Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic.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

Chapter 2: Conducting a Hazard Analysis

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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. Underlined text in yellow highlights represents a correction from the draft Chapter 2 that we issued for public comment in August 2016.

2.1 Purpose of this Chapter

The guidance provided in this chapter is intended to help you conduct a hazard analysis in accordance with the PCHF requirements. The hazard analysis must be written, regardless of the results of the analysis, and must include two elements: (1) a hazard identification and (2) a hazard evaluation. You conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are hazards requiring preventive controls. See 21 CFR 117.130.

2.2 Overview of a Hazard Analysis

Part 117 does not define the term "hazard analysis." See Box 2-1 for a definition of "hazard analysis" that was developed by the Food Safety Preventive Controls Alliance (FSPCA).

Box 2-1. A Definition for "Hazard Analysis"

Hazard Analysis

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

Food Safety Preventive Controls Alliance

This section will guide you through the steps involved in conducting a hazard analysis. The PCHF requirements do not specify that you must use a "Hazard Analysis Worksheet" to conduct your hazard analysis. However, you may find it useful to use such a worksheet. See Form 2-B in Appendix 2 of this guidance and Box 2-3 in this chapter.

The PCHF requirements do not specify that you must use a certain format for conducting a hazard analysis. You may use formats other than the Hazard Analysis Worksheet that we provide in this guidance (including the use of a written narrative) as long as your hazard analysis contains the elements of hazard identification and hazard evaluation.

You use the hazard analysis to determine appropriate preventive controls. Your hazard analysis should provide justification for your decisions. You may group products together in a single hazard analysis worksheet if the food safety hazards and controls are essentially the same for all products in the group, but you should clearly identify any product or process differences. Keep in mind that you will need to refer to your written hazard analysis when you reanalyze or

modify your FSP and that it can be a resource for you when you are asked by inspectors or auditors to justify why certain hazards were or were not included in your FSP.

The hazard analysis helps you to focus resources on the most important controls applied to provide safe food. If you do not conduct the hazard analysis correctly, and do not identify all hazards warranting preventive controls within the food safety plan, the food safety plan will not be effective in protecting consumers and preventing food safety issues, no matter how well your facility follows the plan. A proper analysis of biological, chemical (including radiological), and physical hazards associated with food ingredients, finished products, and the processes used calls for good judgment, detailed knowledge of the properties of the raw materials/other ingredients and manufacturing processes, and access to appropriate scientific expertise.

2.3 Recommended Activities Prior to Conducting a Hazard Analysis

Although the PCHF requirements do not specify that you must do so, we recommend that you conduct certain preliminary steps, and set up a Hazard Analysis Worksheet, as a useful framework for organizing and documenting your hazard analysis.

2.3.1 Conduct Preliminary Steps

Box 1-2. Preliminary Steps

1. Assemble a Food Safety Team
2. Describe the product, its distribution, intended use, and consumer or end user of the product
3. Develop a process flow diagram and verify it on site
4. Describe the process

Your written hazard analysis is part of your food safety plan, which must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals (21 CFR 117.126(a)(2)). Although the PCHF requirements do not specify that you must do so, we recommend that a Food Safety Team of individuals with expertise in the day-to-day operations of your facility conduct your hazard analysis under the oversight of a Preventive Controls Qualified Individual. The individuals may include personnel from production, sanitation, quality control, laboratory, and maintenance. Using people from different functions within the facility can help provide a complete understanding of the process and things that can go wrong. You can supplement the expertise of the Food Safety Team by competent technical experts from other off-site functions within the firm (where applicable), such as research and development (R&D), technical applications groups, and quality management, as well as from outside experts from universities, cooperative extension services, trade associations, private consulting firms, or other sources.

The effectiveness of your Food Safety Team will be impacted by the quality and completeness of the information provided to them about the facility and food product(s) to be evaluated. Therefore, in order for your Food Safety Team to conduct the hazard analysis, we recommend that you define and document the following details for the facility:

- Product description, including its distribution, intended use, and identification of consumer or end user;
- Process flow diagram; and
- Detailed process description to supplement the process flow diagram.

