol Esters
NACMCF	National Advisory Committee on Microbiological Criteria for Foods
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)
PCBs	Polychlorinated biphenyls
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)

Abbreviation	What It Means
PCQI	Preventive controls qualified individual
PDP	Principal display panel on a food label
PFAS	Per- and polyfluoroalkyl substances
ppb	Parts per billion
ppm	Parts per million
PPO	Propylene oxide
QC	Quality control
RAC	Raw agricultural commodity
ROP	Reduced oxygen packaging
RPM	FDA's Regulatory Procedures Manual
RTD	Resistance temperature detector
RTE food	Ready-to-eat food
SAHCODH	Serious adverse health consequences or death to humans
SAHCODH hazard	Serious adverse health consequences or death to humans hazard
Seafood HACCP guidance	Fish and Fishery Products Hazards and Controls Guidance
SME	Subject matter expert
STEC	Shiga-toxin producing *E. coli*
TCS food	Time/Temperature Control for Safety Food
TDT	Thermal Death Time
USDA	U.S. Department of Agriculture
WHO	World Health Organization

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)

* In January 2017, we issued the draft guidance entitled "Control of *Listeria monocytogenes* in Ready-to-Eat Foods." When finalized, this guidance will reflect FDA's current thinking on this topic. In this document we simply refer to that guidance as "the *Listeria* guidance," without specifying its status as draft guidance or final guidance.

V. Training

This guidance generally does not address the requirements in part 117 applicable to the qualifications of individuals who manufacture, process, pack, or hold food. See 21 CFR 117.4, which establishes requirements for:

- plant management and the owner, operator, or agent in charge of a facility to ensure that all individuals who manufacture, process, pack, or hold food are qualified to perform their assigned duties (21 CFR 117.4(a));
- qualifications of all individuals engaged in manufacturing, processing, packing, or holding food to:
  - be a qualified individual as that term is defined in § 117.3 - i.e., have 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 (see 21 CFR 117.4(b)(1)); and
  - receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties (see 21 CFR 117.4(b)(2));
- additional qualifications of supervisory personnel, such that responsibility for ensuring compliance by individuals with the requirements of part 117 must be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food (see 21 CFR 117.4(c)); and
- records that document training required by 21 CFR 117.4(b)(2) (see 21 CFR 117.4).

See also 21 CFR 117.180, which establishes additional requirements for:

- a PCQI to have 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 be otherwise qualified through job experience to develop and apply a food safety system (see 21 CFR 117.180(c)(1));
- a qualified auditor to have technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function (see 21 CFR 117.180(c)(2)); and
- records documenting all applicable training in the development and application of risk-based preventive controls (see 21 CFR 117.180(d)).

The standardized curriculum recognized as adequate by FDA has been developed by the Food Safety Preventive Controls Alliance (FSPCA). The first edition of the the FSPCA Preventive Controls for Human Food training curriculum ("participant manual") was published in 2016; the participant manual is available on the FSPCA website (see Table 8 in section VI). The FSPCA manual contains an appendix with food safety plan "worksheets" or "forms" that are used in the training; these forms can also be used in or adapted for documenting various aspects of a food safety plan (*e.g.*, the hazard analysis, process preventive controls, corrective actions). Appendix 2 of this guidance contains Food Safety Plan Forms that we adapted from the FSPCA forms published in the FSPCA participant manual. Although we recommend using these forms, there is no standardized or mandated format for documenting the food safety plan; you can use other formats that provide all of the information that 21 CFR part 117 requires for each required component of the food safety plan.

Training topics for personnel other than a PCQI and a qualified auditor vary as appropriate to an individual's assigned duties. For example:

- All personnel who enter production areas should have adequate training about the importance of health and hygiene in preventing contamination of food and food production areas;
- Human resource personnel should have training adequate to enable them to ensure that all personnel receive training necessary to perform their assigned functions;
- Personnel with responsibilities for purchasing should have adequate training regarding the importance of applicable food safety specifications and supply-chain controls (with associated supplier approval and verification activities) for the raw materials and other ingredients that they purchase;
- Personnel with responsibilities for receiving raw materials and other ingredients should have adequate training regarding the importance of inspecting shipments at receipt and using proper storage conditions, including when applicable refrigeration and segregation (*e.g.*, when applicable, segregation of raw foods from RTE foods and segregation of foods with different food allergen profiles);

- Personnel with responsibilities for maintenance should have adequate training regarding the potential for maintenance activities to introduce contamination or lead to allergen cross-contact;
- Personnel with responsibilities for cleaning and sanitizing the plant, including food-contact surfaces, should have adequate training regarding each step in the cleaning/sanitizing process and actions to take if there are visual observations or other indication that a step was not performed correctly or was not effective;
- Personnel with responsibilities for food production should have adequate training in the procedures for food production, including the importance of each step in production and actions to take if there is a problem during production;
- Personnel with responsibilities for sampling surfaces for environmental pathogens should have adequate training in the procedures for collecting the samples;
- Personnel with responsibilities for laboratory testing of food or environmental samples should have adequate training in conducting that laboratory testing;
- Supervisory personnel should have adequate training in the procedures, included in the food safety plan, applicable to their supervisory responsibilities; and
- Plant management should have adequate training in the food safety plan as a whole.

VI. Resources

The tables in this section are a compilation of resources that could be useful in developing and implementing your food safety plan. These resources are available as of the date that we make this guidance available. We have verified the website addresses listed for these resources, as of the date that we make this guidance available, but websites are subject to change over time. In addition, the policies, recommendations, and information in these resources can change over time. We recommend that you periodically review websites listing FDA's CPGs, FDA's Guidance for Industry, FDA's Compliance Programs and Import Alerts, and Codex Standards, Codes of Practice, and Guidelines for new or modified policies, recommendations, and information.

