Guide to Minimize Food Safety Hazards of Fresh-cut Produce: Draft Guidance for Industry

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For questions regarding this draft document contact FDA's Technical Assistance Network by submitting your question at http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

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Contains Nonbinding Recommendations

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Guide to Minimize Food Safety Hazards of Fresh-cut Produce: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic.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.

I. Introduction

This guidance is intended for those persons ("you") who are subject to our regulation, in 21 CFR part 117 (part 117), entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk Based Preventive Controls for Human Food" and who manufacture, process, pack, or hold fresh-cut produce. In this guidance, "fresh-cut produce" means any fresh fruit or vegetable or combination thereof that has been physically altered from its whole state after being harvested from the field (e.g., by chopping, dicing, peeling, ricing, shredding, slicing, spiralizing, or tearing) without additional processing (such as blanching or cooking). Fresh-cut produce may or may not undergo a wash or other treatment before being packaged for use by the consumer or a retail food establishment. Fresh-cut produce can be a single commodity or two or more mixed in the same package, such as coleslaw or fruit salads, and sometimes called "ready to use," "pre-cut," or "value added" produce. Fresh-cut produce also does not include produce that has been processed by freezing, cooking, canning, or packing in a juice, syrup, or dressing.

Fresh-cut produce can be ready-to-eat (RTE) or not ready-to-eat (NRTE)[2]. Examples of RTE fresh-cut produce include broccoli florets, cauliflower florets, cut celery stalks, cut melon, peeled baby carrots, riced cauliflower, salad mixes (raw vegetable salads), sectioned grapefruit, shredded cabbage, shredded lettuce, sliced bell peppers, sliced mushrooms, sliced pineapple,

[1] This guidance has been prepared by the Office of Food Safety, Division of Produce Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

[2] Note that our 2008 guidance entitled "Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables" only addressed RTE fresh-cut produce, because it described fresh-cut produce as not requiring additional preparation, processing, or cooking before consumption, with the possible exception of washing or the addition of salad dressing, seasoning, or other accompaniments. This guidance addresses NRTE fresh-cut produce in addition to RTE fresh-cut produce due to changes in the marketplace since we developed the 2008 guidance.

sliced tomatoes, and spiral-cut zucchini squash. Examples of NRTE fresh-cut produce include cubed butternut squash and cubed sweet potatoes.

This guidance is intended for you regardless of whether:

- You are only subject to the current good manufacturing practice requirements for human food in part 117 (CGMP requirements); or

- You are subject to both the CGMP requirements and the requirements for hazard analysis and risk-based preventive controls for human food (the human food preventive controls requirements, or PCHF requirements).

The purpose of this guidance is to help you comply with the CGMP requirements and PCHF requirements of part 117. For additional information on the CGMP requirements and the PCHF requirements, see section II.A. This guidance does not describe all requirements of part 117, but rather highlights those requirements that are most relevant to fresh-cut produce processing establishments. Because fresh-cut produce processing establishments, and the types of fresh-cut produce they produce, are diverse, the recommendations in this guidance will be most useful when you adapt these recommendations to the specific procedures, practices, and processes at your establishment.

This guidance is not intended for farms that only grow, harvest, or pack raw agricultural commodities (RACs), including those farms that grow, harvest, or pack RACs in accordance with our regulation, in 21 CFR part 112 (the produce safety regulation), entitled "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption." However, if you are a farm mixed-type facility (i.e., you are a farm, but also conduct activities outside the farm definition that require you to be registered as a food facility), this guidance applies to your fresh-cut processing activities.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance documents describe our 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 guidance means that something is suggested or recommended, but not specifically required.

II. Background

A. Regulatory Framework

Subparts A, B, and F of part 117 include CGMP requirements for manufacturing, processing, packing and holding human food. In particular, the CGMP requirements in subpart B (entitled Current Good Manufacturing Practice) address topics such as personnel, plant and grounds, equipment and utensils, sanitary operations and facilities, processes and controls, and warehousing and distribution. With few exceptions (such as for farms and activities of 'farm mixed-type facilities' that fall within the definition of farm, and for establishments solely engaged in the holding and/or transportation of one or more RACs), the CGMP requirements in part 117 apply to all persons who manufacture, process, pack, or hold human food, including

fresh-cut produce.[3] See Table 1 for a list of those CGMP requirements, in subpart B, discussed in this guidance.

Table 1.—CGMP Requirements of Subpart B Discussed in this Guidance

Section	Description
117.10	Personnel
117.20	Plant and grounds
117.35	Sanitary operations
117.37	Sanitary facilities and controls
117.40	Equipment and utensils
117.80	Processes and controls
117.93	Warehousing and distribution
117.95	Holding and distribution of human food by-products for use as animal food
117.110	Defect action levels

Subparts A, C, D, E, F, and G of part 117 include the PCHF requirements for hazard analysis and risk-based preventive controls, for preventive control management components (i.e., monitoring, corrective actions and corrections, and verification), and for associated records. With some exceptions (e.g., for "qualified facilities," such as facilities that are a very small business as defined in 21 CFR 117.3), the PCHF requirements apply to any food establishment that is required to register as a food facility under our regulation "Registration of Food Facilities" in 21 CFR part 1, subpart H. See 21 CFR 117.5 for a complete list of exemptions from the PCHF requirements.

This document discusses PCHF requirements that are in subparts C, F, and G. See Table 2 for a list of the PCHF requirements in subparts C, F, and G.

Table 2.—PCHF Requirements in Subparts C, F, and G

Subpart	Section	Description
C	117.126	Food safety plan
C	117.130	Hazard analysis
C	117.135	Preventive controls
C	117.139	Recall plan
C	117.140	Preventive control management components
C	117.145	Monitoring
C	117.150	Corrective actions and corrections
C	117.155	Verification
C	117.160	Validation
C	117.165	Verification of implementation and effectiveness
C	117.170	Reanalysis

[3] Although not specified in part 117, we do not apply the CGMP requirements to restaurants and retail food establishments.

Subpart	Section	Description
C	117.180	Requirements applicable to a preventive controls qualified individual and a qualified auditor
C	117.190	Implementation records required for subpart C
F	117.301 through 117.335	Requirements Applying to Records That Must Be Established and Maintained
G	117.405 through 117.475	Supply-Chain Program

Although this guidance provides specific recommendations for complying with the PCHF requirements when manufacturing, processing, packing, or holding fresh-cut produce, we are developing a separate, comprehensive guidance to help all food facilities that are subject to PCHF requirements – not just fresh-cut processing facilities – comply with the PCHF requirements. See our guidance entitled "Hazard Analysis and Risk-Based Preventive Controls for Human Food," currently available as draft guidance [4](Ref. 1). This document refers to that comprehensive guidance as the PCHF guidance.[5] The PCHF guidance will include separate chapters directed to topics such as conducting a hazard analysis, identifying potential hazards, and preventive controls, including both general recommendations for preventive controls and specific recommendations for certain types of preventive controls (such as time/temperature controls, sanitation controls, and food allergen controls). The PCHF guidance also will include appendices that identify potential hazards for specific foods and provide forms, adapted from forms developed by the Food Safety Preventive Controls Alliance (FSPCA)[6], which you can use to help you document your hazard analysis and preventive controls. This document often refers you to the PCHF guidance rather than repeat the comprehensive guidance that will be included in the PCHF guidance.

See the Glossary in section XX for the following definitions:

- Several terms that are defined in 21 CFR 117.3 and used in this guidance;
- The term "produce" as defined in the produce safety regulation (21 CFR 112.3); and

[4] When finalized, this guidance will represent the current thinking of FDA on this topic.

[5] The PCHF guidance is being developed as a series of chapters. In developing this guidance, we first will issue each chapter as draft guidance (i.e., not for implementation) and request public comment; we then will finalize each chapter after considering and incorporating the public comments as appropriate. The Table of Contents of the PCHF guidance provides the titles of the planned chapters. Over time, the status of each chapter will change from draft guidance to final guidance. For simplicity, in this guidance regarding fresh-cut produce we refer you to "the PCHF guidance," and describe the information that the chapter "will" address, without distinguishing chapters that have not yet issued in draft, chapters that are draft guidance, and chapters that we have finalized.

[6] The FSPCA is a broad-based public-private alliance consisting of key industry, academic, and government stakeholders whose mission is to support safe food production by developing a nationwide core curriculum, training, and outreach programs to assist companies producing human and animal food in complying with FDA Food Safety Modernization Act (FSMA) requirements for hazard analysis and risk-based preventive controls. For additional information about FSPCA, see their website at https://www.ifsh.iit.edu/fspca.

- Some additional terms, not defined in part 117 or the produce safety regulation, that we use in this guidance.

See section XXI for a table of abbreviations commonly used in this guidance.

B. Outbreaks of Foodborne Illness Associated with Fresh-cut Produce

In recent years, the market for fresh-cut produce has expanded dramatically due to consumer demand for fresh, healthy, and convenient foods (Ref. 2). Recent trends, such as spiralized vegetables (e.g., zucchini noodles or "zoodles") will likely continue to increase the popularity of fresh-cut produce in the United States. However, a variety of produce commodities, including fresh-cut varieties, have also been associated with foodborne illness outbreaks. Because many types of fresh-cut produce are RTE foods that consumers eat without cooking that could destroy pathogens, preventive controls to significantly minimize or prevent the contamination of fresh-cut produce with pathogens play a key role in food safety.

FDA compiles and maintains data on reported outbreaks and illnesses associated with FDA-regulated foods. Between 1996 and 2010, produce accounted for 23.3% of the total reported outbreaks and 42.3% of the total outbreak-related illnesses (78 FR 3504 at 3507, January 16, 2013). Both domestic produce and imported produce were identified as vehicles in these outbreaks. Many factors play a role in the contamination of produce with pathogenic microorganisms, including worker health and hygiene, the quality of agricultural water, the use of animal manure and other materials of animal origin as fertilizer, growing and harvesting operations, and equipment and building sanitation (Ref. 3). One example of an outbreak associated with on-farm contamination is the 2006 multistate outbreak of *E. coli* O157:H7 infections associated with consumption of fresh spinach that led to 199 illnesses, 102 hospitalizations, and 3 deaths (Ref. 4). Follow-up investigation related to this outbreak indicated that initial contamination of the spinach occurred on-farm.

Over the last few decades, illnesses linked to contamination of fresh-cut produce with pathogenic microorganisms have been reported in the United States (Ref. 5). Between 1996 and 2010, fresh-cut fruits and vegetables accounted for 16.8% of the total produce-related outbreaks (78 FR 3504 at 3507, January 16, 2013). From 2002 to 2017, there were 39 outbreaks of foodborne illness linked to the consumption of fresh-cut produce, resulting in approximately 3,432 illnesses, 643 hospitalizations and 15 deaths (Ref. 6).

Although produce can become contaminated before it reaches a fresh-cut processing establishment (e.g., at the grower, as was the case in the 2006 outbreak associated with spinach (Ref. 4), or at a packinghouse), the available evidence demonstrates that the practices or conditions at a fresh-cut processing establishment also can lead to contamination of fresh-cut produce. For example, a listeriosis outbreak caused by diced celery that had been contaminated with *Listeria monocytogenes* and then served in chicken salad prepared by a hospital in Texas was linked back to a fresh-cut processing establishment (Ref. 7). Investigators from the Texas State Department of Health and FDA noted structural defects as well as inadequate handling and cleaning of produce at the fresh-cut processing establishment that produced the diced celery. Investigators found the outbreak strain of *L. monocytogenes* in environmental samples collected from floors, surfaces, and equipment in every room of the plant. Environmental samples

collected on four subsequent visits to the establishment detected widespread and continuing presence of the outbreak strain in the plant. For a review of some other examples in which the practices or conditions at a fresh-cut processing establishment have led to contamination of fresh-cut produce, see Ref. 8.

C. Factors That Can Lead to the Contamination of Fresh-cut Produce with Pathogens

Several factors can lead to contamination of fresh-cut produce. For example:

- As discussed in section II.B, produce can be contaminated on-farm (Ref. 4). When incoming produce is contaminated, processing produce into fresh-cut products increases the risk of bacterial growth and contamination by breaking the natural exterior barrier of the produce (Ref. 9). The release of plant cellular fluids when produce is chopped or shredded provides a nutritive medium in which pathogens, if present, can survive or grow (Ref. 9). Thus, if pathogens are present when the surface integrity of the fruit or vegetable is broken, pathogen growth can occur and contamination may spread.

- Handling practices that are common at fresh-cut processing establishments, such as mixing large batches of fresh-cut produce, have the potential to spread contamination across a larger volume of product (Ref. 5).

