Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration's (FDA or we) on this topic.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

Chapter 5: Application of Preventive Controls and Preventive Control Management Components

Table of Contents

[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 5 that we issued for public comment in August 2016.

5.1 Purpose of this Chapter

The guidance provided in this chapter is intended to help you identify and implement preventive controls, and associated preventive control management components, as a part of your food safety plan. See 21 CFR 117.135 and 117.140. Note that if you determine through your hazard analysis that there are no hazards requiring preventive controls, you must still document that determination in your written hazard analysis (see 21 CFR 117.130(a)(2)). However, you would not need to establish preventive controls and associated preventive control management components.

This chapter provides an overview of the application of preventive controls to significantly minimize or prevent the occurrence of biological, chemical, and physical hazards in finished foods and the food production environment. This chapter also provides an overview of preventive control management components (i.e., monitoring, corrective actions, and corrections, and verification activities (and their associated records)). Chapters 6 through 13 of this guidance provide more detailed examples of the application of preventive controls and associated preventive control management components.

This chapter does not provide all the details needed for complete programs. You have the flexibility to identify and implement preventive controls, and associated preventive control management components, from among all procedures, practices, and processes that are available to you and that would provide assurances that the hazard is controlled (i.e., significantly minimized or prevented).

5.2 Overview of the Application of Preventive Controls for Biological Hazards

Table 5-1 provides examples of the application of preventive controls to significantly minimize or prevent the occurrence of ingredient-related and process-related biological hazards.

Table 5-1 provides general information about the effects of the listed preventive controls but is not intended to imply that a particular preventive control has been validated for control of specific pathogens in specific foods. You are responsible for validating specific preventive controls as appropriate to the nature of the preventive control and its role in your facility's food safety system (see 21 CFR 117.160(a)).

Table 5-1 does not address the application of preventive controls to facility-related hazards. See "Chapter 10 – Sanitation Controls" of this guidance for additional information on the application of sanitation controls to address facility-related hazards.

Table 5-1 Application of Common Preventive Controls to Ingredient-Related and Process-Related Biological Hazards

Preventive Control	Common Procedures, Practices, and Processes	Applicability to Spore-Forming Bacterial Pathogens	Applicability to Vegetative Bacterial Pathogens	Applicability to Bacterial Toxins	Applicability to Parasites
Process Control – Lethal Treatments	Heat (e.g., cooking, roasting, baking)	In general, heat processes will not eliminate spores of bacterial pathogens	Eliminates vegetative cells of pathogens	Will not eliminate preformed toxins of *S. aureus* and *B. cereus* emetic toxin	Heat processing will inactivate parasites found in foods; specific times and temperatures are dependent on the parasite, food matrix, and process used
Process Control – Lethal Treatments	Irradiation, ionizing	The doses approved in the U.S. will not eliminate spores of bacterial pathogens in most foods	Eliminates vegetative cells of pathogens	Will not eliminate preformed toxins of *S. aureus* and *B. cereus* emetic toxin	Limited uses for parasite control; depending on dose, approved uses for foodborne pathogens may inactivate parasites found in foods
Process Control – Lethal Treatments	Antimicrobial Fumigation, e.g., Propylene Oxide (PPO) or Ethylene Oxide (ETO)	Will not eliminate spores of bacterial pathogens	Defined PPO processes have been shown to reduce *Salmonella* by 5 logs in certain foods	Unknown, but unlikely to have an effect on preformed toxins of *S. aureus* and *B. cereus* emetic toxin	Ozone has been found to inactivate select parasites (e.g., *C. parvum* oocysts)

Preventive Control	Common Procedures, Practices, and Processes	Applicability to Spore-Forming Bacterial Pathogens	Applicability to Vegetative Bacterial Pathogens	Applicability to Bacterial Toxins	Applicability to Parasites
Process Control – Lethal Treatments	High Pressure Processing (HPP)	In general, HPP will not eliminate spores of bacterial pathogens (FDA, 2000)	Eliminates vegetative cells of pathogens (FDA, 2000)	Will not eliminate preformed toxins of *S. aureus* and *B. cereus*	• Will eliminate parasitic worms of *Trichinella spiralis* at $\geq$ 200 MPa for 10 min • No infectivity of *Cryptosporidium* oocysts when treated by HPP at $5.5X10^8$ Pa (80,000 psi) for 60 sec in apple and orange juice • Information is lacking on the pressure resistances of other parasites
Process Control – Time / Temperature of Holding	Refrigeration	Used to control growth of sporeforming bacterial pathogens	Depending on the temperature, refrigeration will inhibit growth of many pathogens. However, pathogens such as *L. monocytogenes* and some strains of *B. cereus* may grow at refrigeration temperatures	Will prevent the formation of toxins of *S. aureus*. Depending on the temperature, will prevent formation of *B. cereus* toxins. Will have no effect on preformed toxins	Limited information; generally not applicable to parasites because parasites do not grow in food