Table 3. FDA Compliance Policy Guides Cited as a Resource in This Guidance*

Topic	CPG	Link
Aflatoxin M1	CPG Sec 527.400 Whole Milk, Lowfat Milk, Skim Milk - Aflatoxin M1. November 2005.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-527400-whole-milk-lowfat-milk-skim-milk-aflatoxin-m1
Aflatoxins	CPG Sec. 555.400 Aflatoxins in Human Food: Guidance for FDA Staff. June 2021.	https://www.fda.gov/media/149666/download

Topic	CPG	Link
Aflatoxins – Brazil nuts	CPG Sec. 570.200 Aflatoxins in Brazil Nuts: Guidance for FDA Staff. June 2021	https://www.fda.gov/media/72053/download
Aflatoxins – Pistachio nuts	CPG Sec. 570.500 Aflatoxins in Pistachio Nuts: Guidance for FDA Staff. June 2021.	https://www.fda.gov/media/72084/download
Aflatoxins - Peanuts	CPG Sec. 570.375 Aflatoxins in Peanuts and Peanut Products: Guidance for FDA Staff. June 2021.	https://www.fda.gov/media/72073/download
Aflatoxins – Animal food	CPG Sec. 683.100 Action Levels for Aflatoxins in Animal Food: Guidance for FDA Staff. March 2019.	https://www.fda.gov/media/121202/download
Food allergens	CPG Sec. 555.250 Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens. 2005.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-555250-statement-policy-labeling-and-preventing-cross-contact-common-food-allergens-new
Food allergens	CPG Sec 555.250 DRAFT: Major Food Allergen Labeling and Cross-contact. 2023.**	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-555250-draft-major-food-allergen-labeling-and-cross-contact
Hard or sharp foreign objects	CPG Sec. 555.425 Foods, Adulteration Involving Hard or Sharp Foreign Objects. May 2005.	https://www.fda.gov/media/71953/download
Hypoglycin A Toxin	CPG Sec. 550.050 Canned Ackee, Frozen Ackee, and Other Ackee Products - Hypoglycin A Toxin. April 2014.	https://www.fda.gov/media/88521/download
3-MCPD	CPG Sec. 500.500 Guidance Levels for 3-MCPD (3-chloro-1,2-propanediol) in Acid-Hydrolyzed Protein and Asian-Style Sauces. March 2008.	https://www.fda.gov/media/71760/download
Mercury - Grain	CPG Sec. 578.400 Treated Grain Seed - Mercury Residue. October 1980.	https://www.fda.gov/media/72102/download
Microbiological hazards – Dairy products	CPG Sec. 527.300 Dairy Products - Microbial Contaminants and Alkaline Phosphatase Activity. December 2010.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-527300-microbial-contaminants-alkaline-phosphatase-activity
Patulin – Apple juice	CPG Sec 510.150 Apple Juice, Apple Juice Concentrates, and Apple Juice Products - Adulteration with Patulin. November 2005.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-510150-apple-juice-apple-juice-concentrates-and-apple-juice-products-adulteration-patulin
PCBs	CPG Sec. 565.200 Red meat adulterated with PCBs. November 1987.	https://www.FDA.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074589.htm
Pesticides	CPG Sec. 575.100 Pesticide Residues in Food and Feed - Enforcement Criteria. March 1995.	https://www.fda.gov/media/75151/download
Pesticides	CPG Sec. 575.100 Pesticide Chemical Residues in Food - Enforcement Criteria (CPG 7141.01) (Draft Guidance)*** January 2008.	https://www.fda.gov/media/77986/download

Topic	CPG	Link
Pits - Dates	CPG Sec. 550.300 Dates and Date Material; Imported and Domestic - Adulteration Involving Mold, Insect Excreta, Sour, Dirty, Worthless and Pits. 2005.	https://www.fda.gov/media/71813/download
Pits - Olives	CPG Sec. 550.600 Olives - Adulteration Involving Pits; Rot; Insect Infestation. 2005.	https://www.fda.gov/media/71862/download
Pits and pit fragments - Prunes	CPG Sec. 550.700 Dried Prunes, Dehydrated Low Moisture Prunes, and Pitted Prunes - Adulteration Involving Insects; Decomposition; Dirt; Pits; and Pit Fragments. 2005.	https://www.fda.gov/media/71909/download
Radionuclides	CPG Sec. 555.880 Guidance Levels for Radionuclides in Domestic and Imported Foods. 2005.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-555880-guidance-levels-radionuclides-domestic-and-imported-foods
Salmonella spp.	CPG Sec. 555.300 Foods, Except Dairy Products - Adulteration with *Salmonella*. March 1995.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-555300-foods-except-dairy-products-adulteration-salmonella

*In addition to the specific link we provided, you can access FDA's Compliance Policy Guides at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/manual-compliance-policy-guides.

** In 2023, FDA issued for public comment a draft compliance policy guide entitled "CPG Sec 555.250 DRAFT: Major Food Allergen Labeling and Cross-contact" (88 FR 31507, May 17, 2023). When finalized, this draft CPG will replace existing guidance, in CPG Sec 555.250 Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens, for FDA staff on FDA's enforcement policy regarding major food allergen labeling and cross-contact.

*** The regulation of food containing pesticide chemical residues is governed by sections 201, 402 and 408 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321, 342, and 346a). These sections of the FD&C Act were amended by the passage of the Food Quality Protection Act of 1996 (FQPA). In 2008, FDA issued as draft guidance a revised CPG Sec. 575.100 that, when finalized, will represent FDA's current thinking on enforcement criteria for pesticide residues in food and feed, taking into account the provisions of the FQPA.