- During manufacturing/processing or packing, fresh-cut produce can be contaminated by an environmental pathogen such as *L. monocytogenes* or *Salmonella* spp. that is present in the food production environment (Ref. 7).[7]

- The potential for pathogens to survive or grow is increased by the high moisture and nutrient content of fresh-cut fruits and vegetables and by the potential for temperature abuse during processing, storage, transport, and retail display (Ref. 9).

III. How to Apply This Guidance to Your Operations Based on the Regulatory Framework That Applies to Your Food Establishment

In this guidance, we identify CGMP and PCHF requirements that are most relevant to fresh-cut processing establishments, and specific recommendations related to those requirements. CGMPs are sometimes described as "prerequisite programs" that would be in place at a food establishment to support and provide a foundation for preventive-based food safety systems (Ref. 10). The CGMP and PCHF requirements are mutually supportive and reinforcing and, thus, you should consider your CGMPs and the role of those CGMPs in the food safety system as you conduct your hazard analysis and establish and implement preventive controls to address identified hazards. For example:

- The CGMP requirements include requirements for sanitary operations (in 21 CFR 117.35) and for using chemical, microbial, or extraneous-material testing procedures

[7] See the discussion of environmental pathogens in section III.

where necessary to identify sanitation failures or possible allergen cross-contact and food contamination (in 21 CFR 117.80(a)(5)). The PCHF requirements include requirements for sanitation controls (in 21 CFR 117.135(c)(3)) and for environmental monitoring (in 21 CFR 117.165(a)(3)) as a verification[8] if contamination of an RTE food with an environmental pathogen is identified as a hazard requiring a preventive control. Thus, both CGMP and PCHF requirements apply with respect to sanitation operations in your fresh-cut processing establishment and with respect to testing to identify whether sanitation operations are effectively implemented.

- The CGMP requirements include requirements for manufacturing operations, such as requirements to perform steps such as washing, peeling, trimming, cutting, and sorting and inspecting, so as to protect food against allergen cross-contact and against contamination (in 21 CFR 117.80(c)(10)). The PCHF requirements include requirements for process controls (in 21 CFR 117.135(c)(1)).

In this guidance, we provide recommendations for how you can comply with certain CGMP and PCHF requirements during the manufacturing, processing, packing, and holding of fresh-cut produce. When discussing our recommendations for complying with CGMP requirements, we use terms such as "control" or "control measure" rather than the term "preventive control," which is associated with PCHF requirements.

In this guidance, we provide more detailed recommendations for implementing certain requirements of part 117 and fewer recommendations for implementing other requirements that are more self-explanatory. For example, in Appendix 1 we provide an example of a sanitation master schedule that you could use for conducting sanitary operations in accordance with the requirements for sanitary operations in 21 CFR 117.35. However, we do not provide specific recommendations for how to comply with the requirement (in 21 CFR 117.10(a)) that personnel be instructed to report certain health conditions to their supervisors, because this requirement is self-explanatory. Because this guidance does not repeat the full text of all requirements of part 117, you should familiarize yourself with the complete requirements of part 117. You can access them on the Internet at the Electronic Code of Federal Regulations.

Some PCHF requirements that are expressly directed to RTE foods apply to RTE fresh-cut produce. For example, the hazard evaluation required by 21 CFR 117.130 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 (21 CFR 117.130(c)(1)(ii)). The definition of "environmental pathogen" identifies *Listeria monocytogenes* and *Salmonella* spp. as examples of environmental pathogens (21 CFR 117.3). In addition, the PCHF requirements include requirements for environmental monitoring (in 21 CFR 117.165(a)(3)) as a verification of preventive controls if contamination of an RTE food with an environmental pathogen is identified as a hazard requiring a preventive control. For additional information about these requirements, see the PCHF guidance (Ref. 1). For additional

[8] Although not specified in 21 CFR 117.165(a)(3), environmental monitoring as a verification activity is usually a verification of sanitation controls.

information on control of the environmental pathogen *L. monocytogenes* in RTE foods, see our draft guidance for the control of *L. monocytogenes* in RTE foods (the *Listeria* guidance) (Ref. 11).[9]

IV. CGMP Requirements Regarding Personnel (21 CFR 117.10)

The CGMP requirements regarding personnel specify the measures you must take to prevent personnel from contaminating fresh-cut produce, food contact surfaces (FCSs), or food-packaging materials. The primary areas of focus of the CGMP requirements regarding personnel are disease control (21 CFR 117.10(a)) and cleanliness (i.e., hygienic practices) (21 CFR 117.10(b)). Personnel include full-time and part-time employees, temporary or seasonal employees, and contract personnel.

A. Disease Control

The CGMP requirements for disease control specify that any person who, by medical examination or supervisory observation, is shown to have, or appears to have, illness, open lesion, including boils, sores, or infected wounds by which there is a reasonable possibility of food, FCSs, or food-packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (e.g., by an impermeable cover) (21 CFR 117.10(a)). In addition, personnel must be instructed to report certain health conditions to their supervisors (21 CFR 117.10(a)). The principal reason for excluding personnel with such conditions is to prevent foodborne illness from consumption of food that is contaminated with pathogenic microorganisms through transfer of the pathogenic microorganisms from personnel to the food being produced.

Many symptoms (e.g., vomiting, diarrhea, abdominal cramps, fever, and jaundice) associated with illnesses that warrant exclusion from food production operations (particularly communicable illnesses) would be obvious to the affected personnel and symptoms such as lesions often would be obvious to supervisory personnel as well. You should take steps to ensure that all personnel are aware of the importance of reporting applicable illnesses and being excluded from operations or areas of the plant where they could contaminate food, FCSs, or food-packaging materials. One way to ensure that personnel are aware of this responsibility is through the required training in the principles of food hygiene and food safety, which includes the importance of employee health and personal hygiene (21 CFR 117.4). Production workers who are sick could be re-assigned to duties that are unlikely to lead to contamination of food, such as clerical duties. If an office worker who has job duties that include delivering paperwork to the production line is ill, another office worker could deliver the paperwork during the illness.

[9] In January 2017, we issued the draft guidance entitled "Control of *Listeria monocytogenes* in Ready-to-Eat Foods" (Ref. 11) 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.

A mechanic who is ill should not repair equipment with FCSs unless the FCSs will be thoroughly cleaned and sanitized after repair.

Some individuals who are infected do not show symptoms (i.e., they are "asymptomatic"). In many cases, an asymptomatic individual can spread a communicable disease. If neither you nor the individual know that the individual has an asymptomatic infection, it is unlikely that the individual would be excluded from working in operations where the individual could contaminate food, FCSs, or food-packaging materials. If this happens, the hygienic practices required by 21 CFR 117.10(b) (particularly the requirements for handwashing and maintaining gloves) can help reduce the potential for an asymptomatic individual to contaminate food, FCSs, or food-packaging materials. See the discussion of hygienic practices in section IV.B.

Supervisors have an important role in ensuring that employees are aware of, and report, applicable health conditions that warrant exclusion from food production operations and areas of the plant where food is processed or exposed. One way to ensure that supervisors are aware of this responsibility is through the required training in the principles of food hygiene and food safety, which includes the importance of employee health and personal hygiene (21 CFR 117.4). Supervisors should be aware that they should look for any obvious symptoms of an applicable health condition in personnel (e.g., if an employee makes frequent trips to the toilet facilities). Signage and visual aids, such as posters, can also serve to remind employees to report applicable health conditions.

B. Cleanliness (Hygienic Practices)

The CGMP requirements for cleanliness address hygienic practices such as wearing suitable outer garments, washing hands, maintaining gloves, wearing effective hair restraints, storing personal items, and confining activities such as eating food, chewing gum, drinking beverages, and using tobacco to areas other than areas where food may be exposed or where equipment or utensils are washed (21 CFR 117.10(b)). You should refer to 21 CFR 117.10(b) for the complete requirements for cleanliness.

1. Clothing

Your personnel who handle food, FCSs, or food-packaging materials must wear suitable outer garments to protect against allergen cross-contact and against contamination of food, FCSs, or food-packaging materials (21 CFR 117.10(b)(1)). Examples of suitable outer garments include smocks, aprons, coveralls, hair nets, beard guards, and footwear covers. Strategies that you can use to avoid contamination of food, FCSs, or food-packaging materials through outer garments include wearing clothing and footwear that are dedicated for food processing operations, changing clothing and footwear as necessary and appropriate during food processing operations, and replacing outer garments when they become damaged or can otherwise no longer be cleaned.

2. Washing Hands

The CGMP requirements specify that personnel who work in direct contact with food, FCSs, or food-packaging materials must wash their hands at the following times: before starting work, after each absence from the work station, or at any other time when the hands may have become

soiled or contaminated (21 CFR 117.10(b)(3)). Examples of times when hands can become contaminated are using the restroom, touching the nose or mouth (particularly after coughing or sneezing) or other skin, and contacting contaminated surfaces (e.g., unclean equipment, walls, floors, trash, objects (such as hoses, pallets, and the bottom of buckets) that have been in contact with the floor) and tools that do not contact food (e.g., brooms and shovels)). See Appendix 3 for an example of a training aid to instruct personnel on adequate handwashing procedures.

3. Maintaining gloves

The CGMP requirements specify that gloves used in food handling must be maintained in an intact, clean, and sanitary condition (21 CFR 117.10 (b)(5)), but do not specify the types of gloves (e.g., disposable gloves or reusable gloves). Thus, you have flexibility to choose the type of gloves that work best for your operations. You should regularly evaluate the condition of reusable gloves to determine whether they should be cleaned or replaced (e.g., due to holes, tears or cracks). When determining an appropriate frequency for cleaning gloves, you should consider how the ways in which the gloves will be used impact the potential for the gloves to contaminate food, FCSs, and food-packaging materials.

4. Eating, chewing gum, drinking beverages, and using tobacco products

The CGMP requirements specify that personnel must not eat, chew gum, drink beverages, or use tobacco products in an area in which food may be exposed or where equipment or utensils are washed (21 CFR 117.10 (b)(8)). You should confine these activities to designated areas (e.g. break rooms, designated smoking areas, and lunch rooms) and locate them at a sufficient distance from fresh-cut processing operations and FCSs so that spillage of partially consumed food, chewing gum, beverages, and tobacco products do not serve as a potential source of contamination to fresh-cut produce or FCSs. Locating these designated areas near hand-washing facilities may help to facilitate handwashing after consuming these products. Your supervisors should also observe that your personnel follow the required practices and be prepared to address observations of unhygienic practices.

5. Other requirements for cleanliness (hygienic practices)

The CGMP requirements specify that you must take any other necessary precautions to protect against allergen cross-contact and against contamination of food, FCSs, or food-packaging materials with microorganisms or foreign substances (21 CFR 117.10 (b)(9)). We recommend that your procedures for addressing accidents in which personnel are injured include procedures to reduce the potential for bodily fluids to contaminate food, FCSs, or food-packaging materials.

V. CGMP Requirements Regarding Plant and Grounds (21 CFR 117.20)

The CGMP requirements regarding plant and grounds address measures to prevent plant and grounds from contaminating food, FCSs, or food-packaging materials.

A. Grounds

The CGMP requirements regarding the grounds of a food processing plant specify methods for adequately maintaining grounds to protect against the contamination of food. For example:

- If grounds are under the control of the plant's operator, such methods address storage of equipment; removal of litter; maintenance of yards and parking lots; draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests; and operating systems for waste treatment and disposal (21 CFR 117.20(a)(1) through (4)).

- If bordering grounds that are not under the operator's control are not adequately maintained, the operator of the plant must exercise care in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination (21 CFR 117.20(a)(5)).

You should refer to 21 CFR 117.20(a) for the complete requirements.

Examples of steps you can take to comply with the CGMP requirements regarding grounds include:

- Adequately remove debris, unused equipment, and vegetation; and

- Adequately drain grounds.

B. Plant Construction and Design

The CGMP requirements regarding plant construction and design specify that the plant must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (i.e., manufacturing, processing, packing, and holding). For example, the plant must:

- Provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe food (21 CFR 117.20(b)(1));

- Permit the taking of adequate precautions to reduce the potential for allergen cross-contact and for contamination of food, FCSs, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material (21 CFR 117.20(b)(2));

- Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, FCSs, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food, FCSs, or food-packaging materials with clothing or personal contact (21 CFR 117.20(b)(4));

- Provide adequate lighting and ventilation (21 CFR 117.20(b)(5) and (6)); and

- Where necessary, provide adequate screening or other protection against pests (21 CFR 117.20(b)(7)).

You should refer to 21 CFR 117.20(b) for the complete requirements. You also should refer to our *Listeria* guidance (Ref. 11) for specific recommendations on plant construction and design to reduce the potential for contamination of fresh-cut produce with *L. monocytogenes*.