A product description and how the product will be distributed helps team members understand elements of the product that may impact food safety, such as whether temperature controls are needed during distribution. The description should include the full name of the finished product, including descriptors such as ready-to-eat (RTE), frozen; the packaging type and material; and storage and distribution details. Understanding how the product will be used by the consumer (e.g., consumed with or without further processing, such as cooking) and knowing the intended consumer of the product (e.g., whether the food is intended for general public or specifically intended for a more susceptible population such as infants and young children (e.g., infant formula), the elderly (e.g., foods manufactured for nursing homes), or immunocompromised persons (e.g., foods manufactured for hospitals) helps to identify hazards of particular concern and the need for more stringent controls or verification activities.

The purpose of a process flow diagram is to provide a clear, simple description of the steps involved in the processing of your food product and its associated ingredients as they "flow" from receipt to distribution. The process flow diagram should cover all steps in the process that the facility performs, including receiving and storage steps for each raw material or other ingredient, preparation, processing, packaging, storage and distribution of the product. Additionally the process flow diagram should identify the equipment (e.g., pumps, surge tanks, hoppers, fillers) used in the operations. An accurate process flow diagram serves as a useful organizational format for elements of the food safety plan, because it identifies each of the steps that must be evaluated in the hazard analysis. You should verify the process flow diagram on-site in order to ensure no steps have been overlooked.

The purpose of a detailed process description is to explain what happens at each of the process steps. Information such as the maximum length of time a food is exposed to ambient temperature during processing, whether a food is handled manually, and whether rework is incorporated into product can be important for an accurate hazard analysis.

2.3.2 Set Up the Hazard Analysis Worksheet

Once you have assembled the Food Safety Team and started gathering the information you will use in your hazard analysis, we recommend that you set up a document that you will use to organize the hazard analysis. In this guidance, we describe how to set up an adaptation of the "Hazard Analysis Worksheet" used in HACCP systems to organize your hazard analysis. In this section of this chapter, we discuss how to set-up this worksheet (see Box 2-3, which shows a form adapted from a form used by the FSPCA). In the next section of this chapter, we provide details that will help you use the worksheet to conduct your analysis.

- Column 1: Here, you will list (1) receipt of ingredients used in the process as a means of identifying hazards associated with an ingredient (you may group some ingredients, e.g., "spices"); and (2) processing steps. The process flow diagram recommended as a preliminary step (see Box 1-2) can help you to identify the processing steps that are included in the hazard analysis.
- Column 2: Here, you will list the results of your hazard identification – i.e., the food safety hazards that potentially could be introduced, controlled, or enhanced at this step (known or reasonably foreseeable hazards). Include all ingredient-related hazards, process-related hazards, and hazards that may be introduced from the environment.

- Column 3: Here, you will record the conclusions of your hazard evaluation – i.e., the determinations you make of whether each listed food safety hazard requires a preventive control (Yes or No).
- Column 4: Here, you will record the reasons that led to the conclusions of your hazard evaluation (i.e., the Yes/No conclusions listed in column 3). Explaining your reasons for a "No" conclusion can be just as important as explaining your reasons for a "Yes" conclusion. To be thorough and to have readily available answers to questions about your hazard analysis, you may find it useful to take a conservative approach by listing in Column 2 several potential hazards even though they clearly do not require a preventive control (especially when there has been significant debate over whether something is actually a potential hazard for the facility), and explain the reasons for your "No" conclusion. This can be useful both during your own review of your food safety plan and during review of your food safety plan by others – e.g., if an inspector or auditor questions whether a particular hazard was considered.
- Column 5: Here, you will identify preventive controls that will significantly minimize or prevent the food safety hazard (e.g., process, allergen, sanitation, supply-chain or other) for those hazards you identified as requiring a preventive control (i.e., a "Yes" in column 3).
- Column 6: Because the worksheet breaks your production process into multiple steps, and the preventive control may be applied at a step in the process other than the step where you listed the hazard, you specify whether the preventive control will be applied at this particular step (Yes/No). It is important to note that identifying a hazard at a processing step as one that requires a preventive control does not mean that the hazard must be controlled at that processing step.

Box 2-3. Example Hazard Analysis Work Sheet (Also see Form 2-B, Appendix 2)[2]

(1) Ingredient / Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step B = biological C = chemical, including radiological P = physical	(3) Are any potential food safety hazards requiring preventive control? (Yes/No)	(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supplier, other preventive control*	(6) Is the preventive control applied at this step? (Yes/No)

2.4 Conducting a Hazard Analysis

2.4.1 Identify Potential Hazards (Ingredient-Related Hazards, Process-Related Hazards, and Hazards that May Be Introduced from the Environment (Hazard Identification)

See 21 CFR 117.130(b).