Preventive Control	Common Procedures, Practices, and Processes	Applicability to Spore-Forming Bacterial Pathogens	Applicability to Vegetative Bacterial Pathogens	Applicability to Bacterial Toxins	Applicability to Parasites
Process Control – Time / Temperature of Holding	Freezing	Used to control growth of spore forming bacterial pathogens, but the spores will survive freezing well	Freezing prevents growth of vegetative cells of pathogens. Depending on the temperature, the numbers of some pathogens may be reduced over time; however you cannot count on freezing to eliminate pathogens, and many can survive for an extended time	Freezing that prevents growth will prevent formation of toxins of *S. aureus* and *B. cereus* but have no effect on preformed toxins	There are specific schedules of time and temperature shown to inactivate parasites; *Cyclospora* is known to be at least somewhat resistant to freezing because an outbreak occurred attributed to raspberries in cake that was previously frozen at about 26°F (–3.3° C)
Process Control – Formulation	Water activity control	Reducing the water activity (e.g., by adding solutes such as sugar and salt) to 0.92 or below will inhibit outgrowth of spores	Reducing the water activity (e.g., by adding solutes such as sugar and salt) to 0.85 or below will inhibit growth of vegetative cells of pathogens	Water activity that prevents growth will prevent formation of toxins of *S. aureus* and *B. cereus* but have no effect on preformed toxins	Limited information; generally not applicable to parasites because they do not grow in food

Preventive Control	Common Procedures, Practices, and Processes	Applicability to Spore-Forming Bacterial Pathogens	Applicability to Vegetative Bacterial Pathogens	Applicability to Bacterial Toxins	Applicability to Parasites
Process Control – Formulation	Acidification	Lowering the pH by the addition of acid can inhibit spores from germinating, will not eliminate the spores	In, general, you can rely on added acid to prevent growth of vegetative bacterial pathogens, but you cannot rely on added acid to eliminate vegetative cells of bacterial pathogens	A pH that prevents growth will prevent formation of toxins of *S. aureus* and *B. cereus* but have no effect on preformed toxins	No information for use as control in foods
Process Control – Formulation	Adding preservatives	Will not eliminate spores of bacterial pathogens, but can prevent germination of spores of certain species	Various preservative chemicals have specific action against some vegetative cells of bacterial pathogens and/or fungi that prevent growth	Formulations that prevent growth will prevent formation of toxins of *S. aureus* and *B. cereus* but have no effect on preformed toxin	No information for use as control in foods
Process Control – Dehydration	Air drying	Will not eliminate spores of bacterial pathogens, but limits or inhibits outgrowth	While drying may inactivate some pathogens, others (e.g., *Salmonella*) may survive drying for fairly long times	Drying that prevents growth will prevent formation of toxins of *S. aureus* and *B. cereus* but have no effect on preformed toxin	No information on effect on parasites in foods

Preventive Control	Common Procedures, Practices, and Processes	Applicability to Spore-Forming Bacterial Pathogens	Applicability to Vegetative Bacterial Pathogens	Applicability to Bacterial Toxins	Applicability to Parasites
Process Control – Dehydration	Freeze drying	In general, serves to preserve microorganisms, but inhibits outgrowth	In general, serves to preserve microorganisms, but inhibits growth	Drying that prevents growth will prevent formation of toxins of *S. aureus* and *B. cereus* but have no effect on preformed toxin	No information on effect on parasites in foods
Process Control – Dehydration	Spray drying	In general, spores of bacterial pathogens will not be eliminated, but inhibits outgrowth	Some pathogens may survive spray drying depending upon the product formulation. Growth will be inhibited	Drying that prevents growth will prevent formation of toxins of *S. aureus* and *B. cereus* but have no effect on preformed toxin	No information on effect on parasites in foods

Chapters 6 through 9 of this guidance provide specific examples of the application of some of these preventive controls. Table 5-2 lists these chapters and the examples covered in these chapters. Table 5-2 also lists examples of sanitation controls, which are covered in Chapter 10.