Examples of steps you can take to comply with the CGMP requirements regarding plant construction and design include:

- Locate the doors leading to the outside in an area other than in a processing area;

- Close all exterior doors and entrances when not in use, and ensure an adequate seal when exterior doors and entrances are closed, to prevent entry by pests (Ref. 12);

- Fit floor drains with seals and grates adequate to prevent pest entry;

- Design product areas to have traffic patterns that separate intact RACs and finished product from each other using either linear product flow (intact RACs to finished product) or physical partition (Ref. 11). See Figure 3 in Ref. 13 for an example of product and personnel flow patterns in a fresh-cut processing plant and Appendix 3 in Ref. 11 for an example of air flow in a food processing plant;

- Use positive air pressure in the fresh-cut processing area (Ref. 11 and Ref. 14);

- Use construction material that is smooth (Ref. 15) and easily cleanable, such as stainless steel or plastic whenever practical for constructing food storage and processing areas to reduce the potential for microbial harborage that could lead to contamination of food. Alternatively, when doing so is not practical, give special attention to cleaning these surfaces as part of your sanitary operations;

- Do not construct a floor flume transfer from the produce cooling and packing operation into or across an area housing fresh-cut produce operations whenever practical. If it is not practical to avoid such a floor flume transfer, we recommend that you use floor flumes with caution due to the potential for water aerosol contamination of the room air and nearby equipment surfaces;

- Plumb flume water to a floor drain (rather than to the floor) with a backflow preventer (Ref. 16) if practical to do so. Alternatively, when doing so is not practical, give special attention to standing water (Ref. 11) as part of your sanitary operations;

- Either do not construct trench drains, or equip trench drains for automatic flushing whenever practical, taking care to ensure that automatic flushing does not create aerosols that could contaminate food or FCSs. If you use trench drains and automatic flushing is

not practical, we recommend that you give special attention to the areas around the trench drains during your sanitary operations; and

- When applicable, locate any microbiology laboratory as far away as practical from the processing area, because routine microbiological testing usually involves enrichment procedures that enable microorganisms to multiply before conducting analytical tests to detect them.

During new construction or renovations, you should carefully consider the potential for *L. monocytogenes* to spread to areas in the plant where RTE foods, food contact surfaces, or food-packaging materials will be exposed to the environment. For example, new construction and renovations could cause significant disruption to air patterns, walls, ceilings, or floors that ordinarily act as a barrier to reduce the potential for cross-contamination of food, food contact surfaces, non-food contact surfaces, or food-packaging materials. Actions you should take depend on the type of construction activity and the potential for contamination.

The *Listeria* guidance (Ref. 11) includes comprehensive recommendations for the types of actions that you could take to reduce the potential for *L. monocytogenes* to contaminate food, FCSs, or food-packaging material in certain circumstances. Examples of such recommendations as they would apply to a fresh-cut produce processing establishment include:

- Design and construct the plant so that walls, ceilings, windows, doors, floors, drains, and overhead fixtures (e.g., pipes, air vents, and lights) in areas where fresh-cut produce is processed or exposed are manufactured using materials that will prevent condensate buildup and resist deterioration when exposed to food or cleaning chemicals; when surfaces deteriorate, they can become hard-to-clean and result in contamination with, and harborage of, microorganisms;

- Design and construct the roof so that it drains freely and does not leak;

- Do not place windows that can be opened in areas where fresh-cut produce is processed or exposed (when practical); alternatively, you could use positive air pressure or other mitigation measures in fresh-cut processing areas with such windows; and

- Avoid construction materials made of porous or absorbent materials, such as wood or foam, in areas where fresh-cut produce is processed or exposed and in other wet processing areas in the plant, to reduce the potential for harborage of *Listeria monocytogenes*.

VI. CGMP Requirements Regarding Sanitary Operations (21 CFR 117.35)

The CGMP requirements for sanitary operations address general maintenance, substances used in cleaning and sanitizing, storage of toxic materials, pest control, sanitation of FCSs, sanitation of non-FCSs, and storage and handling of cleaned portable equipment and utensils.

- The CGMP requirements for general maintenance specify that buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition and kept in repair adequate to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and against contamination of food, FCSs, or food-packaging materials (21 CFR 117.35(a)).

- The CGMP requirements for substances used in cleaning and sanitizing and for storage of toxic materials include limitations on the use and storage of toxic materials in a plant where food is processed or exposed (21 CFR 117.35(b)).

- The CGMP requirements for pest control permit the use of pesticides to control pests in the plant only under precautions and restrictions that will protect against the contamination of food, FCSs, and food-packaging materials (21 CFR 117.35(c)).

- The CGMP requirements for sanitation of FCSs specify that all FCSs, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food and specifically address FCSs used for manufacturing/processing, packing, or holding low-moisture food; food contact-surfaces used in wet processing; and single-service articles (21 CFR 117.35(d)).

You should refer to 21 CFR 117.35 for the complete requirements.

Examples of steps you can take to comply with the CGMP requirements regarding sanitary operation are:

- Use a step-wise process for cleaning and sanitizing (e.g., Pre-clean (e.g., dry clean), Pre-rinse, Soap and Scour, Post-Rinse, Prepare for Inspection, Pre-op Inspection, and Sanitize and Assemble) (Ref. 11);

- Establish and implement a preventive maintenance program that is designed to minimize breakdowns and prevent contamination that could occur during repair of equipment. Examples of what a preventive maintenance program could address are schedules for examination and maintenance of equipment such as valves, gaskets, O-rings, pumps, screens, filters, hoists, and chiller plates. (If you establish your preventive maintenance program as a preventive control, you would include a written maintenance program in your food safety plan (21 CFR 117.126(b)(2) and 117.135(b)));

- Clean and sanitize after maintenance repairs (Ref. 11);

- Store chemicals used at the plant in a secure and designated area;

- Review the cleanability of a surface prior to purchase and before installation;

- Align the flow of equipment and tools at the plant with traffic patterns of people or, where applicable, with traffic patterns of tools and equipment used for cleaning and

sanitizing equipment (Ref. 17) before the tools or equipment are used across designated zones;

- Establish adequate controls to maintain sanitary operations during construction; and
- Arrange for pesticides to be applied only by persons who are qualified to do so by education, training, or experience (or a combination thereof).

See Appendix 1 for an example of a master sanitation schedule for general maintenance in your plant. If you use this master sanitation schedule, we recommend that you tailor it to your operations as appropriate. For example, the frequency of cleaning could be more than, or less than, the frequency in the example master sanitation schedule depending on the specific characteristics of your plant and equipment.

See the *Listeria* guidance (Ref. 11) for specific recommendations regarding sanitation programs to control *Listeria monocytogenes.*

VII. CGMP Requirements Regarding Sanitary Facilities and Controls (21 CFR 117.37)

The CGMP requirements regarding sanitary facilities and controls address the water supply, plumbing, toilet and handwashing facilities, and disposal of sewage, rubbish, and offal.

A. Water Supply

The CGMP requirements for the water supply specify that the water supply must be adequate for the operations intended and must be derived from an adequate source. Any water that contacts food, FCSs, or food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils and food-packaging materials, or for employee sanitary facilities (21 CFR 117.37(a)).

Adequate water quality is critical in fresh-cut processing due to the potential for pathogen infiltration into cut or sliced produce and to the absence of a “kill step” (i.e., a processing step lethal to pathogens). To be adequate for use in a fresh-cut processing establishment, the water should be potable.

B. Plumbing

The CGMP requirements specify that plumbing must be of adequate size and design and adequately installed and maintained to provide functionality with respect to: the quantity of water carried throughout the plant; conveyance of sewage and liquid disposable waste from the plant; avoiding the potential for water to be a source of contamination to food, water supplies, equipment, or utensils, or for creating an unsanitary condition; adequate floor drainage; and providing that there be no backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing (21 CFR 117.37(b)).

Examples of steps you can take to prevent water from becoming a source of contamination are:

- Design properly sloping floors to drains (e.g., 1/4 inch per foot) to provide adequate drainage, and seal and keep drains in good repair;
- Design floor drains to prevent the accumulation of water in or around the drains, and make drains accessible for cleaning. This is especially important in areas where floors are subject to a flooding-type of cleaning;
- Construct trench drains for automatic flushing;
- Use solid sanitizers (e.g., blocks or rings of quaternary ammonium compounds) to maintain drains to minimize the potential for them to be a source of contamination;
- Design collection areas for waste stream water to prevent contamination of food and equipment; and
- Design drains with sufficient capacity to be adequate to handle increased water flow due to increased production capacity without drain back-ups.

C. Toilet Facilities

The CGMP requirements for toilet facilities specify that each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, FCSs, or food-packaging materials (21 CFR 117.37(d)).

Examples of steps you can take to prevent toilet facilities from being a potential source of contamination are:

- Provide self-closing doors and/or provide doors that do not open into areas where food is exposed to airborne contamination, except where alternative means have been taken to protect against such contamination (such as double doors or positive air-flow systems);
- Ensure that toilet facilities are constructed and installed appropriately, including with adequate backflow prevention (Ref. 15); and
- Ensure that toilet facilities are maintained and kept in good repair.

D. Hand-Washing Facilities

The CGMP requirements for handwashing facilities specify that each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, FCSs, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature (21 CFR 117.37(e)).

Examples of steps you can take to provide adequate handwashing facilities are:

- Provide handwashing (and, where appropriate, hand-sanitizing) facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands;

- Provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices;

- Design and construct devices or fixtures (such as water control valves – e.g., knee, foot, or elbow faucet controls) to protect against recontamination of clean, sanitized hands;

- Provide adequate supplies of soap, single service towels, and a covered waste receptacle; and

- Ensure that handwashing facilities are maintained, cleaned, and kept in good repair.

E. Disposal of Sewage and Rubbish

The CGMP requirements for sanitary facilities and controls address disposal of sewage (21 CFR 117.37(c)) and storage and disposal of rubbish to minimize the development of odor, minimize the potential for the waste to become an attractant and harborage or breeding place for pests, and protect against contamination of food, FCSs, food-packaging materials, water supplies, and ground surfaces (21 CFR 117.37(f)).

The production of fresh-cut produce generates a large quantity of waste that can serve as food and shelter for pests. We recommend that you take this into account when designing your waste disposal system. We also recommend that you segregate all waste in designated areas, removed from food production areas, to minimize the potential that waste will attract pests to food production areas or will provide a harborage or breeding place for pests in food production areas.

You should refer to 21 CFR 117.37 for the complete requirements.

VIII. CGMP Requirements Regarding Equipment and Utensils (21 CFR 117.40)

The CGMP requirements regarding equipment and utensils address the design, construction, and maintenance of equipment and utensils. For example, the CGMP requirements in 21 CFR 117.40(a)(1) through (3) specify that:

All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be:

- So designed and of such material and workmanship as to be adequately cleanable;

- Adequately maintained to protect against allergen cross-contact and contamination;

- Designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants; and

- Installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.

In addition, the CGMP requirements in 21 CFR 117.40(a)(4) through (6) and (b) specify that:

- FCSs must be corrosion-resistant when in contact with food;
- FCSs must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures;
- FCSs must be maintained to protect food from allergen cross-contact and from being contaminated by any source, including unlawful indirect food additives; and
- Seams on FCSs must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.

You should refer to 21 CFR 117.40 for the complete requirements. Examples of steps you can take to comply with these CGMP requirements are:

- Design equipment and tools with surfaces that are smooth, non-absorbent, sealed, and sloped (e.g., without horizontal edges that would prevent drainage), where feasible, in order to drain freely;
- Cover junctures in FCSs;
- Use an equipment design standard to obtain information to enhance existing or new designs for equipment containing FCSs, such as the sanitary standards inventoried by 3-A Sanitary Standards, Inc.;[10]
- Construct work surfaces such as tables, counters, and cutting boards with stainless steel, and with curved edges, when doing so is practical for your operation. Alternatively, you could give special attention to these surfaces through your sanitation practices (see section VI).
- Sharpen any knives that you use frequently, and replace those knives that are damaged or cannot be maintained in a sanitary condition;
- Inspect cutting blades and belts frequently during processing operations for damage, build-up of food residue, or cleaning needs; and
- Take steps to ensure that ice machines or storage bins do not become a source of contamination of food, FCSs, or food-packaging material by ensuring that they are

[10] 3-A Sanitary Standards, Inc. is a non-profit association (representing equipment manufacturers, processors, regulatory sanitarians and other public health professionals) that has established an inventory of Sanitary Standards and Accepted Practices for dairy and food processing equipment and systems.

constructed of food-grade materials, examining their interiors to ensure that they are clean, avoiding cross-connections in ice machines, and not storing utensils (such as scoops or cups) in the same containers as the ice.

The CGMP requirements specify that holding, conveying, and manufacturing systems must be of a design and construction that enables them to be maintained in an appropriate clean and sanitary condition (21 CFR 117.40(d)). We recommend that any conveyor belts you use be smooth belts rather than grip-tread or textured belts. Smooth conveyor belts are easier to clean than grid-tread or textured belts, which have indentations molded into their surfaces to provide greater adherence between the product and the belt. These indentations can serve as a source of significant bacterial contamination (Ref. 18).