We recommend that you start your identification of hazards potentially associated with a food or process (the "known or reasonably foreseeable hazards") with a brainstorming session to generate a list of biological, chemical, and physical hazards. Consider the following as you work through this process:

- Information about the product description, intended use, and distribution.
- In-plant experience regarding the likelihood of hazards being associated with the finished products. This may include information from product testing results, consumer complaints, or knowledge of

[2] Adapted from a form available from the FSPCA in "FSPCA Preventive Controls for Human Food Training Curriculum, First Edition – 2016." The 2016 FSPCA form includes some additional features, such as a separate column for "Yes" and "No" responses and a separate row at each step for biological, chemical, and physical hazards (labeled B, C, and P, respectively). You can obtain the FSPCA form, including any later version if the form changes, from the FSPCA website (https://www.ifsh.iit.edu/sites/ifsh/files/departments/fspca/pdfs/FSPCA_Ap2_Worksheets__V1.1_Fillable.pdf)

facility personnel about the condition, function, and design of the facility that may be relevant to contamination.

- Raw materials and ingredients used in the product. Hazards, such as food allergen hazards or pathogens known to be associated with specific types of foods, may be introduced during product formulation. For example, mayonnaise is formulated with egg, which is a food allergen; "egg" must be included on the label and the mayonnaise may be a source of allergen cross-contact in your facility.
- Activities conducted at each step in the manufacturing process. Some processes may introduce hazards (e.g., a broken chopping blade can introduce metal fragments; a broken glass container can introduce glass fragments; improper cooling can allow low numbers of microbial pathogens to increase).
- Equipment used to make the product. Some types of equipment are more difficult to clean than others or are more prone to damage, which may increase the risk of hazards (e.g., biological or physical) being introduced into the product.
- Types of packaging and packaging materials. Reduced oxygen packaging, used to increase shelf life (e.g., potato salad packaged in a plastic container with a snap lid), may create an environment that supports the growth of *Clostridium botulinum (C. botulinum)*.
- Sanitary practices. You should consider the sanitary conditions within the processing facility (e.g., cleanliness of equipment and processing environment) and employee hygiene when identifying hazards. Hard-to-clean equipment may result in pathogen harborage sites. Producing foods with different food allergens on the same line may result in allergen cross-contact.
- External information. Sources may include scientific papers, epidemiological studies (e.g., data from previous outbreaks associated with ingredients or processes relevant to a product), information from applicable government or industry food safety guidance documents, and historical data for similar products, if available.

After reviewing all the relevant information, the Food Safety Team can then develop a list of biological, chemical, and physical hazards that may be introduced, increased (e.g., due to pathogen growth), or controlled at each step described on the flow diagram. Enter those in column 2 of the Hazard Analysis Worksheet.

We recommend that you consult Chapter 3 and Appendix 1 of this guidance to help you identify potential hazards. Chapter 3 of this guidance provides a review of biological, chemical, and physical hazards and Appendix 1 of this guidance provides tables describing potential ingredient-related hazards and process-related hazards. The hazards identified in Chapter 3 and in Appendix 1 do not represent an exhaustive list of hazards potentially associated with a food facility or food. You are responsible for identifying any hazard that may be associated with your process or product, even if it is not listed in Chapter 3.

You may find the following list of questions helpful during the hazard identification process. We adapted this list from Hazard Analysis and Critical Control Point Principles and Application Guidelines published by the National Advisory Committee on Microbiological Criteria for Foods.

<u>Examples of questions to be considered when identifying potential hazards</u>

1. Ingredients

    a. Does the food contain any ingredients that may present microbiological hazards, chemical hazards, or physical hazards?

b. Is all the water used at any point in the manufacturing process of the appropriate quality standard?

c. What are the sources of the ingredients (geographical regions, specific supplier details)?

2. Intrinsic Factors – physical characteristics and composition of the product during and after processing

    a. What hazards may result if the food composition is not controlled?

    b. Does the food permit survival or promote pathogen growth and/or toxin formation during subsequent steps in the manufacturing process or distribution/storage?

    c. Are there similar products already in the marketplace, and if so, which hazards have been associated with those products? What is the food safety record of those products?