Table 4. FDA Guidance for Industry Cited as a Resource in This Guidance*

Topic	Guidance	Link
Acidified foods	Guidance for Industry: Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g (Food Process Filing Forms) to FDA in Electronic or Paper Format. November 2016.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-submitting-forms-food-canning-establishment-registration-and-food-process-filing
Acrylamide	Guidance for Industry. Acrylamide in Foods. March 2016.	https://www.fda.gov/media/87150/download

Topic	Guidance	Link
Antimicrobial substances	Guidance for Industry: Antimicrobial food additives. 1999.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-antimicrobial-food-additives
Arsenic – Cereals for infants	Guidance for Industry: Action level for inorganic arsenic in rice cereals for infants. August 2020.	https://www.fda.gov/media/97234/download
Arsenic – Apple juice	Guidance for Industry: Action Level for Inorganic Arsenic in Apple Juice. 2023.	https://www.fda.gov/media/86110/download
Bottled water (Allowable levels for inorganic substances in accordance with 21 CFR 165.110(b)(4)(iii)(A)***	Small Entity Compliance Guide: Bottled Water and Arsenic. April 2009.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-bottled-water-and-arsenic
Chemical hazards	Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed. August 2000.	https://www.fda.gov/FoodGuidances
Cochineal extract and carmine	Cochineal extract and carmine: Declaration by name on the label of all foods and cosmetic products that contain these color additives; Small Entity Compliance Guide. April 2009.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-declaration-name-label-all-foods-and-cosmetic-products-contain
Enforcement policy	Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs: Guidance for Industry. 2018.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-policy-regarding-certain-entities-subject-current-good-manufacturing-practice-and
Enforcement policy	Current Good Manufacturing Practice and Preventive Controls, Foreign Supplier Verification Programs, Intentional Adulteration, and Produce Safety Regulations: Enforcement Policy Regarding Certain Provisions. 2022.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-current-good-manufacturing-practice-and-preventive-controls-foreign-supplier
Food allergens	Guidance for Industry: Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling and Consumer Protection Act of 2004. Edition 5. 2022.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-allergen-labeling-edition-5
Food allergens	Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Guidance for Industry (Draft Guidance). 2022.**	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-questions-and-answers-regarding-food-allergen-labeling-edition-5
Food labeling (refrigerated foods)	Guidance on Labeling of Foods That Need Refrigeration by Consumers. 1997. (Also available at 62 FR 8248, February 24, 1997)	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-labeling-foods-need-refrigeration-consumers

Topic	Guidance	Link
HACCP systems - Seafood	Fish and Fishery Products Hazards and Controls Guidance. June 2022.	https://www.fda.gov/food/seafood-guidance-documents-regulatory-information/fish-and-fishery-products-hazards-and-controls
HACCP systems - Juice	Guidance for Industry: Juice HACCP Hazards and Controls Guidance. February 2004.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-juice-hazard-analysis-critical-control-point-hazards-and-controls-guidance-first
Human Food By-Products	Human Food By-Products For Use As Animal Food: Draft Guidance for Industry #239**	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-239-human-food-products-use-animal-food
Lead - Candy	Guidance for Industry: Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy. November 2006.	https://www.fda.gov/food/guidance-documents-regulatory-information-topic/guidance-industry-lead-candy-likely-be-consumed-frequently-small-children
Lead - Juice	Draft** Guidance for Industry: Action Levels for Lead in Juice. April 2022.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-action-levels-lead-juice
Lead – Food for babies and young children	Draft** Guidance for Industry: Action Levels for Lead in Food Intended for Babies and Young Children	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-action-levels-lead-food-intended-babies-and-young-children
Microbiological hazards – Fresh-cut produce	Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables. 2008.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-guide-minimize-microbial-food-safety-hazards-fresh-cut-fruits-and-vegetables
Microbiological hazards – Fresh-cut produce	Draft** Guidance for Industry: Guide to Minimize Food Safety Hazards of Fresh-cut Produce. 2018.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-guide-minimize-food-safety-hazards-fresh-cut-produce
Microbiological hazards - LACF	Guide to Inspections of Low Acid Canned Food Manufacturers Part 1 - Adminstrative Procedures/Scheduled Processes	https://www.fda.gov/low-acid-canned-food-manufacturers-part-1-adminstrative-proceduresscheduled-processes
Listeria monocytogenes	Control of *Listeria monocytogenes* in Ready-To-Eat Foods: Guidance for Industry (Draft Guidance). 2017.**	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-control-listeria-monocytogenes-ready-eat-foods
Mycotoxins - Fumonisin	Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds. November 2001.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-fumonisin-levels-human-foods-and-animal-feeds

Topic	Guidance	Link
Mycotoxins - DON	Guidance for Industry and FDA: Advisory Levels for Deoxynivalenol (DON) in Finished Wheat Products for Human Consumption and Grains and Grain By-Products used for Animal Feed. July 2010.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-and-fda-advisory-levels-deoxynivalenol-don-finished-wheat-products-human
Recalls	Index of Model Press Releases.	https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls
Recalls	Industry Guidance For Recalls.****	https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls
Recalls	Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C. Guidance for Industry and FDA Staff. 2022.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/initiation-voluntary-recalls-under-21-cfr-part-7-subpart-c
Recalls	Product Recalls, Including Removals and Corrections. Guidance for Industry. 2020.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-recalls-including-removals-and-corrections
Recalls	Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls Guidance for Industry and FDA Staff. 2020.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/public-availability-lists-retail-consignees-effectuate-certain-human-and-animal-food-recalls
Recalls	Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C. Guidance for Industry and FDA Staff. 2019.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/public-warning-notification-recalls-under-21-cfr-part-7-subpart-c
Recalls	Questions and Answers Regarding Mandatory Food Recalls: Guidance for Industry and FDA Staff. 2018.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-and-fda-staff-questions-and-answers-regarding-mandatory-food-recalls
Recordkeeping required by 21 CFR part 1, subpart J	Guidance for Industry: Questions and Answers Regarding Establishment and Maintenance of Records By Persons Who Manufacture, Process, Pack, Transport, Distribute, Receive, Hold, or Import Food (Edition 5). February, 2012.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-establishment-and-maintenance-records-persons-who
Registration of food facilities	Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Seventh Edition). August 2018.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-facility-registration-seventh-edition