The CGMP requirements specify that each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment (21 CFR 117.40(e)). We recommend that you locate the device you use for this purpose in an area of the refrigerator compartment that is more likely to be warm (e.g. near the door, on the cooler/refrigerator wall). Although doing so may not reflect the temperature within the compartment as a whole, it could provide you with an early warning if there is a problem with the refrigeration compartment and the temperature begins to rise.

Additionally, the CGMP requirements specify that instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food must be accurate and precise and adequately maintained, and adequate in number for their designated uses (21 CFR 117.40(f)). Instruments and controls used to monitor wash water used in the production of fresh-cut produce are particularly relevant to fresh-cut processing establishments. (See the discussion in section XVII of the monitoring of the concentration of free chlorine when using added chlorine in the wash water as a process control in the production of fresh-cut leafy vegetables.)

IX. CGMP Requirements Regarding Processes and Controls (21 CFR 117.80)

A. General Requirements Regarding Processes and Controls

The CGMP requirements regarding processes and controls establish general requirements in 21 CFR 117.80(a). For example, the general CGMP requirements in this section specify that adequate precautions must be taken to ensure that production procedures do not contribute to allergen cross-contact and to contamination from any source and that chemical, microbial, or extraneous-material testing procedures be used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination (21 CFR 117.80(a)(4) and (5)).

You should refer to 21 CFR 117.80(a) for the complete requirements.

Examples of steps you can take to comply with the general CGMP requirements regarding processes and controls are:

- Limit access to the plant and to its processing areas; and
- Restrict the movement of lift trucks, bins, totes, maintenance tools, cleaning implements, clothing, and personnel from receiving and storage zones to processing and packaging areas.

B. Raw Materials and Ingredients

The CGMP requirements establish specific requirements for raw materials and other ingredients in 21 CFR 117.80(b). For example, the CGMP requirements in this section for raw materials and other ingredients address practices such as inspecting, segregating, and handling raw materials and other ingredients as necessary to ascertain that they are clean and suitable for processing into food, and washing or cleaning raw materials as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not cause allergen cross-contact or increase the level of contamination of the food (21 CFR 117.80(b)(1)).

You should refer to 21 CFR 117.80(b) for the complete requirements. Examples of steps you can take to comply with the CGMP requirements regarding raw materials and ingredients are:

- Inspect delivery vehicles carrying fresh produce and food-packaging material for cleanliness;
- Inspect incoming fresh produce for physical hazards (such as animal and plant debris, stones, metal, wood, and other foreign material (e.g., staples from boxes, wire and plastic strapping from boxes, nails, or wires from crates)), either visually or by using detectors (such as metal detectors) and removing such physical hazards; and
- Visually inspect incoming fresh produce for damage, filth, and infestation and either trim it to remove any damaged, rotten, or moldy material or reject it.

C. Manufacturing Operations

The CGMP requirements in 21 CFR 117.80(c) for manufacturing operations address practices such as:

- Maintaining equipment and utensils and food containers in an adequate condition through appropriate cleaning and sanitizing, as necessary, and, insofar as necessary, taking equipment apart for thorough cleaning (21 CFR 117.80(c)(1));
- Conducting all food manufacturing, processing, packing, and holding under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food (21 CFR 117.80(c)(2));

- Holding food that can support the rapid growth of undesirable microorganisms at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding (21 CFR 117.80(c)(3));

- Taking adequate measures to protect against the inclusion of metal or other extraneous material in food (21 CFR 117.80(c)(8)); and

- Performing steps such as washing, peeling, trimming, cutting, and sorting and inspecting so as to protect food against allergen cross-contact and against contamination; food must be protected from contaminants that may drip, drain, or be drawn into the food (21 CFR 117.80(c)(10)).

You should refer to 21 CFR 117.80(c) for the complete requirements.

Examples of steps you can take to comply with the CGMP requirements regarding processes and controls for manufacturing operations are:

- Give special attention, through your sanitary operations, to cleaning procedures for containers (such as wooden bins) that cannot be sanitized;

- Use equipment such as sieves, traps, magnets, and metal detectors to prevent inclusion of metal and extraneous material, or to detect metal if such contamination does occur;

- Wash RACs and processed produce (e.g., using spray or submersion techniques) by procedures such as:

    - Conducting an initial wash to remove dirt and debris where practicable;

    - In wash steps subsequent to the initial wash to remove dirt and debris, using antimicrobial chemicals[11] in wash water to minimize the potential for microbial contamination of processing water and subsequent cross-contamination of RACs and processed produce[12];

[11] See 21 CFR 173.315 (Chemicals used in washing or to assist in the peeling of fruits and vegetables) for examples of antimicrobial chemicals used in wash water to minimize the potential for microbial contamination of processing water and subsequent cross-contamination of RACs and processed produce.

[12] For a comprehensive discussion of factors to consider in the design and implementation of the use of antimicrobial substances as a process control in wash water, see section XVII. Section XVII provides recommendations specific to the design and implementation of adding sodium hypochlorite as an antimicrobial substance to wash water as an example of a process preventive control. Although section XVII is specifically directed to recommendations for compliance with the PCHF requirements for process preventive controls, the information in section XVII can help you to design and implement control measures that add an antimicrobial substance to wash water to comply with CGMP requirements. In addition, the information in section XVII can be generalized to help you design and implement control measures that use antimicrobial substances other than chlorine.

- Where water is reused in a series of processes, arranging water flow to be counter to the movement of produce through different operations, with the result that as produce is further processed, it is exposed to the cleanest water;

- Minimizing the build-up of organic material in wash water - e.g., by filtering recirculating water or using an industrial screen to scoop plant material or other debris from tanks.

- Hold fresh-cut produce under refrigeration conditions even if the fresh-cut produce is not a "time/temperature control for safety" (TCS) food.[13]

X. CGMP Requirements Regarding Warehousing and Distribution (21 CFR 117.93) and Defect Action Levels (21 CFR 117.110)

A. Warehousing and Distribution

The CGMP requirements regarding warehousing and distribution specify that storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container (21 CFR 117.93). As discussed in section IX, we recommend that you hold fresh-cut produce under refrigeration conditions even if the fresh-cut produce is not a TCS food.

The regulation entitled "Sanitary Transportation of Human and Animal Food" (21 CFR part 1, subpart O; the Sanitary Transportation Rule) requires shippers, loaders, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of certain foods in the United States to use sanitary transportation practices that ensure food is not made unsafe during transport. The Sanitary Transportation Rule applies to the receipt and shipment of foods that require temperature control for safety and foods that are not completely enclosed by a container, and therefore applies to the receipt and shipment of many types of fresh-cut produce. Regarding the transportation of fresh-cut produce by motor or rail vehicle in the United States, achieving compliance with the Sanitary Transportation Rule will also ensure compliance with the requirements of 21 CFR 117.93 for transporting food under conditions that will protect against allergen cross-contact and against biological, chemical, and physical contamination of food.

However, compliance with the Sanitary Transportation Rule will not necessarily ensure compliance with the requirement of 21 CFR 117.93 to store food under conditions that will

[13] "TCS food" means a food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation. Due to the wide range of foods subject to part 117, FDA has not yet developed guidance with specific time/temperature recommendations for foods subject to part 117. We note that the FDA Food Code, which has been widely adopted in state laws, recommends holding most TCS foods at 41°F (7°C) or lower (Ref. 19). The discussion of TCS food in Annex 3 of the Food Code lists cut melons, cut tomatoes, and cut leafy greens as examples of TCS food because intrinsic factors (such as pH, water activity, or combinations of pH and water activity) are unable to control bacterial growth once pathogens are exposed to the cellular fluids and nutrients after cutting (Ref. 19).

protect against deterioration of the food and the container, because the Sanitary Transportation Rule does not address food storage. Also, the Sanitary Transportation Rule does not address deterioration of food and food containers during transportation, unless such deterioration creates a condition that causes the food to become unsafe.

B. Defect Action Levels

The CGMP requirements regarding defect action levels (21 CFR 117.110) specify that:

- The manufacturer, processor, packer, and holder of food must utilize at all times quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible; and

- The mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food.

Part 117 defines a defect action level as 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 FD&C Act (21 CFR 117.3). Examples of naturally occurring, unavoidable defects are insects, insect larvae, insect filth, mold, and rodent filth (Ref. 20).

As discussed in the Defect Action Levels Handbook (Ref. 20), we set these action levels because it is economically impractical to grow, harvest, or process raw products that are completely free of non-hazardous, naturally occurring, unavoidable defects. Even if we have an established defect action level for a given defect in a given food commodity, you should not assume that you should only maintain a level of defect in your product that is just below that level. The defect action levels do not represent an average of the defects that occur in food --the averages are actually much lower. The defect action levels represent limits at which we may regard the food product adulterated under section 402(a)(3) of the FD&C Act.

For additional information on naturally occurring, unavoidable defects and defect action levels, see the Defect Levels Handbook (Ref. 20).

XI. CGMP Requirements for Holding and Distribution of Human Food By-Products for Use as Animal Food (21 CFR 117.95)

It is not uncommon for human food manufacturers to send by-products to local farmers or animal food manufacturers for use as animal food. To address this practice, the CGMP requirements in 21 CFR 117.95 specify that:

- Human food by-products held for distribution as animal food without additional manufacturing or processing by the human food processor, as identified in 21 CFR 507.12, must be held under conditions that will protect against contamination, including the following:

  - Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food (21 CFR 117.95(a)(1));

  - Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash (21 CFR 117.95(a)(2)); and

  - During holding, human food by-products for use as animal food must be accurately identified (21 CFR 117.95(a)(3));

- Labeling that identifies the by-product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed (21 CFR 117.95(b)); and

- Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against contamination of the human food by-products for use as animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food (21 CFR 117.95(c)).

FDA is developing guidance on the use of human food by-products in animal food, including diversion of human food products to animal food use. In 2016, FDA issued for public comment a draft guidance for industry entitled "Human Food By-Products For Use As Animal Food" (Ref. 21 and 81 FR 58521, August 25, 2016). FDA issued additional guidance on certain manufacturing processing activities conducted on human food by-products in section III. D. (pages 19-20) of guidance for industry entitled "Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs" (Ref. 22 and 83 FR 598, January 5, 2018). If you intend to distribute human food products for use in animal food, we recommend that you consult these currently available guidance documents.

XII. PCHF Requirements for a Food Safety Plan and for Reanalysis of a Food Safety Plan (21 CFR 117.126 and 117.170)

A. Requirements for a Food Safety Plan

The PCHF requirements for a food safety plan specify that:

- You must prepare, or have prepared, and implement a written food safety plan (21 CFR 117.126(a)(1)); and

- The food safety plan must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals (PCQIs) (21 CFR 117.126(a)(2)).

The written food safety plan must include the following (21 CFR 117.126(b)(1) through (7)):

- The written hazard analysis;
- The written preventive controls;
- The written supply-chain program;
- The written recall plan;
- The written procedures for monitoring the implementation of the preventive controls;
- The written corrective action procedures; and
- The written verification procedures.

The food safety plan is a record that is subject to the recordkeeping requirements of part 117, subpart F (21 CFR 117.126(c)). See part 117, subpart F and section XVIII of this document for information about the recordkeeping requirements.

A food safety plan consists of the primary documents in a preventive controls food safety system that provides a systematic approach to the identification of food safety hazards that must be controlled to prevent or minimize the likelihood of foodborne illness or injury. It contains a collection of written documents that describes activities that ensure the safety of food during manufacturing, processing, packing, and holding. Chapter I of the PCHF guidance (Ref. 1) will provide additional information about the food safety plan.

There is no standardized or mandated format for documenting the food safety plan. However, the FSPCA has developed worksheets to help you do so. Additionally, we have released version 1.0 of our Food Safety Plan Builder, a software program which may be useful in documenting the food safety plan. The detailed information is available on our web page entitled "Food Safety Plan Builder" (Ref. 23).

B. Reanalysis of a Food Safety Plan

The PCHF requirements for reanalysis of a food safety plan specify that:

- You must conduct a reanalysis of the food safety plan as a whole at least once every 3 years (21 CFR 117.170(a)); and
- You must conduct a reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan, in any of the following circumstances (21 CFR 117.170(b):
    - Whenever a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;

- Whenever you become aware of new information about potential hazards associated with the food;

- Whenever appropriate after an unanticipated food safety problem in accordance with 21 CFR 117.150(b); or

- Whenever you find that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective.

The reanalysis must be done or overseen by a preventive controls qualified individual (21 CFR 117.170(e)). A food safety plan that is reanalyzed must be revised if the reanalysis reveals a reasonable potential for a new hazard or a significant increase in a previously identified hazard (21 CFR 117.170(d)). You must validate, as appropriate to the nature of the preventive control and its role in your food safety system, any additional preventive controls needed to address the hazard identified, within timeframes specified in 21 CFR 117.170(c).