3. Processing procedures

    a. Does the process include a controllable processing step that destroys pathogens? If so, which pathogens? Consider not only vegetative cells but also spores, which are typically more resistant to inactivation treatments compared to their vegetative counterparts.

    b. Is the product susceptible to recontamination between processing and packaging? If so, what are the biological, chemical (including radiological), or physical hazards potentially associated with the process environment?

4. Microbial content of the food

    a. What is the baseline microbial content of the food?

    b. Does the microbial population change during the normal storage time of the food prior to consumption?

    c. Do changes in the microbial population affect the safety of the food?

    d. Based on the answers to the above questions, is there a significant likelihood of any biological hazards?

5. Facility design

    a. Does the layout of the facility provide an adequate separation of raw materials from RTE foods when this is necessary for food safety? If not, what are the hazards that could contaminate the RTE product?

b. Is positive air pressure maintained in product packaging areas? Is this required for product safety?

c. Is the traffic pattern for people and moving equipment a significant source of contamination?

6. Equipment design and use

a. Will the equipment provide the necessary time-temperature control to ensure a safe product?

b. Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerances required to produce a safe product?

c. Is the equipment reliable and maintained in good repair?

d. Is the equipment easy to clean and sanitize?

e. Can parts of the equipment contaminate the product and thereby introduce physical hazards?

f. What product safety devices are used to control the potential for physical hazards to contaminate the product? Examples include: metal detectors, magnets, sifters, filters, screens, thermometers, bone removal devices, dud detectors

g. Are allergen protocols needed for using the same equipment for different products?

7. Packaging

a. Does the method of packaging affect the rate of growth of microbial pathogens and/or the formation of toxins?

b. Is the package clearly labeled with the appropriate storage instructions, e.g., “Keep refrigerated,” if required for safety?

c. Does the package include instructions for the safe handling and preparation of the food by the end user?

d. Is the packaging material resistant to damage and effective in preventing post-packaging microbial contamination?

e. Are tamper-evident packaging features used?

f. Is each package and case legibly and accurately coded?

g. Does each package contain the proper label?

h. Are allergenic ingredients included in the list of ingredients on the label?

8. Employee health, hygiene, and education

    a. Can employee health or personal hygiene practices impact the safety of the food being processed, and in what way(s)?

    b. Do the employees understand the process and the factors they must control to assure the preparation of safe foods?

    c. Will the employees inform management of a problem that could impact food safety?

9. Storage conditions between packaging and the end user

    a. What is the likelihood that the food will be improperly stored at the wrong temperature?

    b. Would an error in storage lead to a microbiologically unsafe food?

10. Intended use and user

    a. Will the food be heated by the consumer?

    b. Will there likely be leftovers? If so, how and maximally for how long should they be stored? How should they be re-heated?

    c. Is the food intended for the general public?

    d. Is the food intended for consumption by a population with increased susceptibility to illness or a particular hazard (e.g., Infants, the elderly, the immuno-compromised, or pregnant women)?

    e. Is the food intended to be used for institutional feeding (e.g., in school cafeterias, hospitals) or in private homes?

2.4.2 Evaluate Potential Hazards to Determine Whether the Hazard Requires a Preventive Control (Hazard Evaluation)

See 21 CFR 117.130(c).

- Under 21 CFR 117.130(c)(1)(i), you must assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.
- Under 21 CFR 117.130(c)(1)(ii), you must include an evaluation of environmental pathogens whenever an RTE food is exposed to the environment prior to packaging and the packaged food does

not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.

- Under 21 CFR 117.130(c)(2), you must consider the effect of certain factors on the safety of the finished food for the intended consumer.

We discuss each of these points in the remainder of this section.

Consult the hazards in Chapter 3 and controls in Chapters 4 and 5 of this guidance document for each of the potential hazards that you entered in Column 2 of the Hazard Analysis Worksheet. These chapters offer guidance for completing your hazard analysis and developing your FSP. Chapters 6-13 each contain a section "Understand the Potential Hazard" that provides information about the significance of the hazard, the conditions under which it may develop in a processed product, and methods available to control the hazard.

Once you have identified all potential hazards, the next step is to evaluate each hazard and determine whether the hazard poses a significant risk to the end user or consumers in the absence of a preventive control. Narrow the list of potential hazards that you entered in column 2 to those that require a preventive control.

For example, at the receiving step for ingredients, you may identify soy as an allergen in your product because soy protein is one of the ingredients. Because it is an allergen, you would mark "Yes" in column 3 and explain that soy may cause allergic reactions in some consumers in column 4.