Topic	Guidance	Link
Reportable Food Registry	Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry As Established by the Food and Drug Administration Amendments Act of 2007. 2009.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-reportable-food-registry-established-food-and-drug
Reportable Food Registry	Draft Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry As Established by the Food and Drug Administration Amendments Act of 2007 (Edition 2). 2010.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-questions-and-answers-regarding-reportable-food-registry-established-food
Salmonella spp. - Peanut-derived product	Guidance for Industry: Measures to Address the Risk for Contamination by *Salmonella* Species in Food Containing a Peanut-Derived Product as an Ingredient. March 2009.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-measures-address-risk-contamination-salmonella-species-food-containing-peanut
Salmonella spp. - Pistachio-derived product	Guidance for Industry: Measures to Address the Risk for Contamination by *Salmonella* Species in Food Containing a Pistachio-Derived Product as an Ingredient. September 2011.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-measures-address-risk-contamination-salmonella-species-food-containing-pistachio
Salmonella spp. - Testing	Guidance for Industry Testing for *Salmonella* Species in Human Foods and Direct-Human-Contact Animal Foods. March 2012.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-testing-salmonella-species-human-foods-and-direct-human-contact-animal-foods
Third-party certification	Guidance for Industry and FDA Staff: Model Accreditation Standards for Third-Party Certification Body Accreditation for Food Safety Audits. 2022.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-and-fda-staff-model-accreditation-standards-third-party-certification-body

* In addition to the specific link we provided, or if that link is no longer operative, you can access most of FDA's Guidance for Industry applicable to human food at https://www.fda.gov/FoodGuidances.

** A draft guidance, when finalized, will represent FDA's current thinking on the specified topic.

*** See 21 CFR 165.110 for allowable levels for contaminants and toxic elements other than arsenic.

**** FDA website with links to specific guidance.

Table 5. FDA Compliance Programs* and Import Alerts Cited as a Resource in This Guidance**

Topic	Title and Link
Drug residues	Import Alert 36-04. Detention without physical examination of honey and blended syrup due to unsafe drug residues https://www.accessdata.fda.gov/cms_ia/importalert_111.html
Mycotoxins	Import Alert 23-14, Detention Without Physical Examination of Food Products Due to the Presence of Mycotoxins Published Date: 06/06/2022 https://www.accessdata.fda.gov/CMS_IA/importalert_581.html
Mycotoxins	Compliance Program 7307.001 Mycotoxins in Domestic and Imported Foods https://www.fda.gov/media/140749/download
Toxic elements	Import Alert 99-42 Detention Without Physical Examination of Foods Due to Heavy Metal Contamination https://www.accessdata.fda.gov/cms_ia/importalert_1167.html
Various	Food Compliance Programs. https://www.fda.gov/food/compliance-enforcement-food/food-compliance-programs

*For a complete list of our Food Compliance Programs, including those for biological hazards, see https://www.fda.gov/food/compliance-enforcement-food/food-compliance-programs#food_ds

**For a searchable database of our Import alerts, including those for biological hazards, see https://www.accessdata.fda.gov/CMS_IA/default.htm

Table 6. Codex Standards, Codes of Practice, and Guidelines Cited as a Resource in This Guidance*, **

Topic	Title	Link
Acrylamide	Code of Practice for the Reduction of Acrylamide in Foods. CXC 67-2009.	https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B67-2009%252FCXP_067e.pdf
Aflatoxin – Tree Nuts	Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts. CAC/RCP 59-2005.	https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B59-2005%252FCXP_059e.pdf
Aflatoxin - Peanuts	Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts. CAC/RCP 55-2004.	https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B55-2004%252FCXP_055e.pdf
Aflatoxin – Dried Figs	Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Dried Figs. CAC/RCP 65-2008.	https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B65-2008%252FCXP_065e.pdf
Arsenic - Rice	Code of Practice for the Prevention and Reduction of Arsenic Contamination in Rice. CXC 77-2017.	https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1%E2%80%8C&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B77-2017%252FCXC_077e.pdf
Cadmium – Cocoa Beans	Codex Code of Practice for the Prevention and Reduction of Cadmium Contamination in Cocoa. CXC 81-2022	https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B81-2022%252FCXC_081e.pdf
Contaminants and toxins	General Standard for Contaminants and Toxins in Food and Feed. CXS 193-1995.	https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B193-1995%252FCXS_193e.pdf
Food allergens	Codex Code of Practice on Food Allergen Management for Food Business Operators. CXC 80-2020	https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B80-2020%252FCXC_080e.pdf

Topic	Title	Link
HACCP systems	General Principles of Food Hygiene. CXC 1-1969.	https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B1-1969%252FCXC_001e.pdf
Lead	Code of Practice for the Prevention and Reduction of Lead Contamination in Foods. CXC 56-2004	https://www.fao.org/3/cc0579en/cc0579en.pdf
3-Monochloropropane-1,2-Diol (3-MCPD)	Code of Practice for the Reduction of 3-Monochloropropane-1,2- Diol During the Production of Acid-HVPs and Products That Contain Acid-HVPs. CXC 64-2008	https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B64-2008%252FCXP_064e.pdf
3-Monochloropropane-1,2-Diol Esters (3-MCPDEs) and Glycidyl Esters (GEs)	Code of Practice for the Reduction of 3-Monochloropropane-1,2- Diol Esters (3-MCPDEs) and Glycidyl Esters (GEs) In Refined Oils and Food Products Made with Refined Oils. CXC 79-2019.	https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B79-2019%252FCXC_079e.pdf
Mycotoxin	Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals. CXC 51-2003.	https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B51-2003%252FCXC_051e.pdf
Mycotoxins	Code of Practice for the Prevention and Reduction of Mycotoxins in Spices. CXC 78-2017.	https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B78-2017%252FCXC_078e.pdf
Ochratoxin A - Coffee	Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Coffee. CAC/RCP 69-2009. (CXC-69-2009)	https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B69-2009%252FCXP_069e.pdf