Table 5-2 Chapters in this Guidance that Provide Examples of the Application of Common Preventive Controls for Ingredient-Related and Process-Related Biological Hazards

Hazard	Preventive Control	Examples of Preventive Controls	Chapter
Bacterial pathogens that survive the lethal treatment	Process Control – Lethal Treatments	• Cooking of RTE soups (frozen and refrigerated) • Baking of RTE cookies	6
Bacterial pathogens that grow, including those that produce toxin, due to time/ temperature abuse	Process Control – Time / Temperature of Holding	• Refrigeration of fresh fruit salads • Control of temperature during thawing to prevent microbial growth	7
Bacterial pathogens that grow, including those that produce toxin, due to poor formulation control	Process Control - Formulation	• Acidification of prepared vegetable salads • Water activity control in refrigerated cookie dough	8

Hazard	Preventive Control	Examples of Preventive Controls	Chapter
Bacterial pathogens that grow, including those that produce toxin, due to inadequate drying	Process Control – Drying/dehydration	• Drying of milk to produce spray-dried milk powder	9
Bacterial pathogens that contaminate product due to poor sanitation	Sanitation Control – Cleaning / sanitizing food contact surfaces	• Controlling presence of bacterial pathogens in RTE prepared sandwiches by sanitation	10
Recontamination of an RTE product with an environmental pathogen	Sanitation – Prevention of recontamination from the environment	• Use of hygienic zoning as a component of a program for prevention of recontamination of ice cream with environmental pathogens	10

5.3 Overview of the Application of Preventive Controls for Chemical Hazards

5.3.1 Examples of the Application of Preventive Controls for Chemical Hazards

Table 5-3 provides examples of the application of preventive controls to significantly minimize or prevent the occurrence of ingredient-related chemical hazards in finished foods. See "Chapter 12 – Preventive Controls for Chemical Hazards" of this guidance for further examples of the implementation of preventive controls for chemical hazards.

Table 5-3 Examples of the Control of Ingredient-Related Chemical Hazards

Preventive Control	Common Procedures, Practices, and Processes	Examples of Applicability to Chemical Hazards
Supply-Chain Program	Establish and implement a risk-based supply-chain program with supplier approval and verification activities (as a means of ensuring that raw materials and other ingredients are procured from those suppliers that can meet company specifications and have appropriate programs in place)	• Applicability to heavy metals: approved suppliers control arsenic and lead in raw agricultural commodities such as rice and carrots • Applicability to naturally occurring toxins: approved suppliers control growth of mycotoxin-forming fungi in stored raw agricultural commodities that are purchased by the facility as raw materials • Applicability to food and color additives and substances associated with a food intolerance: approved suppliers control presence of or use of identified substances and ensure safe levels are not exceeded
Supply-Chain Program	Conduct verification activities appropriate to the hazard	• Sampling and testing (by supplier or receiving facility) to verify supplier control for chemical hazards such as pesticides, drug residues, heavy metals, and mycotoxins, when a supply-chain-applied control has been applied for such hazards • On-site audit to verify control of food allergens, such as when purchasing roasted almonds from a facility that handles multiple tree nuts
Process Controls	Recipe management procedures as appropriate	Facility programs to control product formulation to ensure that safe levels are not exceeded
Process Controls	Storage conditions	Control of moisture in stored raw agricultural commodities to prevent formation of mold
Process Controls	Physical sorting	Facility processing practices to sort (e.g., based on color, physical damage, or presence of mold) raw agricultural commodities to reduce levels of mycotoxins in processed foods

5.3.2 Considerations Applicable to Radiological Hazards

Contamination of foods by radionuclides (a radiological hazard) is a rare event. The most common way these radionuclides are incorporated into foods is through use of water that contains a radionuclide during the manufacture of a food. For example, in certain locations in the United States, high concentrations of radium-226, radium-228 and uranium have been detected in private wells (Ayotte et al., 200; Focazio et al., 2001). The most relevant information that would lead you to consider and evaluate a specific radiological hazard to determine whether it is a hazard requiring a preventive control would be publicly disseminated information following a particular event, such as contamination arising from accidental release from a

nuclear facility or from damage to a nuclear facility from a natural disaster. For example, in 2011, radioactivity was detected in milk, vegetables and seafood produced in areas neighboring a nuclear power plant damaged during an earthquake and tsunami in Japan. We have issued guidance on levels of concern for radionuclides that could be a known or reasonably foreseeably hazard in certain circumstances, such as after an accident at a nuclear facility (FDA, 2001).