XIII. PCHF Requirements for a Hazard Analysis (21 CFR 117.130)

Part 117 defines "hazard" as any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury (21 CFR 117.3) and requires that facilities subject to PCHF requirements conduct a hazard analysis (21 CFR 117.130). The PCHF requirements for hazard analysis specify that:

- You must 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 any hazards requiring a preventive control. The hazard analysis must be written regardless of its outcome (21 CFR 117.130(a));

- The hazard identification must consider known or reasonably foreseeable hazards that include biological, chemical, and physical hazards, as well as known or reasonably foreseeable hazards that may be present in the food because they occur naturally, they may be unintentionally introduced, or they may be intentionally introduced for purposes of economic gain (21 CFR 117.130(b));

- The hazard analysis must include an evaluation of the identified hazards to 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, and 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 (21 CFR 117.130(c)(1)); and

- The hazard evaluation must consider the effect of several factors on the safety of the finished food for the intended consumer (e.g., the formulation of the food; the condition, function, and design of the facility and equipment; raw materials and other ingredients; and intended or reasonably foreseeable use) (21 CFR 117.130(c)(2)).

Appendix 1 of the PCHF guidance (Ref. 1) will provide information on potential biological, chemical, and physical hazards in several food categories. Within Appendix 1 of the PCHF guidance, Tables 1H, 2H, and 3H will provide information about potential biological, chemical, and physical hazards, respectively, in the category "Fruits and Vegetables," including fresh-cut produce. For your convenience, Table 3 summarizes the information presented in the August 2016 draft of the PCHF guidance. Because we could revise this information after considering public comments to the August 2016 draft of Appendix 1 and more recent scientific information, you should check our website for any additions or deletions to Tables 1H, 2H, and 3H after we finalize the PCHF guidance. For example, Appendix 1 in the draft PCHF guidance that we issued for public comment in August 2016 included *Cyclospora* as a potential biological hazard in frozen fruit (such as raspberries, melon, blueberries, sliced strawberries, and tropical fruit) but did not include *Cyclospora* as a potential biological hazard in fresh-cut vegetables or fruits. We are considering including *Cyclospora* as a potential biological hazard in fresh-cut vegetables and fruits in the PCHF guidance, and included *Cyclospora* in Table 3, in light of two outbreaks of foodborne illness associated with consumption of fresh-cut vegetables in 2018 (Ref. 24 and Ref. 25).

Table 3.--Potential Biological, Chemical, and Physical Hazards in Fresh-cut Produce (Adapted from the PCHF guidance (Ref. 1))

Category	Biological hazards	Chemical hazards	Physical hazards	Example Products
Refrigerated fresh-cut vegetables	• *Clostridium botulinum** • Pathogenic *E. coli* • *Salmonella* spp. • *L. monocytogenes* • *Shigella* spp. • *Staphylococcus aureus* • *Giardia lamblia* • *Cyclospora*** • Bacterial growth and/or toxin lack of time/temperature control • Bacterial growth and/or toxin formation due to reduced oxygen packaging • Recontamination with environmental pathogens	Pesticides	Metal	• Leafy greens (Single and Mixed greens that have been chopped or otherwise processed) • Shredded Carrots • Avocado Chunks • Leafy green salad blends • Diced Onions • Cut Tomatoes • Sliced Mushrooms
Refrigerated fresh-cut fruits	• Pathogenic *E. coli* • *Salmonella* spp. • *L. monocytogenes* • *Shigella* spp. • *Cyclospora*** • Bacterial growth and/or toxin lack of time/temperature control • Recontamination with environmental pathogens	• Mycotoxin/ natural toxins • Pesticides	Metal	• Mixed Fruit Salad • Packaged Single Fruits • Cut Melon • Apple Slices • Cut Pineapples • Cut Mango

* You should consider the potential for an enhanced risk from *C. botulinum* for products that are in a reduced oxygen environment.
** Not included in Appendix 1 of the draft PCHF guidance issued for public comment in August 2016.

You should refer to 21 CFR 117.130 for the complete requirements for hazard analysis. The following chapters and appendices in the PCHF guidance (Ref. 1) will provide additional information about conducting a hazard analysis:

- Chapter 2: Conducting a Hazard Analysis;
- Chapter 3: Potential Hazards Associated with the Manufacturing, Processing, Packing, and Holding of Human Food;
- Appendix 1: Potential Hazards for Foods and Processes (Tables 1H, 2H, and 3H); and
- Appendix 2: Food Safety Plan Forms.

Chapter 2 and Appendix 2 of the PCHF guidance (Ref. 1) will discuss worksheets developed by the FSPCA for you to use in conducting a hazard analysis.

XIV. PCHF Requirements for Preventive Controls (21 CFR 117.135)

A. General Information about Preventive Controls

Part 117 defines "preventive controls" as 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 by the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

The PCHF requirements for preventive controls specify that:

- You must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. Preventive controls include controls at critical control points (CCPs) (if there are any CCPs) and controls, other than those at CCPs, that are also appropriate for food safety. Preventive controls must be written (21 CFR 117.135(a) and (b)).
- Preventive controls include process controls, food allergen controls, sanitation controls, supply-chain controls, a recall plan, and any other procedures, practices, and processes (such as hygiene training and other CGMPs) necessary to provide the assurances required by 21 CFR 117.135(a) (21 CFR 117.135(c)).

You should refer to 21 CFR 117.135 for the complete requirements.

We are developing the following chapters and appendices to provide additional information about preventive controls in the PCHF guidance, including information that could be useful to processors of fresh-cut produce (Ref. 1):

- Chapter 4: Preventive Controls;
- Chapter 5: Application of Preventive Controls and Preventive Control Management Components;
- Chapter 10: Sanitation Controls;
- Chapter 11: Food Allergen Controls;
- Chapter 12: Preventive Controls for Chemical Hazards;
- Chapter 13: Preventive Controls for Physical Hazards;
- Chapter 14: Recall Plans;
- Chapter 15: Supply-Chain Program for Human Food Products;
- Chapter 16: Validation of a Process Control;
- Appendix 2: Food Safety Plan Forms;
- Appendix 3: Bacterial Pathogen Growth and Inactivation; and
- Appendix 4: Sanitation and Hygienic Zoning.

We also are developing 4 chapters in the PCHF guidance to target specific types of process controls – i.e., use of heat treatments, time/temperature control, formulation control, and drying/dehydration as process controls. Among these chapters targeting specific types of process controls, the chapter most relevant to a fresh-cut processing operation will be Chapter 7: Use of Time/Temperature as a Process Control.

You should refer to the applicable chapters of the PCHF guidance for comprehensive guidance on preventive controls as these chapters become available. In sections XIV.B through XIV.D of this document, we briefly discuss process controls, food allergen controls, and sanitation controls as those controls could apply to a fresh-cut operation. In section XVI of this document, we discuss supply-chain controls. In section XIV.E of this document, we discuss some types of preventive controls that can be useful to significantly minimize or prevent biological hazards that can be introduced through common routes of contamination.

B. Process Controls

Part 117 specifies requirements for process controls in 21 CFR 117.135(c)(1). Process controls include procedures, practices, and processes to ensure the control of parameters during

operations such as heat processing, acidifying, irradiating, and refrigerating foods. Process controls must include, as appropriate to the nature of the control and its role in your food safety system:

- Parameters associated with the control of the hazard; and
- The maximum or minimum value, or combination of values to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.

See section XVII for a discussion of a process control commonly used in the production of fresh-cut produce – i.e., use of an antimicrobial substance added to wash water.

C. Food Allergen Controls

Part 117 specifies requirements for food allergen controls in 21 CFR 117.135(c)(2). Food allergen controls include procedures, practices, and processes to control food allergens and must include those procedures, practices, and processes employed for:

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

In a fresh-cut operation, allergen controls could be appropriate in foods such as salads and sandwiches, which could contain salad dressing that contains egg or milk or other food allergens (such as tree nuts)).

D. Sanitation Controls

Part 117 specifies requirements for sanitation controls in 21 CFR 117.135(c)(3). Sanitation controls include procedures, practices, and processes to ensure that your facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards, and must include, as appropriate to your facility and the food, procedures, practices, and processes for:

- The cleanliness of FCSs, including food-contact surfaces of utensils and equipment; and
- The prevention of allergen cross-contact and cross-contamination from insanitary objects and from personnel to food, food-packaging material, and other FCSs and from raw product to processed product.

In most cases, RTE fresh-cut produce is exposed to the environment prior to packaging and the packaged RTE fresh-cut produce does not receive a treatment or otherwise include a control measure (such as a formulation lethal to an environmental pathogen) that would significantly minimize an environmental pathogen. In these circumstances, your hazard analysis for RTE

fresh-cut produce must include an evaluation of environmental pathogens (such as *Salmonella* spp. and *L. monocytogenes*) (21 CFR 117.130(c)(1)(ii)).

- If your fresh-cut operation is a wet-processing operation (e.g., if you produce fresh-cut melons or leafy vegetables), and your hazard analysis identifies *L. monocytogenes* as a hazard requiring a preventive control, you should refer to our *Listeria* guidance (Ref. 11) for recommendations for sanitation controls and for environmental monitoring as verification of sanitation controls.

- If your fresh-cut operation is a dry-processing operation (e.g., if you produce chopped nuts), and your hazard analysis identifies *Salmonella* spp. as a hazard requiring a preventive control, you may find it useful to follow industry recommendations for the control of environmental pathogens in low-moisture foods (Ref. 26).

E. Considering Potential Routes of Contamination

As discussed in section II.C, several factors can lead to contamination of fresh-cut produce with pathogens. In developing preventive controls to provide assurance that pathogens will be significantly minimized or prevented, we recommend that you consider these factors. For example:

- You can reduce the potential for incoming produce to be a source of contamination through your supply-chain controls. See section XVI for a discussion of supply-chain controls.

- You can significantly minimize or prevent the spreading of contamination across large volumes of product by adding an antimicrobial substance to water used to wash fresh-cut produce. See section XVII for an example of using an antimicrobial substance added to wash water.

- You can significantly minimize or prevent the potential for contamination of fresh-cut produce by an environmental pathogen such as *L. monocytogenes* or *Salmonella* spp. through sanitation controls. If your fresh-cut operation is a wet-processing operation, see the *Listeria* guidance (Ref. 11) for recommendations for sanitation controls and for environmental monitoring as verification of sanitation controls. If your fresh-cut operation is a dry-processing operation, you may find it useful to follow industry recommendations for the control of environmental pathogens in low-moisture foods (Ref. 26).

- You can significantly minimize or prevent the survival or growth of pathogens during processing, storage, and transport by treating fresh-cut produce as TCS food. Chapter 7: Use of Time/Temperature as a Process Control in the PCHF guidance (Ref. 1) will provide recommendations for TCS food.

XV. PCHF Requirements for Preventive Control Management Components (21 CFR 117.140)

With some exceptions, the PCHF requirements in 21 CFR 117.140 specify that your preventive controls are subject to the following preventive control management components (PC management components) as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in your food safety system:

- Monitoring in accordance with 21 CFR 117.145;
- Corrective actions and corrections in accordance with 21 CFR 117.150; and
- Verification in accordance with 21 CFR 117.155.

The exceptions are for the supply-chain program, which is subject to a subset of the PC management components (specified in 21 CFR 117.140(b)), and for the recall plan, which is not subject to any PC management components (21 CFR 117.140(c)).

You should refer to 21 CFR 117.140 for the complete requirements for PC management components and to 21 CFR 117.3 for definitions of the terms "monitor," "correction," and "verification." Chapter 5 of the PCHF guidance (Ref. 1) will provide additional information about PC Management Components. As with the process control chapters in the PCHF guidance, for this guidance we adapted the Process Control form developed by the FSPCA to present an example of a worksheet that you can use when applying the PC management components to the use of chlorine as a process control in wash water. See Appendix 2 in this guidance for that worksheet.

See section XVII of this document for specific recommendations for how you could apply the PC management components when adding an antimicrobial substance as a process control in wash water.

XVI. PCHF Requirements for a Supply-Chain Program (Part 117, Subpart G) and Example of a Supply-Chain Program in the Production of Fresh-cut Leafy Vegetables

A. Requirements of Subpart G

Subpart G of part 117 requires a receiving facility to establish and implement a risk-based supply-chain program for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control (21 CFR 117.405 (a)(1)). Part 117 defines a "receiving facility" as a facility that is subject to subparts C and G of part 117 and that manufactures/processes a raw material or other ingredient that it receives from a supplier (21 CFR 117.3). Part 117 defines a "supplier" as 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 (21 CFR 117.3).