Topic	Title	Link
Ochratoxin A - Cocoa	Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Cocoa. CAC/RCP 72-2013. (CXC 72-2013)	https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B72-2013%252FCXP_072e.pdf
Pits (stones) - Olives	Standard for Table Olives. CXS 66-1981.	https://www.fao.org/fao-who-codexalimentarius/sh-proxy/pt/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B66-1981%252FCXS_066e.pdf
Pits (stones) - Dates	Standard for Dates. CXS 143-1985.	https://www.fao.org/fao-who-codexalimentarius/sh-proxy/pt/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B143-1985%252FCXS_143e.pdf
Pits (stones) – Stone fruits	Standard for Canned Stone Fruits. CXS 242-2003. 2017. (Applies to stone fruits of the genus *Prunus*)	https://www.fao.org/fao-who-codexalimentarius/sh-proxy/pt/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B242-2003%252FCXS_242e.pdf
Salmonella spp.	Codex Code of Hygienic Practice for Low-Moisture Foods. CXC 75-2015.	https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B75-2015%252FCXC_075e.pdf
Salmonella spp. and Cronobacter spp.	Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children. CAC/RCP 66-2008. (CXC 66-2008)	https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B66-2008%252FCXP_066e.pdf
Validation	Guidelines for the validation of food safety control measures. CXG 69-2008.	https://www.fao.org/fao-who-codexalimentarius/sh-proxy/pt/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B69-2008%252FCXG_069e.pdf

*Codex Standards in this table, and other Codex Standards applicable to food safety, are available at https://www.fao.org/fao-who-codexalimentarius/codex-texts/list-standards/pt/. Codex Codes of Practice in this table, and other Codex codes of Practice applicable to food safety, are available at https://www.fao.org/fao-who-codexalimentarius/codex-texts/codes-of-practice/en/. Codex guidelines listed in this table, and other Codex guidelines, are available at https://www.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/en/. Codex Standards, Codes of Practice, and Guidelines are available in several languages. To obtain a specific Standard, Code of Practice, or Guideline in a specific language, select the check mark for that language for that Standard, Code of Practice, or Guideline.

** Codex standards for chemical contaminants in food could be helpful for use as a guide for levels of chemical contaminants in foods when FDA has not established a maximum level for a particular chemical hazard in a particular food or group of foods.

Table 7. Resources for Designing Validation Studies

Organization	Document	How to Access	Applicability
Alliance for Innovation & Operational Excellence (AIOE)	Anderson, D and LA Lucore. 2020. Validating the reduction of *Salmonella* and other pathogens in heat processed low-moisture foods	Available from the OpX website by registering (free): https://www.opxleadershipnetwork.org/quality/download/pathogen-reduction-validation	Thermal processes Low moisture foods
American Frozen Foods Institute (AFFI)	Process validation - Considerations for In-Plant Blanching Study - Considerations for Lab-Scale Blanching Study - How to Validate Your Blancher	https://affi.org/safety/validation/	Frozen vegetables
Almond Board of California	- Guidelines for Validation of Blanching Processes, v1.0, April 13, 2007. - Guidelines for Validation of Oil Roasting Processes, v1.0, April 13, 2007. - Guidelines for Validation of Dry Roasting Processes, v1.2, October 23, 2007. - Guidelines for Process Validation Using Enterococcus faecium NRRL-B-2345, v1.2, October 24, 2007. - Guidelines for Validation of Propylene Oxide Pasteurization, v3.0, October 1, 2008. - Guidelines for Validation of Propylene Oxide Treatment for In-shell Almonds, v2.0, October 1, 2008. - Guidelines for Process Validation Using *Enterococcus faecium* NRRL-B-2354 as a Surrogate Microorganism in Almond Process Validation, 2014.	https://www.almonds.com/almond-industry/processors-and-suppliers/processing-safe-product/pasteurization-program	Tree nuts and other low moisture foods (as appropriate)
Chilled Foods Association	Guidelines for setting shelf life of chilled foods in relation to non-proteolytic Clostridium botulinum. 2018.	https://www.chilledfood.org/product/guidelines-for-setting-shelf-life-of-chilled-foods-in-relation-to-non-proteolytic-clostridium-botulinum/	Chilled foods
Codex Alimentarius Commission (Codex)	Codex. Guidelines for the validation of food safety control measures (CXG 69-2008)	https://www.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/en/ https://www.fao.org/fao-who-codexalimentarius/sh-proxy/pt/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B69-2008%252FCXG_069e.pdf	General applicability

Organization	Document	How to Access	Applicability
European branch of the International Life Sciences Institute, ILSI Europe	Ceylan, E., A Amezquita, N. Anderson, R. Betts, L. Blayo, F. Garces-Vega, E. Gkogka, L.J. Harris, P. McClure, A Winkler, and H. M. W. den Besten. 2021. Guidance on validation of lethal control measures for foodborne pathogens in foods.	Compr. Rev. Food Sci. Food Saf. 20:2825–2881. DOI: 10.1111/1541-4337.12746. Available at: https://ift.onlinelibrary.wiley.com/doi/full/10.1111/1541-4337.12746	General applicability; describes product and process factors essential in designing a validation study, selection criteria for identifying an appropriate target pathogen or surrogate organism.
Institute for Food Safety and Health (IFSH)	Gombas, D.; Y. Luo; J. Brennan; G. Shergill; R. Petran; R. Walsh; H. Hau; K. Khurana; B. Zomorodi; J. Rosen; R. Varley; K. Deng. 2017.Guidelines to validate control of cross-contamination during washing of fresh-cut leafy vegetables.	J. of Food Prot. 80:312-330. 2017 https://doi.org/10.4315/0362-028X.JFP-16-258	Commercial packinghouse and fresh-cut wash systems
Institute for Food Safety and Health (IFSH)	Shazer, A.; D. Stewart; K. Deng; M. Tortorello. 2017. Approaches toward identification of surrogates to validate antimicrobial washes as preventive controls for fresh-cut leafy greens.	J. of Food Prot. 80:1600-1604. 2017 https://doi.org/10.4315/0362-028X.JFP-17-069	Commercial packinghouse and fresh-cut wash systems
International Commission on Microbiological Specifications for Foods (ICMSF)	ICMSF. 2011. Microorganisms in Foods 8, Use of Data for Assessing Process Control and Product Acceptance. Chapter 2-Validation of Control Measures	https://www.springer.com/gp/book/9781441993731 Book and individual chapters can be purchased.	General applicability
International Association for Food Protection (IAFP)	Consortium of Food Process Validation Experts. Validation of Antimicrobial Interventions for Small and Very Small Processors: A How-to Guide to Develop and Conduct Validations	*Food Prot Trends*, Vol. 22, No. 2, p. 95-104.	General Applicability
National Advisory Committee on the Microbiological Criteria for Foods (NACMCF)	NACMCF. 2010. Parameters for determining inoculated pack/challenge study protocols.	*J Food Prot* 73:140-202. 2010.	General applicability for studies that involve inoculation of product.
PMMI OpX Leadership Network Products Safety Solutions Group	Validating the Reduction of *Salmonella* and Other Pathogens in Heat Processed Low-Moisture Foods: Spotlight on Baking	https://www.opxleadershipnetwork.org/quality/download/spotlight-baking	Baking Processes
University of California, Davis	Theofel, C, S Yada, and LJ Harris. Surrogate organisms for low moisture foods – published treatments [tables and references]	https://ucfoodsafety.ucdavis.edu/sites/g/files/dgvnsk7366/files/inline-files/303737.pdf	Low-moisture foods