Your hazard analysis does not need to consider sources of radiation used in accordance with a food additive regulation. Such sources are safe for their intended use. As with any other equipment and substances used in the manufacture of food, you must comply with all applicable safety requirements established either under the terms of a food additive regulation or by an authority such as the Occupational Safety and Health Administration. Although the two most likely sources of radiological hazards that you would need to address are water used in the production of foods (as an ingredient or cleaning aid), and accidental contamination of your food product (or its ingredients) from accidental release of radionuclides from a nuclear facility, the PCHF requirements do not limit your responsibilities to these two sources, because we cannot anticipate what might be a source in the future.

5.3.3 Examples of the Control of Food Allergen Hazards

Table 5-4 provides examples of the application of preventive controls to significantly minimize or prevent the occurrence of the ingredient-related and process-related undeclared food allergen hazards within finished foods. See "Chapter 11 – Food Allergen Controls" of this guidance for additional information on the application of food allergen controls.

Table 5-4 Application of Common Preventive Controls to Ingredient-Related and Process-Related Food Allergen Hazards

Preventive Control	Common Procedures, Practices, and Processes	How the Preventive Control Can Significantly Minimize or Prevent Undeclared Food Allergens due to Incorrect Product Label	How the Preventive Control Can Significantly Minimize or Prevent Undeclared Food Allergens due to Cross-Contact
Allergen Control – Labelling	Perform label design and review during product development prior to commercialization and label review for each new batch of labels received.	Label design and review minimize the potential for the label to not identify all of the food allergens present in the food	N/A
Allergen Control – Labelling	Implement procedures for application of correct label to product.	Label application procedures can help minimize the potential for an incorrect label to be applied to an allergen-containing food	N/A

Preventive Control	Common Procedures, Practices, and Processes	How the Preventive Control Can Significantly Minimize or Prevent Undeclared Food Allergens due to Incorrect Product Label	How the Preventive Control Can Significantly Minimize or Prevent Undeclared Food Allergens due to Cross-Contact
Allergen Control – Allergen cross-contact	Identify and mark food allergen-containing ingredients (e.g., by color coding or with food allergen icons) at receiving.	N/A	Clearly identifying food allergens associated with raw materials or other ingredients simplifies handling practices to prevent allergen cross-contact
Allergen Control – Allergen cross-contact	Segregate and store food allergen-containing materials at receiving and warehousing.	N/A	Segregation of different food allergens can minimize the potential for allergen cross-contact during storage
Allergen Control – Allergen Cross-contact	Open and handle food allergen-containing ingredients at separate times / contain by using separate rooms, or by scheduling use of the same rooms at different times.	N/A	Handling food allergens separately can minimize the potential for inadvertent incorporation of a food allergen into a product for which it is not an ingredient
Allergen Control – Allergen Cross-contact	Schedule production of products based on food allergen-containing recipes. Schedule production of products that do not contain food allergens before production of products that do contain food allergens or schedule production of products with a unique food allergen last.	N/A	Production scheduling can minimize the potential for inadvertent incorporation of food allergen into a product for which it is not an ingredient
Allergen Control – Allergen cross-contact	Physically separate processes for products that do not contain food allergens from products that do contain food allergens or separate processes for products that do not contain the same food allergens	N/A	Separating processes containing different food allergens can minimize the potential for inadvertent incorporation of food allergen into a product for which it is not an ingredient
Allergen Control – Allergen cross-contact	Implement production procedures for rework and work-in-process (WIP): using “like into like,” appropriate storage and handling, tracking	N/A	Control of rework can minimize the potential for inadvertent incorporation of food allergen into a product for which it is not an ingredient

Preventive Control	Common Procedures, Practices, and Processes	How the Preventive Control Can Significantly Minimize or Prevent Undeclared Food Allergens due to Incorrect Product Label	How the Preventive Control Can Significantly Minimize or Prevent Undeclared Food Allergens due to Cross-Contact
Sanitation Control – Cleaning food contact surfaces	Use full wet cleaning to remove food allergen residues prior to producing a product that does not contain that food allergen on the same line.	N/A	Cleaning can minimize the presence of food allergen residues, preventing inadvertent incorporation of food allergen into a product for which it is not an ingredient
Sanitation Control – Cross-contact	Use hygienic zoning for physical separation of process operations, including personnel, that involve foods with and without a specific food allergen	N/A	Hygienic zoning can help prevent inadvertent incorporation of food allergen into a product for which it is not an ingredient
Sanitation Control - Cross-contact	Use dedicated cleaning utensils and equipment for removing food allergen residues from food processing equipment	N/A	Use of dedicated cleaning utensils/equipment can prevent transfer of food allergen residues, thereby preventing inadvertent incorporation of food allergen into a product for which it is not an ingredient