You are a receiving facility as that term is defined in 21 CFR 117.3. Your suppliers will be the farms that grow the produce that you use in your fresh-cut operations. In many cases, your suppliers will be subject to the produce safety regulation. An exception that is relevant to this guidance is when the RACs that you receive are designated as "rarely consumed raw" in 21 CFR 112.2(a), and therefore exempt from the standards of the produce safety regulation.[14] Examples of RACs that are designated as rarely consumed raw in the produce safety regulation are winter squash, sweet potatoes, and asparagus.

If you are a processor of fresh-cut produce, you are a receiving facility even if you are a "farm mixed-type facility" because your business satisfies the criteria in the "farm" definition in 21 CFR 1.227 for some of the activities that you conduct, but your business also satisfies the definition of "facility" in 21 CFR 1.227 for the manufacturing/processing activities that you conduct in the production of fresh-cut produce.

Subpart G specifies:

- The requirement to establish and implement a supply-chain program (21 CFR 117.405);
- General requirements applicable to a supply-chain program (21 CFR 117.410);
- Responsibilities of the receiving facility (21 CFR 117.415);
- Requirements for using approved suppliers (21 CFR 117.420);
- Requirements for determining appropriate supplier verification activities (including determining the frequency of conducting the activity) (21 CFR 117.425);
- Requirements for conducting supplier verification activities for raw materials and other ingredients (21 CFR 117.430);
- Requirements for an onsite audit (21 CFR 117.435); and
- Requirements for records documenting the supply-chain program (21 CFR 117.475).

You should refer to subpart G for the complete requirements. Chapter 15 of the PCHF guidance (Ref. 1) will contain comprehensive recommendations to help a receiving facility comply with the requirements of subpart G for establishing and implementing a supply-chain program for its suppliers. You should refer to Chapter 15 of the PCHF guidance for those comprehensive recommendations.

[14] See subpart A of the produce safety regulation for additional information about the coverage of the produce safety regulation.

B. Example of Supplier Approval, Receiving and Verification Activities in the Production of Fresh-cut Leafy Vegetables

The purpose of this example is to illustrate how you could establish and implement a supply-chain program for the production of fresh-cut leafy vegetables if you are subject to PCHF requirements. Specifically, in this example we discuss a fresh-cut processing establishment that produces fresh-cut romaine lettuce and receives romaine lettuce from either of two domestic primary production farms that each grow, harvest, and pack a variety of leafy vegetables, including romaine lettuce. The growing, harvesting, and packing activities of the farms are subject to the produce safety regulation. The fresh-cut processing establishment purchases romaine lettuce directly from the farms, without going through a distributor. To comply with the requirements of subpart G, the fresh-cut processing establishment:

- Considers the results of its hazard analysis, which identifies pathogenic bacteria (such as pathogenic *E. coli* and *Salmonella* spp.) as hazards requiring a preventive control. Consumption of fresh-cut romaine lettuce contaminated with such pathogenic bacteria can lead to severe adverse health consequences or death (Ref. 9). For such hazards, the appropriate supplier verification activity is an onsite audit of the supplier, and the audit must be conducted before using the raw material or other ingredient from the supplier and at least annually thereafter in most cases[15] (21 CFR 117.430(b)(1)).

- Conducts sampling and testing of romaine lettuce from each of the farmss under consideration as a supplier as a one-time supplier approval activity to verify that the farm's procedures, processes, and practices during its growing, harvesting, and packing operations minimize the contamination of romaine lettuce.

- Conducts the following activities, before first receiving romaine lettuce from the farm (as supplier approval activities) and on an annual basis thereafter (as ongoing supplier verification activities):[16]

    - An onsite audit, including an assessment of the farm's procedures, processes, and practices during its growing, harvesting, and packing operations as related to compliance with the produce safety regulation (21 CFR 117.430(b)(1)); and

    - A review of FDA's "Firm/Supplier Evaluation Resources" Web page (Ref. 27) on the FSMA Data Search & Information Data Dashboard to consider information relevant to each farm's compliance history, such as whether produce from the farm has been recalled due to food safety concerns (21 CFR 117.410(d)(1)(iii)(C)).

- Establishes and follows written procedures for receiving the romaine lettuce, including:

[15] See 21 CFR 117.430(b)(2) for exceptions to this requirement for an annual onsite audit.

[16] Part 117 provides flexibility for other entities in the supply chain to determine, conduct, or both determine and conduct supplier approval and verification activities, with some limitations. Because the example in this guidance specifies that the fresh-cut operation purchases the romaine lettuce directly from a farm, there are no other entities in the distribution chain, and the fresh-cut operation determines and conducts all supplier approval and verification activities.

- A checklist to document that the incoming romaine lettuce is received only from the two farms that have been approved as suppliers; and

- Procedures for receiving romaine lettuce from other farms, on a temporary basis, when necessary and appropriate, and for reviewing the written results of an appropriate inspection of the temporary suppliers for compliance with the produce safety regulation as an appropriate verification activity before receiving romaine lettuce from those temporary suppliers.

- To comply with 21 CFR 117.475, establishes and maintains records, including:

  - Its written supply-chain program (21 CFR 117.475(c)(1));

  - The names and contact information for each of the farms that it approved as its suppliers (21 CFR 117.475(c)(3));

  - Its written procedures for receiving romaine lettuce from each of the farms that it approved as its suppliers (21 CFR 117.475(c)(4));

  - The checklists documenting that the romaine lettuce was received from approved suppliers (21 CFR 117.475(c)(5));

  - An explanation of the reasons for determining its supplier approval and verification activities (21 CFR 117.475(c)(6));

  - The results of the onsite audit (21 CFR 117.475(c)(7));

  - The results of its annual search of our "Firm/Supplier Evaluation Resources" Web page (Ref. 27) on the FSMA Data Search & Information Data Dashboard for information relevant to supplier compliance (21 CFR 117.475(c)(10)); and

  - When applicable (e.g., when the results of an inspection are substituted for an onsite audit as an appropriate verification activity before receiving romaine lettuce from a temporary supplier), documentation of the results of an appropriate inspection of a farm that supplies romaine lettuce on a temporary basis (21 CFR 117.475(c)(15)).

XVII. Adding Sodium Hypochlorite as an Antimicrobial Substance to Wash Water as an Example of a Process Preventive Control in the Production of Fresh-cut Leafy Vegetables

A. Introduction

The purpose of this example is to illustrate how you could establish and implement a process preventive control and associated PC management components (i.e., monitoring, corrective actions and corrections, and verification activities (and their associated records)) to control biological hazards in wash water used during the production of fresh-cut produce. Specifically, in this example, we discuss a fresh-cut processor that washes fresh-cut romaine lettuce in a

recirculating water flume system with sodium hypochlorite added to wash water. The sodium hypochlorite acts as a source of the antimicrobial substance, hypochlorous acid, which functions as a process preventive control to significantly minimize or prevent the cross-contamination of fresh-cut leafy vegetables with biological hazards during washing.

In this example, the processor washes fresh-cut romaine lettuce of various cut sizes (0.5 inches – 1.5 inches) in a single-stage chilled water flume using water from a municipal source. The processor adds liquid sodium hypochlorite and citric acid using an automated system in a recirculation tank to maintain a minimum free chlorine[17] concentration of 20 ppm (10 ppm is the critical limit) and a pH of 6.0-7.5. Water automatically replenishes in the recirculation tank where particulates are removed by a separating screen. The conveyor feeding the product into the flume system stops automatically if the free chlorine concentration drops below the operating limit of 20 ppm. The processor verifies the free chlorine concentration and pH twice per shift using a titration test kit and a calibrated pH meter, respectively. The processor begins processing with new flume water every 8 hours or daily, whichever occurs first.

In this section, we:

- Use the term "wash water" to mean recirculated (not single-pass) water used to wash and convey fresh-cut leafy vegetables (e.g., flume or wash tanks); and

- Focus the discussion of biological hazards on pathogens – i.e., microorganisms of public health significance. (See the definition of "pathogen" in 21 CFR 117.3.) Examples of pathogens relevant to the production of fresh-cut leafy vegetables are pathogenic *Escherichia coli*, *Salmonella*, and *Listeria monocytogenes*.

See Table 4 for our recommendations if your fresh-cut products or procedures are different from the example we discuss in this section.

Table 4.— Recommendations If Your Fresh-cut Products or Washing Procedures Are Different from the Example

If:	Then You Should Consider …	However, …
You wash fresh-cut produce other than leafy vegetables in a recirculating water flume system	Whether (and, if so, how) you could adapt the recommendations in this section to your operations	N/A
You wash fresh-cut produce using a wash system other than a recirculating water flume system (e.g., a single-pass spray system)	Whether adding an antimicrobial to the wash water could be an appropriate preventive control to significantly minimize pathogens during the washing step and, if so, whether and how you could adapt the recommendations in this section to your operations	The specific recommendations we provide for PC management components (e.g., for validation and monitoring/verification) generally apply only to a recirculating water flume system

[17] "Free chlorine" (sometimes called "free available chlorine" or "active free chlorine") is readily measured using commercially available sensors and is produced when sodium hypochlorite is added to water. Among other things, free chlorine consists of hypochlorite ions and hypochlorous acid.

If:	Then You Should Consider …	However, …
You add an antimicrobial other than sodium hypochlorite to your recirculating water flume system	Whether (and if so, how) you could adapt the recommendations in this section to your operations	N/A
You wash RACs before you process the RACs into fresh-cut produce, using either a recirculating water flume system or another wash system (e.g., a single-pass spray system)	Whether adding an antimicrobial to the wash water could be an appropriate preventive control to significantly minimize pathogens during the washing step and, if so, whether and how you could adapt the recommendations in this section to your operations	The specific recommendations we provide for PC management components (e.g., for validation and monitoring/verification) generally apply only to a recirculating water flume system

B. Considerations to Keep in Mind when Adding an Antimicrobial Substance to Wash Water as a Process Preventive Control

1. Regulatory status of sodium hypochlorite and other substances used to treat wash water in contact with fresh-cut leafy vegetables

Any substance that is reasonably expected to become a component of food because of its intended use in wash water used during the production of fresh-cut produce (e.g., by migrating from the wash water into food) must be lawful under sections 402(a)(2)(C) and 409 of the FD&C Act, e.g., because the substance:

- Is covered by a regulation, listed in 21 CFR, that provides for its safe use;
- Satisfies the criteria (in 21 CFR 170.30) for eligibility for classification as "generally recognized as safe" (GRAS);
- Is the subject of a prior sanction issued by FDA or the U.S. Department of Agriculture prior to September 6, 1958 (section 201(s)(4) of the FD&C Act; see the definition of "prior sanction" in 21 CFR 170.3(l));
- Is covered by a Threshold of Regulation (TOR) exemption in accordance with 21 CFR 170.39; or
- Is covered by an effective Food Contact Substance Notification (FCN) (21 CFR part 170, subpart D).

In this example, we discuss a fresh-cut processor that washes fresh-cut romaine lettuce in a recirculating water flume system with sodium hypochlorite added to wash water. Under our food additive regulation in 21 CFR 173.315, sodium hypochlorite may be safely used to wash fruits and vegetables in an amount no more than the minimum required to accomplish the intended technical effect. The label or labeling of the container of sodium hypochlorite must bear adequate use directions to ensure use in compliance with all provisions of the food additive regulation (21 CFR 173.315(d)(2)). The amount of sodium hypochlorite required to accomplish its intended effect for a particular application generally is determined by a validation study for that application. (See the discussion of validation in section XVII.D.)

Although this example uses sodium hypochlorite as the antimicrobial substance, there are other antimicrobial substances that you could use in place of sodium hypochlorite. For example:

- Our food additive regulation in 21 CFR 173.325(g) authorizes the use of acidified sodium chlorite solutions, produced by mixing an aqueous solution of sodium chlorite with any GRAS acid, as an antimicrobial agent in the water applied to processed leafy vegetables;

- Our food additive regulation in 21 CFR 173.300(b)(2) authorizes the use of chlorine dioxide for washing fruits and vegetables that are not RACs;

- Our Inventory of Effective FCNs lists several FCNs for uses of hypochlorous acid or calcium hypochlorite in process water in contact with fruits and vegetables (available at https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/default.htm);[18] and

- Our food additive regulation in 21 CFR 173.315 lists other substances that we have authorized for use in washing fruits and vegetables under certain conditions specified in that regulation (i.e., polyacrylamide, potassium bromide, sodium n-alkylbenzene-sulfonate, sodium dodecylbenzene-sulfonate, sodium 2 ethyl-hexyl sulfate, and sodium mono- and dimethyl naphthalene sulfonates).