For each hazard also consider the following:

- Seriousness of the potential illness or injury resulting from exposure to the hazard, and
- The likelihood of occurrence in the absence of a preventive control.

2.4.2.1 Evaluating severity

To evaluate the severity of a potential hazard, you should consider certain factors, including

- susceptibility of intended consumers to foodborne illness (e.g., infants, children, and immunocompromised persons may be more susceptible to certain foodborne illnesses),
- the potential magnitude and duration of the illness or injury (e.g., how long an individual may be sick, and whether hospitalization or death is common), and
- the possible impact of secondary problems (e.g., chronic sequelae such as kidney damage or reactive arthritis).

If your facility does not have the expertise to evaluate the severity of a potential hazard, you should consult with outside experts.

2.4.2.2 Estimating the likely occurrence

The likelihood of occurrence of a particular food hazard in the food when consumed can be influenced by:

- Frequency of association of the hazard with the food or facility
- Effectiveness of facility programs such as CGMPs
- Method of preparation in the establishment

- Conditions during transportation
- Expected storage conditions
- Likely preparation and handling steps before consumption

Knowing your product, ingredients, processes, preparation methods, packaging, transportation, distribution, and likely use of the product will be helpful in estimating the likely occurrence of potential hazards. Hazards identified in one operation or facility may not be significant in another operation or facility producing the same or similar products because different equipment and processes may be used, the ingredients and their source may be different, or for other reasons. For example, one facility may package a beverage in glass and another may package the same product in plastic. You should consider each operation and facility location individually when estimating the likely occurrence of a food safety hazard.

When estimating likely occurrence, you should consider information from several sources, such as the following:

- Data from outbreaks of foodborne illness,
- Data from recalls,
- Information in the scientific literature, and
- Experience and historical information gathered by your facility.

2.4.2.2.1 Data from outbreaks

Your Food Safety Team should consider foodborne illness outbreaks in the same or similar products, as well as data on foodborne illness outbreaks provided from other product types that may be relevant, or from foods prepared in retail food establishments rather than in manufacturing facilities. Several publicly available resources can provide such information. For example, we provide information on our findings related to outbreaks, including a discussion, whenever possible, of factors that would have contributed to the outbreak at the processing or production site for the foods we regulate. Moreover, the Centers for Disease Control and Prevention (CDC) provides considerable information on outbreaks that occurred from processed foods, as well as from foods prepared in restaurants, retail establishments, and other locations. See Box 2-4 for a list of useful reports and the list of references in section 2.6 of this chapter for how to access these reports. Information may also be available on outbreaks from similar foods that occur in other countries. For example, the European Food Safety Authority (EFSA) publishes summaries of foodborne disease outbreaks in European countries.

Box 2-4. Sources of Data about Outbreaks [3]

Food and Drug Administration (FDA)

- Outbreak investigations – reports for FDA regulated foods

Centers for Disease Control and Prevention (CDC)

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

Center for Science in the Public Interest (CSPI)

- Outbreaks & Recalls

2.4.2.2.2 Data from recalls

Recalls provide useful information in understanding the likely occurrence of potential hazards and the foods in which they occur. We categorize recalls as specified in 21 CFR 7.3(m):

Recall classification means the numerical designation, i.e., I, II, or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.

- 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);
- 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
- 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).

Federal and state websites post information on food recalls. See Box 2-5 for a list of some helpful federal websites that provide data about recalls. See the list of references in section 2.6 of this chapter for the links to access this information.

[3] See section 2.6 of this chapter for information on how to access these sources of data about outbreaks.

Box 2-5. Sources of Data About Recalls[4]

- **Food and Drug Administration (FDA) Recalls, Market Withdrawals, & Safety Alerts**
- **U.S. Department of Agriculture (USDA) Food Safety and Inspection Service Recall Archive**
- **Foodsafety.gov (Gateway to Federal Food Safety Information), Recalls & Alerts**

2.4.2.2.3 Information in the scientific literature

Peer-reviewed scientific journals and other sources of technical literature (e.g., Codex Alimentarius Commission (Codex), the Food and Agriculture Organization and the World Health Organization) provide considerable information on foodborne hazards, including their occurrence, their potential growth in foods (e.g., for biological hazards), and their control. A useful search engine is Google Scholar. USDA provides a microbial modeling program that is available online and can be used to evaluate potential growth of pathogens under a variety of conditions. ComBase is an online tool for quantitative food microbiology. It contains the ComBase database of microbial growth and survival curves and the ComBase Predictor that uses the data to predict growth or inactivation of microorganisms. Keep in mind that modeling programs may not reflect exactly what will occur in a particular food, but they can provide an estimate of relative risk of different scenarios. Codex maintains internationally recognized codes of practice that are based on scientific literature and are available in several languages. Trade associations also provide food safety recommendations for specific types of foods and industry needs.