5.4 Overview of the Application of Preventive Controls for Physical Hazards

Table 5-5 provides an overview of the application of preventive controls to significantly minimize or prevent the occurrence of physical hazards in finished foods. See "Chapter 13 – Preventive Controls for Physical Hazards" of this guidance for further examples for the implementation of preventive controls for physical hazards.

Table 5-5 Applicability of Preventive Controls to Physical Hazards

Preventive Control Category	Common Procedures, Practices, and Processes	Applicability to Metal Hazards	Applicability to Glass Hazards (Products Packed in Glass)	Applicability to Other Hard/Sharp Physical Hazards
Process Control – Exclusion	Use screens, flotation tanks, riffle board, sifters, magnets, inversion/air to exclude metal and glass	Physically removes metal fragments	Physically removes glass	Physically removes hard plastic, wood, stones

Preventive Control Category	Common Procedures, Practices, and Processes	Applicability to Metal Hazards	Applicability to Glass Hazards (Products Packed in Glass)	Applicability to Other Hard/Sharp Physical Hazards
Process Control – Detection	Use metal or X-ray detectors to detect and divert foods containing metal and glass	Metal and X-ray detectors detect metal pieces, which generally allows for exclusion of foods containing metal	X-ray detectors detect glass pieces, which generally allows for exclusion of foods containing glass	X-rays can often detect hazardous objects such as hard plastic, stones, bones, pits

5.5 Preventive Control Management Components

5.5.1 Overview of Preventive Control Management Components

Preventive control management components include monitoring, corrective actions and corrections, and verification activities (and their associated records). You must apply appropriate preventive control management components by considering the nature of the preventive control and its role in the facility's food safety system to ensure the effectiveness of the preventive control. For example, monitoring may be limited for certain control measures such as preventive maintenance for equipment to prevent metal hazards (although you should have a record that the activity took place). When sanitation controls are required for environmental pathogens, little or no monitoring may be needed when cleaning and sanitation are conducted in accordance with established written protocols. Occasional verification that procedures are being followed may suffice. See 21 CFR 117.140.

5.5.2 Monitoring

You must establish and implement written procedures, including the frequency they are to be performed, for monitoring preventive controls (as appropriate to the nature of the preventive control and its role in your food safety system). See 21 CFR 117.145. Chapters 6 through 13 of this guidance provide examples of the application of preventive controls. Each of these chapters contains a section, "Establish Monitoring Procedures," that provides information about appropriate monitoring procedures for each control strategy example discussed.

To fully describe your monitoring program, the procedures should answer four questions: (1) What will be monitored? (2) How will monitoring be done? (3) How often will monitoring be done (frequency)? and (4) Who will do the monitoring?

What you monitor should be directly related to control of the hazard. For example, for process controls you would monitor parameters to ensure the minimum/maximum values are met. For other preventive controls, you could monitor that the activity has been conducted consistent with a defined procedure.

The frequency of monitoring depends upon the circumstances. Continuous monitoring is always desirable, and in some cases necessary. In other cases, it may not be necessary or practical. You should monitor often enough that the normal variability in the values you are measuring can be determined and a deviation from normal will be detected. This is especially true if these values are typically close to the control values. Even with continuous monitoring, you should periodically check the paper or electronic record of the continuous monitoring to determine whether deviations from the control value have occurred. The frequency of that check should be at least daily.

If a measurement shows that a deviation from the control value has occurred, you should assume that the control value had not been met since the last check in which the value was acceptable. As a result, the greater the time span between measurements, the more products you are putting at risk.

You should specify in the written procedures the position of the employee who will do the monitoring and describe how they are to perform the monitoring procedure. See Chapters 6 through 13 of this guidance for monitoring examples that include "who" and "how."

You must document your monitoring of preventive controls. See 21 CFR 117.145(c)(1). Although, as noted above, continuous monitoring (with associated records) is desirable, in some circumstances the monitoring records may be "exception records" that document loss of control. See 21 CFR 117.145(c)(2).