Table 8. Additional Resources Cited in this Guidance

Topic	Source	Resource Title	Resource Link
Animal drugs	FDA website	Search animal drugs	https://animaldrugsatfda.fda.gov/
Audits	International Featured Standards (IFS) website	IFS Food 7 – English*	https://www.ifs-certification.com/index.php/en/standards/4128-ifs-food-standard-en
CGMP	Eastern Research Group. 2004.	Good Manufacturing Practices (GMPs) for the 21st Century - Food Processing. Section Four. Common Food Safety Problems in the U.S. Food Processing Industry: A Delphi Study. 2004.	https://www.fda.gov/food/current-good-manufacturing-practices-cgmps-food-and-dietary-supplements/good-manufacturing-practices-21st-century-food-processing-2004-study-section-4-common-food-safety
Chemical contaminants	FDA website	Chemical Contaminants & Pesticides	https://www.fda.gov/food/chemical-contaminants-pesticides
Chemical contaminants	FDA website	FDA Total Diet Study (TDS)	https://www.fda.gov/food/science-research-food/fda-total-diet-study-tds
Color additives	FDA website	Color additive status list	https://www.fda.gov/industry/color-additive-inventories/color-additive-status-list

Topic	Source	Resource Title	Resource Link
Data and tools in support of food safety risk assessment efforts	Foodrisk.org website	Open Data & Tools	https://www.foodrisk.org/irac/open-data-tools/
Environmental contaminants	Code of Federal Regulations	21 CFR 109.30 Tolerances for polychlorinated biphenyls (PCBs)	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-109/subpart-B/section-109.30
Environmental contaminants	FDA website	Dioxins and PCBs	https://www.fda.gov/food/chemical-contaminants-food/dioxins-pcbs
Environmental contaminants	FDA website	Per- and Polyfluoroalkyl Substances (PFAS)	https://www.fda.gov/food/chemical-contaminants-food/and-polyfluoroalkyl-substances-pfas
Food additives	FDA website	Food additive status list	https://www.fda.gov/food/food-additives-petitions/food-additive-status-list
Food allergens	FDA website	Food Allergens/Gluten-Free Guidance Documents & Regulatory Information	https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/food-allergens-and-gluten-free-guidance-documents-and-regulatory-information
Food allergens	FDA website	Label Declaration of Allergenic Substances in Foods; Notice to Manufacturers. 1996	http://wayback.archive-it.org/7993/20171114013857/https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106546.htm
Food allergens	GMA (now Consumer Brands Association)	Managing allergens in food processing establishments	Available for purchase at https://forms.consumerbrandsassociation.org/forms/store/ProductFormPublic/managing-allergens-in-food-processing-establishments

Topic	Source	Resource Title	Resource Link
Food Code	FDA website	Food Code	https://www.fda.gov/food/retail-food-protection/fda-food-code
Food fraud	United States Pharmacopeial Convention website	Food fraud mitigation guidance	https://www.usp.org/sites/default/files/usp/document/our-work/Foods/food-fraud-mitigation-guidance.pdf
Food fraud	Food Fraud Advisors website	Food Fraud Databases Compared	https://foodfraudadvisors.com/list-of-food-fraud-databases/
Food safety	FAO website	Food safety & quality	https://www.fao.org/food/food-safety-quality/home-page/en/
Food safety	WHO website	Food Safety	https://www.who.int/health-topics/food-safety/
Food safety forms and training manual	FSPCA website	Food Safety Preventive Controls Alliance	https://www.fspca.net
Food ingredient standards	Food Chemicals Codex	Food Chemicals Codex	Available for purchase at https://www.foodchemicalscodex.org/
Foreign material	U.S. Department of Agriculture, Agricultural Marketing Service	Foreign Material Manual	https://www.ams.usda.gov/publications/content/foreign-material-manual

Topic	Source	Resource Title	Resource Link
Game meat	FSIS website	FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A). 2021.	https://www.fsis.usda.gov/guidelines/2021-0014
Game meat	FSIS website	FSIS Stabilization Guideline for Meat and Poultry Products (Revised Appendix B). 2021.	https://www.fsis.usda.gov/guidelines/2021-0013
GRAS substances	FDA website	Generally Recognized as Safe (GRAS)	https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras
HACCP systems	FSIS website	Meat and Poultry Hazards and Controls Guide. 2018.	https://www.fsis.usda.gov/guidelines/2018-0005
HACCP systems	FSIS website	FSIS compliance guideline HACCP systems validation. 2015.	https://www.fsis.usda.gov/guidelines/2015-0011
HACCP systems	Codex website	Hazard analysis and critical control point (HACCP) system and guidelines for its application. Chapter Two in CXC 1-1969.	https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B1-1969%252FCXC_001e.pdf
Information for consumers	FDA website	Consumers	https://www.fda.gov/food/resources-you-food/consumers