We provide other guidance documents that contain product-specific food safety information (e.g., on shell eggs, cheese, fruits, vegetables, and milk). These guidance documents, which represent FDA's current thinking on a topic, are organized by topic and by year of publication, with recently added guidance documents at the top of the page.

2.4.2.2.4 Establishment's historical information

You may already have considerable information on your products from various laboratory tests on finished products, ingredients, in-process materials, or environmental monitoring. In addition, you may have experienced a contamination problem in the past that suggests a hazard is reasonably foreseeable, or received consumer complaints about certain hazards, such as physical hazards.

You should evaluate the potential hazards independently at each processing step to determine whether you should identify that hazard as one requiring a preventive control. For example, you would identify a hazard as one requiring a preventive control if:

- it is reasonably likely that the hazard can be introduced at an unsafe level at that processing step; or
- it is reasonably likely that the hazard can increase to an unsafe level at that processing step; or

[4] See section 2.6 of this chapter for information on how to access these sources of data about recalls.

- the hazard was identified in an ingredient or at another processing or handling step and it can be controlled (i.e., significantly minimized or prevented) at the current processing step.

When evaluating whether a hazard requires a preventive control, you should consider the method of distribution and storage and the intended use and consumer of the product (information which you developed as part of your preliminary steps in conducting a hazard analysis).

If you determine that a potential hazard requires a preventive control, you should answer "Yes" in column 3 of the Hazard Analysis Worksheet. If you determine that it does not require a preventive control, you should answer "No" in that column. In column 4, record your reason for your "Yes" or "No" answer. If the hazard does not require a preventive control, you would not complete columns 5 and 6.

2.4.2.3. Evaluating environmental pathogens whenever a ready-to-eat food is exposed to the environment

If the food you make is ready-to-eat (see the definition in 21 CFR 117.3, which we included in the Glossary in section III of the Introduction of this guidance), the food could be contaminated with environmental pathogens such as *Listeria monocytogenes* (*L. monocytogenes*) or *Salmonella*. See 21 CFR 117.130(c)(1)(ii) for when the PCHF requirements specify that you must consider environmental pathogens in your hazard analysis.

2.4.2.4. Evaluation factors

When evaluating hazards, you must consider the effect of the following on the safety of the finished food for the consumer (21 CFR 117.130(c)(2)):

- The formulation of the food: The addition of certain ingredients such as acids and preservatives may be critical to the safety of the food, because they may inhibit growth of, or kill, microorganisms of public health significance. This could impact the evaluation at steps during production and storage with respect to the hazard of ''pathogen growth.'' A multicomponent food may have individual ingredients that do not support growth of undesirable microorganisms (e.g., because of pH or a_w), but when put together there may be an interface where the pH and a_w change (e.g., pies, layered breads). The formulation may contain an ingredient (e.g., a flavoring, coloring, or incidental additive) that is (or contains) an allergen that requires label control and possibly controls to prevent cross-contact.
- The condition, function, and design of the facility and equipment: The condition, function, or design of a facility or its equipment could potentially result in the introduction of hazards into foods. For example, older equipment (e.g., older slicing, rolling and conveying equipment) may be more difficult to clean (e.g., because of close fitting components or hollow parts) and, thus, provide more opportunities for pathogens to become established in a niche environment than modern equipment designed to address the problem of pathogen harborage in niche environments; in such instances enhanced sanitation controls may be appropriate. Equipment designed such that there is metal-to-metal contact may generate metal fragments; a preventive control such as metal detectors may be appropriate. A facility that manufactures, processes, or packs an RTE product such as fresh soft cheese may have cold, moist conditions that are conducive to the development of a niche where the pathogen *L. monocytogenes* can become established and contaminate food-contact surfaces and, eventually, foods; enhanced sanitation controls may be appropriate for such facilities. Facilities with closely spaced equipment should consider the impact of the close spacing on the potential for allergen cross-contact to be a hazard; targeted food allergen controls may be appropriate.
- Raw materials and other ingredients: A food can become contaminated through the use of contaminated food ingredients. Ingredients such as flavorings, colorings, or incidental additives may

contain ‘‘hidden’’ allergens. Machinery-harvested produce may be contaminated with physical hazards, because the machinery can pick up foreign material from the field.