5.5.3 Corrective Actions and Corrections

You must establish and implement corrective action procedures that would apply if preventive controls are not properly implemented, as appropriate to the nature of the hazard and the nature of the preventive control. These include corrective action procedures that must be taken if you detect the presence of a pathogen or appropriate indicator organism in a ready-to-eat product as a result of product testing or if you detect the presence of an environmental pathogen or appropriate indicator organism through your environmental monitoring activities. See 21 CFR 117.150(a) and (a)(1).

A predetermined corrective action procedure has the following advantages: (1) It provides detailed instructions for an employee to follow in the event of a deviation in applying a preventive control; (2) it can be prepared at a time when an emergency situation is not calling for an immediate decision; and (3) it removes the obligation to reassess the food safety plan in response to a deviation.

Chapters 6 through 13 of this guidance provide examples of the application of preventive controls. Each of these chapters contains a section, "Establish Corrective Action Procedures," that provides information about appropriate corrective action procedures for each control strategy example discussed. An appropriate corrective action procedure must accomplish the following goals: (1) Ensure that the appropriate action is taken to identify and correct the problem that has occurred with the implementation of a preventive control; (2) ensure that the appropriate action is taken when necessary to reduce the likelihood that the problem will recur; (3) ensure that all affected food is evaluated for safety; and (4) ensure that all affected food is prevented from entering into commerce unless an evaluation has determined that the product is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342) or misbranded under 21 section 403(w) of the FD&C Act (21 U.S.C. 343(w)). See 21 CFR 117.150(a)(2).

You must document your corrective actions. See 21 CFR 117.150(d). For example, when documenting a decision that affected product is released into commerce, your documentation should explain how your decision was based on sound evidence that the deviation did not create a food safety hazard. As another example, you should document all product dispositions, including dispositions to reject or destroy the product.

If you have not established a written corrective action procedure for a preventive control, you still must take appropriate corrective actions when an unanticipated food safety problem indicates that a preventive control may not have been properly implemented. See 21 CFR 117.150(b)(1)(i). For example, you would take appropriate corrective actions if you detected a pathogen in a product when your production process should have controlled the pathogen. Although it may not be possible to anticipate all the problems that could happen, corrective actions need to be taken and fully documented when an unanticipated situation occurs. The corrective actions for the unanticipated problems would include standard corrective action procedures (e.g. identify and correct an implementation problem, take steps to reduce the likelihood it will recur, evaluate all implicated product for safety, and prevent adulterated or misbranded product from entering commerce). See 21 CFR 117.150(b)(2)(i). In addition when appropriate you must reanalyze the food safety plan (or the applicable portion of the food safety plan) to determine whether you need to modify the plan. See 21 CFR 117.150(b)(2)(ii).

A correction is an action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure. See the definition of "correction" in 21 CFR 117.3. The term ''correction'' focuses on the first step in a ''corrective action procedure'' (i.e., identify and correct the problem). Corrections may be appropriate instead of corrective actions when minor, isolated problems occur that do not directly impact product safety.

Here is an example of corrections vs. corrective actions. If you observe food residue on "clean" equipment prior to production, corrections would involve re-cleaning and sanitizing the equipment before it is used. Because you observed the food residue prior to production of food, and you corrected the problem in a timely manner, no food is affected and no actions are needed with respect to food. You are not required to record the correction because this isolated incident does not directly impact product safety, and you made the corrections in a timely manner (i.e., before the production starts). On the other hand, if you make an RTE creamed vegetable soup using a continuous heat exchanger and hot-fill process, and after packaging the soup your review of temperature records of the processed soup at the discharge end of the hold tube shows that the soup did not reach the temperature you identified as a critical limit, corrective actions would involve destroying the product, reheating it or sending it to animal food as appropriate,[2] investigating the cause of the problem, and taking the actions needed to reduce the likelihood that the problem will recur based on the root cause of the problem. (Using an automatic flow diversion valve that diverts low-temperature product at the end of the hold tube back to the pre-heat kettle to be re-processed would avoid the need for taking corrective actions on product, although you would still investigate the cause and correct the problem.)