Regardless of which substance you use, you should check the authorizing regulation, FCN, or other documentation (e.g., if you are using a substance on the basis of a conclusion that the use of the substance satisfies GRAS criteria) to identify the applicable conditions for safe use of that substance. For additional information about the lawful use of food additives and GRAS substances, see the information available from our web page entitled "Ingredients and Packaging" (available at https://www.fda.gov/Food/IngredientsPackagingLabeling/default.htm). For additional information about the regulation of antimicrobial substances, including circumstances in which an antimicrobial substance is regulated by the U.S. Environmental Protection Agency as a pesticide chemical, see our guidance entitled "Guidance for Industry: Antimicrobial Food Additives" (Ref. 28.). A decision tree form of that guidance, entitled "Determining Regulatory Authority for Antimicrobial Substances," is available at https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/RegulatoryAuthorityAntimicrobialSubstances/default.htm.

2. What an antimicrobial substance in wash water does and does not do

Adding antimicrobial substances to wash water can help to significantly minimize or prevent pathogen cross-contamination during washing of leafy vegetables and conveying leafy vegetables in water-based systems such as flumes. Importantly, adding antimicrobial substances to wash water does not significantly minimize or prevent pathogens that may require a

[18] Importantly, FCNs are effective only for the manufacturer identified in the Inventory of Effective FCNs and, thus, you would obtain an antimicrobial substance listed in the Inventory of Effective FCNs from the manufacturer listed for that antimicrobial source in the Inventory of Effective FCNs. In other words, if multiple manufacturers produce the same antimicrobial substance as a food contact substance for use in wash water, each manufacturer must obtain its own effective FCN for that source of antimicrobial for use in wash water (21 USC 348(h)(2)(C)).

preventive control at other stages of production, such as pathogens on incoming produce or in the production environment. You should control pathogens on incoming produce through your supply-chain program as discussed in section XVI. You should control pathogens in the production environment through your CGMPs (as discussed in sections IV–XI), and sanitation preventive controls (as discussed in section XIV.D) that are verified with an environmental monitoring program (as discussed in section XIV.D).

3. How characteristics of the wash water can impact the effectiveness of an added antimicrobial substance

The characteristics of your wash water are dynamic in that they are constantly changing during the wash process. These dynamic characteristics can impact the effectiveness of an added antimicrobial substance. Examples of these dynamic characteristics when sodium hypochlorite is added to wash water are pH, organic load, water temperature, product-to-water ratio, rate of water replenishment, and water agitation.

The relative proportion of the most active component of free chlorine, hypochlorous acid, is dependent on pH and temperature; the proportion of hypochlorous acid is greatest at a pH 3 to 7. At low pH (i.e., pH lower than 6.0), you increase the likelihood of toxic chlorine gases forming. Free chlorine is generally more effective at higher temperatures than colder temperatures.

"Organic load" refers to dissolved and suspended solids such as plant particles and exudates. Organic load will accumulate over time in recirculated water and consume free chlorine, thereby reducing its concentration and effectiveness. Factors such as product type, product cut size, product feed rate into the flume system, product-to-water ratio, rate of water replenishment, and water agitation can impact the organic load and, thus, the concentration and effectiveness of the free chlorine in your wash water. As discussed in section XVII.D, the "worst case" conditions for the organic load (i.e., the highest organic load) of your wash water play a role in your validation of the use of sodium hypochlorite added to wash water as a process preventive control.

C. Understand the Potential Hazard

Produce washing systems used in the production of fresh-cut leafy vegetables, if not properly managed, can facilitate the cross-contamination of uncontaminated produce with pathogens that are present on incoming raw leafy vegetables. Cross-contamination of the processed leafy vegetables can result from product-to-product contact, from contaminated particles that accumulate in the water as cut leafy vegetables are washed, or from the water itself (due to pathogens washed off contaminated raw leafy vegetables). Unless the pathogenic microbial load in recirculated water is effectively controlled by the addition of an antimicrobial substance, pathogens can persist in the re-circulated water and, thus, contaminate the next batch of leafy vegetables that is washed.

The survival of pathogens in the wash water, and the potential for cross-contamination of fresh-cut leafy vegetables during processing, depends on a number of factors such as the type of pathogen, the pathogen population size, the effectiveness and concentration of the antimicrobial substance, environmental/operating conditions such as organic load in the water, the pH and temperature of the water, product feed rate into the system, and water agitation. As discussed in

section XVII.D, factors such as these play a role in your validation of the use of sodium hypochlorite added to wash water as a process preventive control.

D. Validation of Sodium Hypochlorite as a Process Preventive Control in Wash Water

With few exceptions, the PCHF requirements specify that you must validate that the preventive controls are adequate to control the hazard as appropriate to the nature of the preventive control and its role in your food safety system. The validation of the preventive controls must be performed (or overseen) by a preventive controls qualified individual (PCQI) (21 CFR 117.160). For the definition of PCQI, see 21 CFR 117.3 and the Glossary in section XX.A.

In this example, sodium hypochlorite added to wash water as a process preventive control is intended to significantly minimize or prevent the contamination of processed leafy vegetables with pathogens during washing. In the following discussion, we describe a hypothetical example of how a fresh-cut leafy green processor validated sodium hypochlorite added to wash water as a process preventive control.

1. Choose the commodity that you will use for validation purposes

If you are validating a substance added to wash water as a process preventive control for multiple leafy vegetable commodities, you may choose a single commodity for the validation study rather than validate the process preventive control on all the commodities. How you choose the commodity depends on the information that you have about the commodity. Because the type and amount of soil on the surface of the commodity will affect the effectiveness of the process preventive control, one way to choose the commodity is to rely on information about the relative organic load associated with those commodities that you process if you have such information (i.e., selecting the commodity known to produce the highest levels of organic load in the water during processing). Another way to choose the commodity is to select the commodity based on its association with outbreaks of foodborne illness, because contamination of fresh-cut produce with pathogens in the wash water has the potential to lead to foodborne illness. In this example, the PCQI chose romaine lettuce because it was the only commodity processed in the system being validated.

2. Identify the target pathogen for the validation study

The target pathogen for validation of a process preventive control is a known or reasonably foreseeable pathogenic contaminant with the greatest resistance to that process control. The target pathogen can be commodity-specific or be based upon information specific to the region in which the produce was grown. In the example of romaine lettuce, the processor's PCQI identified *E. coli* O157:H7 as the target pathogen due to a history of the organism in the region where the suppliers grow the lettuce, the history of outbreaks of *E. coli* O157:H7 infections linked to lettuce, and the severity of illness associated with *E. coli* O157:H7 infection.

3. Scientifically establish the minimum effective concentration of antimicrobial in the wash water

You should scientifically establish the minimum concentration of the active antimicrobial substance (in this example, free chlorine that results after adding sodium hypochlorite) that will be effective as a process preventive control, based either on the published scientific literature or your own scientific study.

If you are conducting your own scientific study, you should determine the minimum effective concentration of your antimicrobial substance under the worst-case conditions using the washing equipment of your processing line, using a nonpathogenic surrogate organism that has similar or more robust survival capabilities under the conditions being evaluated than the target pathogen. Alternatively, you could determine the minimum effective concentration under the worst-case conditions identified for your processing line, using a laboratory-scale or pilot-scale processing line rather than your production processing line, using either a surrogate organism or the target pathogen. Although you should not introduce a pathogen to your production processing line even for a validation study (to eliminate the potential for residual pathogen to contaminate your product), residual pathogen that remains in a laboratory-scale or pilot-scale processing line after a validation study would not affect product, as long as you do not distribute food produced using your laboratory-scale or pilot-scale processing line.

In this example, the PCQI identified a minimum concentration of 10 ppm free chlorine based on a published scientific study of the efficacy of sodium hypochlorite in significantly minimizing *E. coli* O157:H7 cross-contamination during washing of romaine lettuce (Ref. 29). In that study, 10 ppm free chlorine was established as the minimum value for efficacy (i.e., the critical limit). A minimum concentration of 10 ppm free chlorine was also supported by other published scientific studies (Ref. 30 and Ref. 31). In this example, the processing line will stop automatically if the free chlorine concentration drops below a specified concentration, and the PCQI established an operating level of 25 ± 5 ppm free chlorine and an operating limit of 20 ppm free chlorine for when the processing line will stop to limit the potential that the free chlorine concentration would drop below the critical limit of 10 ppm. If your processing line will not stop automatically if the free chlorine concentration drops below a specified concentration, you could establish the same operating level and operating limit, but you would be stopping the system manually.[19]

4. Identify the process parameters that you will use for the validation study

Some features of your processing operation are permanent, such as dimensions of the flume. In this example, the single flume line is 10 feet (3 meters) long by 2.5 feet (0.75 meters) wide. When flowing through the flume, the water is 1.6 feet (0.5 meters) deep; there is only one operating flow rate. Because they do not change, these features are not processing parameters

[19] If you will be stopping the system manually, you should use a continuous monitoring system that records the free chlorine concentration continuously. One option is to use a continuous monitoring system that sounds an alarm if the free chlorine concentration drops below a specified concentration. Another option is to do frequent, manual checks of the record produced by the continuous monitoring system – e.g., every 30 minutes or more frequently based on the results of your validation study.

within the meaning of 21 CFR 117.135(c)(1) and do not need further consideration for the validation study.

Other features of your system are process parameters within the meaning of 21 CFR 117.315(c)(1), and they can be either fixed or variable. For example, a product cut size can be fixed for a particular commodity, and as long as that cut size is never varied, it does not need to be considered further in the validation study. Other process parameters are variable, and the ranges of these parameters that are expected to occur during an acceptable product run must be understood for the validation study. For example, a fresh-cut operation might identify a range of product feed rates for different product commodities but would generally set their feed rate at a fixed point on a given day or batch of product. Other process parameters vary continually during the course of operation (e.g., water replenishment rate and sodium hypochlorite feed rate) and generally stay within a certain range. Other process parameters are set to not deviate outside a set range, such a pH and temperature. These parameters may vary within certain limits. Other features vary but generally change in one continuous direction, such as organic load which continually increases as product is fed into the system.

For each variable process parameter, you should identify the range of values that could occur during processing and select the conditions under which you will perform your validation study. You can design the validation study using either a single operating condition or multiple operating conditions. However, the conditions you should assess in your study should address the reasonably foreseeable conditions that provide the greatest challenge to the effectiveness of the added antimicrobial substance. The conditions under which you perform your validation study will establish the operating conditions that are effective and define the limits for deviations that require corrective actions.

The PCQI determined that there would be variability in free chlorine due to variability in product feed rate and romaine lettuce cut size, each having a direct impact on the accumulation rate and the maximum level of organic load in the flume water. The PCQI conducted a preliminary study and determined that the worst-case operating conditions (i.e., the rate where the organic load in the water accumulated most rapidly and to the highest level) were achieved by setting the speed of the conveyor feeding product into the shredder at the maximum speed used (6,600 pounds/hour) and the smallest product cut size (0.5 inches). Under these operating conditions, during the course of a four-hour study, the PCQI observed that the organic load that accumulated in the water plateaued at a chemical oxygen demand[20] of 2,100 mg O_2/L after two hours of processing. (This plateauing effect is likely a result of the separating screen and automated water replenishment system of this processing line.) During the four hours of processing, the PCQI observed that:

- The temperature and pH of the water stayed within the operational settings (34 – 36°F; pH 6.0 – 7.5); and

[20] "Chemical oxygen demand" is an indirect but quantitative measurement of the amount of organic load in the water.

- The sodium hypochlorite feed rate was variable (i.e., dependent on free chlorine sensor readings).

The PCQI determined that the concentration of free chlorine is the critical factor. Given these conditions for the variable process parameters identified during the preliminary study, what remained for the PCQI to determine was the placement of the sensor used for monitoring the free chlorine concentration. For the purpose of the validation study, the PCQI decided to measure several process parameters (i.e., pH, temperature, and organic load) in addition to free chlorine concentration to fully document the operating conditions of that study.

5. Conduct the validation study

In this example, the output of the validation study is the location where free chlorine concentrations are consistently at the lowest level in the recirculating water system, including during the worst-case conditions. That location is where the processor will place the sensor that measures free chlorine during production. Although the operating level of 25 ± 5 ppm free chlorine is what will be used during normal production of romaine lettuce in this flume line, the PCQI chose to conduct the study at the predetermined critical limit of 10 ppm. The PCQI adapted the validation procedure from a procedure published in the scientific literature (Ref. 30).

The validation trial was repeated three times as follows:

- The wash water system was mapped using calibrated antimicrobial sensors that measured free chlorine by positioning the sensors (as many as practical) in those positions in the water system where the free chlorine was likely to be at the lowest concentration during normal operation. Temperature and pH sensors were added in the same locations as the free chlorine sensors. Chemical oxygen demand (as the measure of organic load) was determined manually from samples collected from the flume tank.

- The system was started with sodium hypochlorite being fed until all free chlorine sensors were reading at 10 ppm free chlorine. The fresh-cut lettuce was then fed into the system at the fastest rate and smallest cut size. It was expected that there would be variability in pH and temperature.