- Transportation practices: The safety of a food can be affected by transportation practices for incoming raw materials and ingredients or for outgoing finished product. For example, when a food requires time/temperature control for safety, time/temperature controls would be important during transportation. Distributing a food in bulk without adequate protective packaging makes the product susceptible to contamination during transportation—e.g., from pathogens or chemicals present in an inadequately cleaned vehicle or from other inadequately protected foods that are being co-transported and are potential sources of contamination.
- Manufacturing/processing procedures: Hazards may arise from manufacturing/processing processes such as cooling or holding of certain foods due to the potential for germination of pathogenic sporeforming bacteria such as *Clostridium perfringens (C. perfringens)* and *Bacillus cereus (B. cereus)* (which may be present in food ingredients) as a cooked product is cooled and reaches a temperature that will allow germination of the spores and outgrowth. Hazards also may arise from manufacturing/processing processes such as acidification due to the potential for germination of spores of *C. botulinum*, with subsequent production of botulinum toxin, if the acidification is not done correctly. Toxins can be produced by the bacteria *Staphylococcus aureus (S. aureus)* or *B. cereus* in a product that has been heated and held at room temperature during the manufacturing process if the product formulation supports growth and toxin formation by the bacteria and *S. aureus* or *B. cereus* is present in the ingredients of the product or is introduced by poor employee hygiene (e.g., *S. aureus*). Physical hazards may occur from metal fragments generated during the manufacture of food on equipment in which metal (e.g., wires, saw blades or knives) is used to cut products during manufacturing.
- Packaging activities and labeling activities: Preventive controls for glass may be needed for products packed in glass. Preventive controls for *C. botulinum* may be needed when packing certain foods in modified atmosphere packaging. Label controls may be needed to ensure all food allergens are listed on the label of packaged foods that contain allergens.
- Storage and distribution: Biological hazards are more likely to require a preventive control during storage and distribution in foods that require refrigerated storage to maintain safety than in shelf-stable foods.
- Intended or reasonably foreseeable use: Some foods that are intended to be cooked by the consumer may also have uses that do not include cooking, such as soup mixes used to make dips. Whenever an RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen, hazards such as *Salmonella* spp., *L. monocytogenes*, and *Escherichia coli* O157:H7 (*E. coli* O157:H7) must be considered to determine if they require a preventive control. (See 21 CFR 117.130(c)(1)(ii).)
- Sanitation, including employee hygiene: Sanitation measures and practices can impact the likelihood of a hazard being introduced into a food. For example, the frequency with which a production line is shut down for a complete cleaning can impact the potential for food residues to transfer pathogens from equipment to foods (e.g., pathogens present on raw produce that could carry over into the next production cycle on a line). Practices directed at worker health and hygiene can reduce the potential for transfer of pathogens such as *Salmonella* spp., hepatitis A, and norovirus.
- Any other relevant factors, such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of some natural toxins): Hazards such as aflatoxin are subject to a weather-dependent effect in that aflatoxin levels in some raw agricultural commodities are more of a problem in some years than in others.

As noted earlier, identifying a hazard at a processing step as one that requires a preventive control does not mean that the hazard must be controlled at that processing step. Once you determine that a hazard requires a preventive control, the next step is to identify control measures to control the hazard.

2.5 Identify Preventive Control Measures

Box 2-6. Definition of "Preventive Controls" in Part 117

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.