You must document all corrective actions in records that are subject to verification records review. When appropriate, you also must document corrections. See 21 CFR 117.150(d). You are not required to document corrections in records that are subject to verification records

[2] For more information on sending human food to animal food use, refer to Draft Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007, Section III.L (FDA, 2010).

review when the corrections are taken in a timely manner and you identify and correct a minor and isolated problem that does not directly impact product safety. See 21 CFR 117.150(c)(2). However, we recommend that you document corrections such as re-running product through a functioning metal detector when the one used on the production line did not reject the test pieces used to verify that the metal detector was operating correctly, because it provides a record of both the problem and the steps you took to correct the problem. If the problem recurs on a frequent basis, such documentation also can alert you that equipment may need to be repaired or replaced. We also recommend that you record corrections taken when equipment is adjusted because, for example, temperature does not meet an operating limit (although the critical limit has not been violated); such information can be useful to identify trends that indicate equipment repairs may be needed.

The record of corrective actions should include information on the following four elements:

First, document the actions taken to identify and correct the problem with implementation of the preventive control. For example, explain how you identified what went wrong with a process control and how you restored process control.

Second, explain what you did to reduce the likelihood that the problem will recur. Evaluation of historical corrective action records can help to identify recurring problems. When critical limit deviations frequently reoccur, the process and the Food Safety Plan may need reanalysis and modification. A formal process may be needed to manage major changes that need to be implemented. This may include reissuing forms, retraining employees, phasing in changes, managing label information, informing suppliers, and other tasks, depending on the nature of the change.

Third, explain how you evaluated the safety of all affected food. Specific technical expertise may be required for this evaluation, depending on the nature of the deviation.

Fourth, explain what you did with any affected food, including identifying the amount of product involved and disposition of the affected product.

5.5.4 Verification

Chapters 6 through 13 of this guidance provide examples of the application of preventive controls. Each of these chapters contains a section, “Establish Verification Procedures,” that provides information about appropriate verification activities for each control strategy example discussed. The information covers validation of the adequacy of control measure (e.g., process establishment); evidence that monitoring is being conducted as required; evidence that appropriate decisions about corrective actions are being made as required; evidence of verification of the implementation and effectiveness of controls (such as product testing or environmental monitoring when appropriate); calibration of instruments, when appropriate, and review of records. See 21 CFR 117.155, 117.160 and 117.165. When calibration or an accuracy check of a preventive control monitoring instrument shows that the instrument is not accurate, you should evaluate the monitoring records since the last instrument calibration to determine whether the inaccuracy would have contributed to a deviation. For this reason, food safety plans with infrequent calibration or accuracy checks can place more products at risk than those with more frequent checks if a problem with instrument accuracy occurs.

5.5.5 Records

Chapters 6 through 13 of this guidance provide examples of the application of preventive controls. Each of these chapters contains a section, "Establish a Recordkeeping System," that provides information about appropriate records for each control strategy example discussed. Types and frequency of records vary, depending on factors such as the nature of the hazard and the nature of the control measure and its role in the food safety system.

5.6 References

Ayotte, J. D., S. M. Flanagan, and W. S. Morrow. 2007. "Occurrence of Uranium and ^{222}Radon in glacial and bedrock aquifers in the northern United States, 1993-2003." *U.S. Geological Survey Scientific Investigations Report* 2007-5037. Accessed April 18, 2016. http://pubs.usgs.gov/sir/2007/5037/.

Cama, V. A., and Y. R. Ortega. 2014. "*Cyclospora cayetanensis*." In *Encyclopedia of Food Safety*, edited by Motarjemi, Y., Moy, G., Todd, E., Elsevier.

Dawson, D. J. 2005. "Foodborne protozoan parasites." *Int J Food Micro* 103:201-227.

Dawson, D. J., C. M. Samuel, V. Scrannage, and C. J. Atherton. 2004. "Survival of *Cryptosporidium* species in environments relevant to foods and beverages." *J Appl Microbiol* 96 (6).

Deng, M. Q., and D. O. Cliver. 1999. "*Cryptosporidium parvum* studies with dairy products." *Int J Food Micro* 46:113-121.

Dixon, B. R. 2014. "Protozoa: *Cryptosporidium* spp. ." In *Encyclopedia of Food Safety*, edited by Motarjemi, Y., Moy, G., Todd, E., 18-22. Waltham: Academic Press.

Erickson, M. C., and Y. R. Ortega. 2006. "Inactivation of protozoan parasites in food, water, and environmental systems." *J Food Protect* 69:2786-2808.

Fayer, R. 1994. "Effect of high-temperature on infectivity of *Cryptosporidium parvum* oocysts in water." *Appl Environ Microb* 60:2732-2735.