Topic	Source	Resource Title	Resource Link
Information for consumers	FDA website	Raw Dough's a Raw Deal and Could Make You Sick	https://www.fda.gov/consumers/consumer-updates/raw-doughs-raw-deal-and-could-make-you-sick
International & Interagency Coordination	FDA website	International & Interagency Coordination	https://www.fda.gov/food/international-interagency-coordination
International & Interagency Coordination	FDA website	International Arrangements	https://www.fda.gov/international-programs/international-arrangements
International & Interagency Coordination	FDA website	International Cooperation on Food Safety	https://www.fda.gov/food/international-interagency-coordination/international-cooperation-food-safety
International & Interagency Coordination	FDA website	Systems Recognition (Food)	https://www.fda.gov/food/international-cooperation-food-safety/systems-recognition-food
Irradiation	FDA website	Irradiation of Food & Packaging	https://www.fda.gov/food/food-ingredients-packaging/irradiation-food-packaging
Irradiation	FDA website	Understanding food irradiation: What industry needs to know	https://www.fda.gov/food/irradiation-food-packaging/understanding-food-irradiation-what-industry-needs-know
Metal detection	Loma Systems website	Guide to Metal Detection	https://www.loma.com/en-us/industry-guides/guide-to-metal-detection

Topic	Source	Resource Title	Resource Link
Metal detection	Mettler Toledo website	- The Metal Detection Guide. Building an Effective Programme - Understanding Sensitivity In Metal Detection -How to Correctly Test Your Industrial Metal Detector	https://www.mt.com/us/en/home/products/Product-Inspection_1/safeline-metal-detection.html
Microbiological hazards	Combase website	A Web Resource for Quantitative and Predictive Food Microbiology	https://www.combase.cc/index.php/en/
Microbiological hazards	FDA website	Bad Bug Book. 2012.	https://www.fda.gov/media/83271/download

Topic	Source	Resource Title	Resource Link
Microbiological hazards	FDA website (A Report of the Institute of Food Technologists for the Food and Drug Administration of the United States Department of Health and Human Services. IFT/FDA Contract No. 223-98-2333; Task Order No. 4)	Evaluation and definition of potentially hazardous foods: Chapter 3 Factors that influence microbial growth	https://www.fda.gov/files/food/published/Evaluation-and-Definition-of-Potentially-Hazardous-Foods.pdf
Microbiological hazards	USDA/ ARS website	Pathogen Modeling Program	https://www.ars.usda.gov/northeast-area/wyndmoor-pa/eastern-regional-research-center/residue-chemistry-and-predictive-microbiology-research/docs/pathogen-modeling-program/
Microbiological hazards - LACF	FDA website	Guide to Inspections of Low Acid Canned Food Manufacturers Part 1 - Administrative Procedures/Scheduled Processes	https://www.fda.gov/low-acid-canned-food-manufacturers-part-1-adminstrative-proceduresscheduled-processes
Outbreaks	CDC website	Estimates of Foodborne Illness	https://www.cdc.gov/foodborneburden/index.html

Topic	Source	Resource Title	Resource Link
Outbreaks	CDC website	Foodborne outbreaks	https://www.cdc.gov/foodsafety/outbreaks/
Outbreaks	European Food Safety Authority website	Monitoring of foodborne diseases	https://www.efsa.europa.eu/en/topics/topic/monitoring-foodborne-diseases
Outbreaks and Recalls	FDA website	Recalls, Outbreaks & Emergencies	https://www.fda.gov/food/recalls-outbreaks-emergencies
Outbreaks and Recalls	Food Safety.gov website	Recalls and Outbreaks	https://www.foodsafety.gov/recalls-and-outbreaks
Pasteurization of milk	FDA website	Grade "A" Pasteurized Milk Ordinance	https://www.fda.gov/food/milk-guidance-documents-regulatory-information/national-conference-interstate-milk-shipments-ncims-model-documents; see also 21 CFR 1240.61 (Mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption at https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1240/subpart-D/section-1240.61)
Pesticides	FDA website	Pesticides	https://www.fda.gov/food/chemicals-metals-pesticides-food/pesticides
Pesticides	FDA website	Pesticide Residue Monitoring Program Reports and Data	https://www.fda.gov/food/pesticides/pesticide-residue-monitoring-program-reports-and-data
Pesticides	Code of Federal Regulations (e-CFR) website	40 CFR Part 180 - Tolerances and Exemptions for Pesticide Chemical Residues in Food	https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-180

Topic	Source	Resource Title	Resource Link
Pesticides	EPA website	Indexes to Part 180 Tolerance Information for Pesticide Chemicals in Food and Feed Commodities	https://www.epa.gov/pesticide-tolerances/indexes-part-180-tolerance-information-pesticide-chemicals-food-and-feed
Pesticides	EPA website	Regulation of pesticide residues on food	https://www.epa.gov/pesticide-tolerances
Physical hazards (glass fragments)	News website	Seavin voluntarily recalls select wines due to potential small pieces of glass in bottles	https://www.clickorlando.com/consumer/2018/05/26/seavin-voluntarily-recalls-select-wines-due-to-potential-small-pieces-of-glass-in-bottles/
Process contaminants	FDA website	3-Monochloropropane-1,2-diol (MCPD) Esters and Glycidyl Esters	https://www.fda.gov/food/chemical-contaminants-food/3-monochloropropane-12-diol-mcpd-esters-and-glycidyl-esters
Process contaminants	FDA website	Acrylamide	https://www.fda.gov/food/chemical-contaminants-food/acrylamide
Recalls	FDA website	Recalls, Market Withdrawals, & Safety Alerts	https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts
Recalls	FDA website	Regulatory Procedures Manual, Chapter 7	https://www.fda.gov/media/71814/download

Topic	Source	Resource Title	Resource Link
Recalls	FDA website	Regulatory Procedures Manual, Chapter 7, Exhibit 7-1, Model Effectiveness Check Letter (Industry).	https://www.fda.gov/media/71814/download
Recalls	FDA website	Regulatory Procedures Manual, Chapter 7, Exhibit 7-2, Model Effectiveness Check Response Format (Industry).	https://www.fda.gov/media/71814/download
Recalls	FDA website	Regulatory Procedures Manual, Chapter 7, Exhibit 7-3, Model Effectiveness Check Questionnaire for Telephone or Personal Visits (Industry).	https://www.fda.gov/media/71814/download
Recalls	FDA website	Regulatory Procedures Manual, Chapter 7, Exhibit 7-4, Model Recall Letter (Generic, All Centers).	https://www.fda.gov/media/71814/download