21 CFR 117.3

For each hazard that your Food Safety Team first identified in Column 2 as potentially associated with an ingredient, processing step, or the environment, and then identified in Column 3 as requiring a preventive control, you must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented. See 21 CFR 117.135. If a process control can be applied at a point or step in the food production process to prevent or eliminate the food safety hazard, or reduce it to an acceptable level, you should classify the point or step as a Critical Control Point (CCP). There are several control approaches, which may or may not include CCPs, that you can consider, depending on the potential hazard and where in the process flow diagram you determine the control measure should be applied. These include:

- Supply-chain controls
- Food allergen controls
- Sanitation controls
- Process controls

Supply-chain controls involve verification of controls used by suppliers to control hazards in raw materials or other ingredients before receipt by a manufacturer/processor. Food allergen controls include labeling and controls to prevent cross-contact, such as product sequencing, in addition to sanitation controls (i.e., to prevent cross-contact with allergens from other foods produced on the same line). Sanitation controls may be important to prevent contamination with microbial pathogens, especially for RTE foods that are exposed to the environment. Process controls are applied at specific processing steps, where critical parameters such as time and temperature may be identified to control the hazard of concern. See Box 2-7 for some examples of in-process controls.

Box 2-7. Examples of In-Process Controls

Examples of In-Process Controls
• Acidification • Cooking • Drying • Fermentation • Filtering • Freezing • High pressure processing • Irradiation • Metal detection • Pasteurization • Refrigeration • Retort processing • Use of x-ray area

For every hazard you identify as requiring a preventive control, you must identify and implement at least one preventive control measure. See 21 CFR 117.135. Importantly, remember that more than one hazard may be addressed by a specific control measure. For example, several vegetative pathogens, such as *Salmonella*, *L. monocytogenes*, and *E. coli* O157:H7, are killed by cooking. Several chapters in this guidance provide one or more control strategy examples for how one or more hazards can be controlled, because there are often more ways than one to control a hazard. The control strategy examples also contain control measure information. Record the control measure(s) that you choose in column 5 of the Hazard Analysis Worksheet for each "Yes" answer in column 3.

When identifying preventive controls for your food process, your Food Safety Team should also consider

- The effect of the control on identified potential food safety hazards (e.g., Does the preventive control significantly minimize or prevent the potential food safety hazards identified? Is the preventive control hazard-specific or does it control more than one hazard? Does the control effectiveness depend upon other controls? Can the preventive control be validated and verified?)
- The feasibility of monitoring those controls (e.g., Are the critical limits (minimum or maximum values) and, if appropriate, operating limits, for the preventive control measureable and practical? Can you obtain the results of monitoring quickly (i.e., real-time) to determine if the process is in control? Are you monitoring a batch or continuous process? Are you monitoring continuously or doing spot checks? Can the parameters be monitored in-line or must the product be sampled? Will the monitored parameters be indirectly linked to the critical limit (i.e., belt speed or pump flow rate for time of process)? Who will perform the monitoring or checks and what are the required qualifications? How is the monitoring to be verified?)

- The location of the control with respect to other processing control measures (e.g., Is the application of the control measure at the last point in the process to ensure control of the targeted potential food safety hazard? Will the failure of an upstream control result in failure of downstream controls (i.e., acidification failure impacting thermal process efficacy for an acidified food)? Are monitoring activities appropriate to ensure control at this step?)
- Corrective actions that will be needed in the event of a failure of a control measure or a significant processing variability (e.g., Can the process control and critical parameter be brought quickly back into control? How will you determine if the control measure is once again under control? Can the implicated product be identified and its safety evaluated? Can the cause of the loss of control be identified and corrected? What actions would be needed to reduce the likelihood of the failure to recur? Can the product be reprocessed? What actions would be necessary to prevent unsafe product from entering commerce (e.g., can product be diverted to animal food or does the product need to be destroyed)?)
- The severity of the consequences in case of a failure of a control measure (e.g., Is it reasonably likely that unsafe food would be produced as a result of the control measure failure? Is the hazard that could occur reasonably likely to cause serious adverse health consequences or death?)
- Whether the control measure is applied to eliminate or significantly reduce the level of the hazard (e.g., Will the control measure eliminate the hazard, or is the control measure only able to minimize the hazard?)
- Synergistic effects between control measures (e.g., Consider whether one control measure can enhance the efficacy of another control measure. For example, formulation process controls may combine the use of preservatives, acidification, and water activity at levels that individually will not control pathogen growth, but they work together to do so.)

You use your written hazard analysis to design the approaches you will use to control the hazards. The more thorough the hazard analysis, the more targeted your controls will be to ensure hazards are significantly minimized or prevented, and the more effective your food safety program will be in preventing illness or injury to consumers.

In the chapters that follow we address managing food safety hazards through heat treatments, time/temperature control, product formulation, sanitation controls, and food allergen controls. We address supply-chain controls in "Chapter 15 – Supply-Chain Program for Human Food Products."

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