Fayer, R., and T. Nerad. 1996. "Effect of low temperatures on viability of *Cryptosporidium parvum* oocysts." *Appl Environ Microb* 62:1431-1433.

Focazio, M. J., Z. Szabo, T. F. Kraemer, A. H. Mullin, T. H. Barringer, and V. T. dePaul. 2001. "Occurrence of selected radionuclides in ground water used for drinking water in the United States: A targeted reconnaissance survey, 1998." *U.S. Geological Survey Water-Resources Investigations Report* 00-4273. Accessed October 14, 2011. http://pubs.usgs.gov/wri/wri004273/pdf/wri004273.pdf.

Food and Drug Administration (FDA). 2000. "Kinetics of microbial inactivation for alternative food processing technologies - overarching principles: Kinetics and pathogens of concern for all technologies." Accessed May 31, 2016. http://www.fda.gov/Food/FoodScienceResearch/SafePracticesforFoodProcesses/ucm100198.htm.

Food and Drug Administration (FDA). 2005. "CPG Sec. 560.750 Radionucleotides in imported foods - levels of concern." Accessed October 14, 2011. http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm212793.htm.

Food and Drug Administration (FDA). 2010. "Draft Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007," Section III.L. Accessed August 17, 2016. http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm212793.htm.

Friedman, D. E., K. A. Patten, J. B. Rose, and M. C. Barney. 1997. "The potential for *C. parvum* oocyst survival in beverages associated with contaminated tap water." *J Food Safety* 17:125-132.

Gamble, H. R. 2014. *Trichinella spiralis* and other *Trichinella* species. In *Encyclopedia of Food Safety*, edited by Motarjemi, Y., Moy, G., Todd, E., Elsevier.

Harp, J. A., R. Fayer, B. A. Pesch, and G. J. Jackson. 1996. "Effect of pasteurization on infectivity of *Cryptosporidium parvum* oocysts in water and milk." *Appl Environ Microb* 62.

Ho, A. Y., A. S. Lopez, M. G. Eberhart, R. Levenson, B. S. Finkel, and A. J. da Silva. 2002. "Outbreak of cyclosporiasis associated with imported raspberries, Philadelphia, Pennsylvania, 2000." *Emerg Infect Dis* 8:783-788.

Kniel, K. E., S. S. Sumner, D. S. Lindsay, C. R. Hackney, M. D. Pierson, A. M. Zajac, D. A. Golden, and R. Fayer. 2003. "Effect of organic acids and hydrogen peroxide on *Cryptosporidium parvum* viability in fruit juices." *J Food Protect* 66:1650-1657.

Korich, D. G., J. R. Mead, M. S. Madore, N. A. Sinclair, and C. R. Sterling. 1990. "Effects of ozone, chlorine dioxide, chlorine, and monochloramine on *Cryptosporidium parvum* oocyst viability." *Appl Environ Microb* 56 (5):1423-1428.

Mahbubani, M. H., A. K. Bej, M. Perlin, F. W. Schaefer III, W. Jakubowski, and R. M. Atlas. 1991. "Detection of *Giardia* cysts by using the polymerase chain reaction and distinguishing live from dead cysts." *Appl Environ Microb* 57:3456-3461.

Ortega, Y. R. 2013. "Chapter 28: Protozoa." In *Food Microbiology - Fundamentals and Frontiers*, edited by Doyle, M., Buchanan, R. L.

Robertson, L. J., A. T. Campbell, and H. V. Smith. 1992. "Survival of *Cryptosporidium parvum* oocysts under various environmental pressures." *Appl Environ Microb* 58:3494-3500.

Rose, J. B., and T. R. Slifko. 1999. "*Giardia*, *Cryptosporidium*, and *Cyclospora* and their impact on foods: A review." *J Food Prot* 62 (1059-1070).

Slifko, T. R., E. Raghubeer, and J. B. Rose. 2000. "Effect of high hydrostatic pressure on *Cryptosporidium parvum* infectivity." *J Food Prot* 63 (9):1262-7.

Sterling, C. R., and Y. R. Ortega. 1999. "*Cyclospora*: An enigma worth unraveling." *Emerg Infect Dis* 5 (1):48-53.

World Health Organization (WHO). 2004. Guidelines for drinking-water quality. 3rd Edition. Geneva, Switzerland. Accessed May 20, 2016. http://www.who.int/water_sanitation_health/dwq/gdwq3rev/en/ and http://www.who.int/water_sanitation_health/dwq/en/waterforhealth.pdf.