Topic	Source	Resource Title	Resource Link
Recalls	FDA website	Regulatory Procedures Manual, Chapter 7, Exhibit 7-5, Model Recall Response Form.	https://www.fda.gov/media/71814/download
Recalls	FDA website	Office of Regulatory Affairs (ORA) Recall Coordinators	https://www.fda.gov/safety/industry-guidance-recalls/ora-recall-coordinators
Recalls	FSIS website	Food Safety	https://www.fsis.usda.gov/food-safety
Recalls	New Zealand Food Safety, Ministry for Primary Industries website	Food recall documents	https://www.mpi.govt.nz/food-business/food-recalls/food-recall-documents/
Reportable food	FDA website	FDA-TRACK: Reportable Food Registry Data Dashboard	https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-reportable-food-registry-data-dashboard
Sanitary transportation of food	FDA website	FSMA Final Rule on Sanitary Transportation of Human and Animal Food	https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-sanitary-transportation-human-and-animal-food
Sanitation	3-A Sanitary Standards, Inc. website	3-A Sanitary Standards and Accepted Practices*	https://www.3-a.org/

Topic	Source	Resource Title	Resource Link
Sanitation	American Meat Institute website	Food Safety Equipment Design Principles CHECKLIST & GLOSSARY. 2021.	https://www.meatinstitute.org/sites/default/files/original%20documents/Sanitation%20booklet%202021.pdf
Sanitation	GMA (now Consumer Brands Association)	Control of *Salmonella* in Low-Moisture Foods Guidance Document.**	https://graphics8.nytimes.com/packages/pdf/business/20090515_moss_ingredients/SalmonellaControlGuidance.pdf
Sanitation	European Hygienic Engineering and Design Group (EHEDG) website	EHEDG Guidelines Doc 8. Hygienic Design Principles. Third Edition. 2018.	https://www.ehedg.org/guidelines/
Sanitation	Lelieveld, HLM, Holah, JT and Napper, D (Eds.) (Elsevier Publishing)	Hygiene in Food Processing: Principles and Practices. 2014.*	N/A
Sanitation	Marriott, NG, Schilling, MW, and Gravani, RB. (Springer International)	Principles of Food Sanitation, Sixth Ed. 2018.*	https://doi.org/10.1007/978-3-319-67166-6

Topic	Source	Resource Title	Resource Link
Sanitation	Schmidt, RH and DJ Erickson, Food Science and Human Nutrition Department, Florida Cooperative Extension Service, Institute of Food and Agricultural Sciences, University of Florida	Sanitary Design and Construction of Food Equipment. 2005.	https://ucfoodsafety.ucdavis.edu/sites/g/files/dgvnsk7366/files/inline-files/26502.pdf
Spices	American Spice Trade Association (ASTA) website	Clean, Safe Spices Guidance Document	https://www.astaspice.org/food-safety-technical-guidance/best-practices-and-guidance/clean-safe-spices-guidance-document/
Spices	FDA website	Risk Profile: Pathogens and Filth in Spices	https://www.fda.gov/food/cfsan-risk-safety-assessments/risk-profile-pathogen-and-filth-spices
Supplier evaluation	FDA website	Firm/Supplier Evaluation Resources for FSMA Rules	https://www.fda.gov/food/food-safety-modernization-act-fsma/firmsupplier-evaluation-resources-fsma-rules
Substance intentionally introduced for purposes of economic gain	FDA website	Melamine	https://www.fda.gov/food/chemical-contaminants-food/melamine

Topic	Source	Resource Title	Resource Link
Toxic elements	FDA website	Metals and Your Food	https://www.fda.gov/food/chemical-contaminants-metals-pesticides-food/metals-and-your-food
Toxic elements	FDA website	Closer to Zero: Reducing Childhood Exposure to Contaminants from Foods	https://www.fda.gov/food/environmental-contaminants-food/closer-zero-reducing-childhood-exposure-contaminants-foods
Validation	FSIS website	FSIS compliance guideline HACCP systems validation. 2015.	https://www.fsis.usda.gov/guidelines/2015-0011
Various	European Union website	Rapid Alert System for Food and Feed (RASFF)	https://food.ec.europa.eu/safety/rasff-food-and-feed-safety-alerts_en
Various	FDA website	Food Defect Levels Handbook	https://www.fda.gov/food/ingredients-additives-gras-packaging-guidance-documents-regulatory-information/food-defect-levels-handbook
Various	FDA website	Food Code	https://www.fda.gov/food/retail-food-protection/fda-food-code
Various	FDA website	Regulatory Procedures Manual	https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual
X-ray detection	Loma systems website	Guide to X-Ray Inspection	https://www.loma.com/en-us/industry-guides/guide-to-x-ray-inspection

*Available for purchase.

** This industry guidance document is also available as a series of three publications in the journal Food Production Trends:

Scott, VN., C Yuhuan, TA Freier, et al. 2009. Control of *Salmonella* in Low-Moisture Foods I: Minimizing Entry of Salmonella into a Processing Facility, *Food Prot Trends*, 29:342–353.

Chen, Y, VN Scott, TA Freier, et al. 2009a. Control of *Salmonella* in Low-moisture Foods II: Hygiene Practices to Minimize Salmonella Contamination and Growth, *Food Prot Trends*, 29:435–445.

Chen, Y, VN Scott, TA Freier, et al. 2009b. Control of *Salmonella* in Low-moisture Foods III: Process Validation and Environmental Monitoring, *Food Prot Trends*, vol. 29, no. 8, pp. 493-508.

VII. References

In this section, we list all references cited in the chapters in this guidance. When a reference includes a website address, FDA has verified the website address, as of the date that the Notice of Availability for the Introduction of this guidance publishes in the *Federal Register*, but websites are subject to change over time.

See section VI of this Introduction for information that we list as a "Resource" rather than a "Reference." The Resources included in section VI often are available on websites rather than in publications such as scientific journals or books.

See Appendix 3 of this guidance for references applicable to Appendix 3.

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