- During the study, the readings from each free chlorine sensor were recorded on a continuous basis. To verify that the operating conditions were as intended, chemical oxygen demand of the flume water was monitored every 30 minutes of the study; pH and temperature were monitored continuously.

- The system was run with product for one hour past the point where the data from the preliminary study demonstrated that the organic load would plateau.

The output of the study was the identification of the sensor location(s) where free chlorine concentrations were consistently at the lowest levels during the course of the three individual trials. The PCQI identified a single position at the end of the flume as the location to place the sensor where it will monitor continuously when product is in the flume.

The conclusions of the validation study are limited to the conditions under which the trials were performed.

E. Establish and Implement Monitoring Procedures

Part 117 requires that, as appropriate to the nature of the preventive control and its role in your food safety system, you establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive control. You must monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed (21 CFR 117.145).

1. What to monitor

In this example, the processor monitors the concentration of free chlorine (minimum of 10 ppm based on the scientific literature, operating limit of 20 ppm). The PCQI determined that it was not necessary to monitor pH or temperature during production because the critical factor is free chlorine, which is monitored continuously, and changes in pH and temperature will be reflected in the concentration of free chlorine.

2. How to monitor and how often to monitor

In this example, an automated sensor that is placed in the location(s) identified as being the mostly likely to have the lowest free chlorine concentration monitors the concentration of free chlorine continuously. The Quality Assurance (QA) Technician checks the reading on the automated sensor twice per shift and records the observed value in the process log.

3. Who performs the monitoring

When a person (rather than a machine) is assigned to perform monitoring, that person must have the education, training, or experience (or a combination of these) necessary to perform the individual's assigned duties (21 CFR 117.4(b)(1)).

In this example, a continuous monitoring free chlorine sensor measures the concentration of free chlorine in the wash water. The QA Technician checks the reading on the automated sensor and records the observed value in the process log.

F. Establish Corrective Action Procedures

Part 117 includes requirements for you to establish and implement corrective action procedures that must be taken if a preventive control is not properly implemented (21 CFR 117.150(a)(1)). The corrective action procedures must identify the steps you will take to ensure that appropriate action is taken to identify and correct a problem; appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur; evaluate all affected food for safety; and prevent all affected food from entering into commerce, if you cannot ensure that the affected food is not adulterated or misbranded under the relevant provisions of the FD&C Act (21 CFR 117.150(a)(2)). However, you do not need to take such corrective actions if you take action in a

timely manner to identify and correct a minor and isolated problem that does not directly impact product safety (i.e., make corrections) (21 CFR 117.150(c)(2)).

Examples of corrective action procedures applicable to use of free chlorine as a process control in wash water include:

- Empty the processing line and discard the product back to the last time the monitored parameters were within the critical limits. The discarded product is either destroyed or diverted to animal food (usually for animals other than pets)[21];
- Clean and sanitize all affected post-wash FCSs;
- The PCQI takes steps to determine (if possible) what caused the free chlorine concentration to drop below the critical limit so that actions can be taken to prevent such occurrences from happening in the future; and
- Replace non-functioning sensor(s), when applicable.

In this example, the conveyor feeding the product into the flume system stops automatically if the free chlorine concentration drops below the operating limit of 20 ppm and the processor makes those adjustments necessary so that the free chlorine concentration again exceeds the operating limit of 20 ppm. Because the adjustment addresses a divergence from an operating limit, without a deviation from a critical limit, the actions taken as a result are not considered to be corrective actions within the meaning of 21 CFR 117.150(a)(2), even though the QA Technician notes all such adjustments in the process log. (See the definition of "adjustment" in the Glossary in section XX.B.) If the concentration of free chlorine drops below the critical limit of 10 ppm, the QA Technician takes corrective actions and notes that deviation from the critical limit as an exception record in the process log.

G. Determine Verification Procedures

Part 117 requires that verification activities include, as appropriate to the nature of the preventive control and its role in your food safety system: (1) Validation; (2) Verification that monitoring is being conducted; (3) Verification that appropriate decisions about corrective actions are being made; (4) Verification of implementation and effectiveness; and (5) Reanalysis (21 CFR 117.155). For a discussion of validating sodium hypochlorite added to wash water as a process preventive control, see section XVII.D.

Part 117 also requires that you verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so you must

[21] As discussed in section XI, FDA is developing guidance on the use of human food by-products in animal food, including diversion of human food products to animal food use (Ref. 21). FDA issued additional guidance on certain manufacturing processing activities conducted on human food by-products in section III. D. (pages 19-20) of guidance for industry entitled "Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs" (Ref. 22 and 83 FR 598, January 5, 2018). In determining whether it is appropriate to divert a food product to animal food use, we recommend that you consult these currently available guidance documents.

conduct activities that include the following, as appropriate to your facility, the food, and the nature of the preventive control and its role in your food safety system:

- Calibration of process monitoring instruments and verification instruments (or checking them for accuracy) (21 CFR 117.165(a)(1));

- Product testing, for a pathogen (or appropriate indicator organism) or other hazard (21 CFR 117.165(a)(2));

- Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples (21 CFR 117.165(a)(3)); and

- Review of certain records by (or under the oversight of) a PCQI, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions (21 CFR 117.165(a)(4)).

Part 117 also requires, as appropriate to your facility, the food, the nature of the preventive control, and the role of the preventive control in your food safety system, that you establish and implement written procedures for: (1) The method and frequency of calibrating process monitoring instruments and verification instruments (or checking them for accuracy); (2) Product testing; and (3) Environmental monitoring (21 CFR 117.165(b)).

In this example, the PCQI determined that the verification activities for free chlorine as a process preventive control are as follows:

- On a weekly basis, a QA Technician checks the accuracy of sensors used for monitoring free chlorine concentration and, if not accurate, has them recalibrated or replaced if they cannot be recalibrated;

- Twice per shift, the QA Technician verifies the free chlorine concentration using a titration test kit and records the results in the process log;

- Within a week of their creation, the PCQI reviews calibration records and initials and dates the records to document that verification review;

- Within a week of their creation, the PCQI reviews process logs (sometimes called “batch records”) documenting the sensor readings observed by the QA Technician and the results of the verification titration tests for free chlorine and initials and dates the records to document that verification review; and

- Within a week of a problem requiring a corrective action, the PCQI reviews the corrective action records and initials and dates the records to document that verification review.

We have previously discussed the limitations of product testing as verification of preventive controls (see 78 FR 3646 at 3819–3820, January 16, 2013 and Responses 516 and 517, 55908 at 56059 - 56061, September 17, 2015).

This example does not discuss verification activities that are not directly related to free chlorine as a process control in wash water. For example, this example does not discuss environmental monitoring for an environmental pathogen as verification of sanitation controls. Likewise, this example does not discuss corrective action procedures that could be associated with such verification activities. For additional information on environmental monitoring for an environmental pathogen as verification of sanitation controls, and corrective action procedures that could be associated with such verification activities, see our *Listeria* guidance (Ref. 11) and Chapter 10 in the PCHF guidance (Ref. 1).

H. Establish and Maintain Records

Part 117 requires that you document the preventive control management components as follows: (1) The monitoring of preventive controls in records that are subject to verification and records review; (2) all corrective actions (and, when appropriate, corrections) in records that are subject to verification and records review; and (3) all verification activities (21 CFR 117.145(b)-(c), 117.150(d), and 117.155(b)).

In this example, the fresh-cut processing establishment maintains the following records applicable to the use of sodium hypochlorite added to wash water as a process preventive control:

- The scientific publications that identified 10 ppm as the minimum concentration of free chlorine to be effective as a process preventive control;
- The results of the validation study; and
- The following records that are initialed and dated by the PCQI to document review of the records:
    - Records of accuracy checks and calibration records for monitoring/measuring devices;
    - Process logs documenting free chlorine concentrations as observed by the QA Technician from the readings on the automated sensor;
    - Free chlorine titration test records;
    - Corrective action records; and
    - Records of any other verification activities conducted.

I. Summary Process Control Chart for Adding Sodium Hypochlorite as an Antimicrobial Substance to Wash Water as an Example of a Process Preventive Control in the Production of Fresh-cut Leafy Vegetables

See Appendix 2 for a summary of the application of PC management components for the example of adding sodium hypochlorite to wash water as a process preventive control in the production of a fresh-cut leafy vegetables using an adaptation of the FSPCA's Process Control Form (Form 2-C (Modified) from Appendix 2 of the PCHF guidance (Ref. 1)).

XVIII. Requirements Applying to Records That Must Be Established and Maintained (Part 117, subpart F)

Subpart F of part 117 establishes requirements applying to required records, including:

- General requirements, such as for records to be accurate, indelible, and legible; contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities; be created concurrently with performance of the activity documented; include the date and, when appropriate, the time of the activity documented; and include the signature or initials of the person performing the activity (21 CFR 117.305);

- Requirements for the food safety plan to be signed by the owner, operator, or agent in charge of the facility upon initial completion and upon any modification (21 CFR 117.310);

- Record retention requirements (21 CFR 117.315);

- Requirements for official review (21 CFR 117.320); and

- Provisions for use of existing records (21 CFR 117.330).

You should refer to part 117, subpart F for the complete requirements.

Because 21 CFR 117.305(c) specifies that records must be indelible, you should not erase a mistake or obscure a mistake by scratching it out or using liquid correction fluid.

As an example of how to record an "actual value," when monitoring temperature you should record the actual temperature that you measure (e.g., 37°F) rather than simply state whether the measured temperature was within the acceptable operating range (e.g., "< 41°F"). As another example, when monitoring the concentration of free chlorine in wash water, you should record the actual concentration observed (e.g., 12 ppm) rather simply state whether the measured free chlorine was within the acceptable operating range (e.g., > 20 ppm).

XIX. Training

A. Training Requirements Specified in Part 117, Subpart A

Part 117 specifies that each individual (including temporary and seasonal personnel) engaged in manufacturing, processing, packing, or holding food or in the supervision thereof must:

- Be a qualified individual, 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 (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 operation, and the individual's assigned duties (21 CFR 117.4(b)(2)).

Part 117 also specifies 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 (21 CFR 117.4(c)).

You should refer to 21 CFR 117.4(b) and (c) for the complete requirements.

B. Required Training in the Principles of Food Hygiene and Food Safety

We recommend that your training in the principles of food hygiene and food safety address the following topics:

- The symptoms (e.g., vomiting, diarrhea, open lesions) of a health condition that presents a reasonable possibility of contamination of food, FCSs, or food-packaging materials and the individual responsibility of all personnel to report such a health condition to supervisory personnel;

- The hygienic practices required by the CGMPs and the role of these hygienic practices as applied in your plant in the production of safe food, with an emphasis on the requirement to wash hands before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated;

- Sources of foodborne pathogens (e.g., pathogens on incoming produce; humans and their waste; animals and their waste);

- Routes of contamination (e.g., pests that may contaminate fresh-cut produce with their excreta if they are not excluded from the produce; a worker with an open wound who handles fresh-cut produce, FCSs, or food-packaging materials; and the potential for cross-contamination (e.g., for contaminants on unclean equipment to transfer to FCSs that have already been cleaned or already are in use for production));

- How to recognize raw or processed produce that may have become contaminated;

- Preventive measures (i.e., taking measures to prevent or minimize contamination at those points where potential routes of contamination exist); and

- Corrective measures (e.g., the types of steps you will take to identify and correct problems, reduce the likelihood that a problem will recur, evaluate affected fresh-cut produce for safety, and prevent fresh-cut produce from entering into commerce if you cannot ensure that it is not adulterated under section 402 of the FD&C Act).

C. Examples of Training Topics Appropriate to Assigned Duties

Part 117 provides flexibility for personnel to be qualified by a combination of education, training, and experience. The specific knowledge, skills, and abilities that personnel need to be a qualified individual to perform their assigned duties depend on the activities that they will conduct. See Table 5 for examples of training topics that could be appropriate for an individual's assigned duties.

Table 5.--Examples of Training Topics Appropriate to an Individual's Assigned Duties

Personnel Function	Training Topics
Purchasing	Awareness of your supply-chain program requirements and the role of those requirements as a preventive control
Receiving	Procedures for receipt, handling, and storage of raw produce to ensure that raw produce is appropriately stored before use in production
Production operations	The control measures employed during production, including the preventive measures, monitoring and verification activities, corrective actions, and records applicable to each employee's position
Maintenance	Measures to prevent contamination of food and FCSs during maintenance operations
Cleaning operations	The principles and methods required for effective cleaning and sanitizing, especially as those methods relate to food safety; How to properly disassemble and reassemble produce processing equipment so that thorough cleaning and sanitation of that equipment can take place; The proper use of sanitizing agents (sanitizers), and the storage of chemicals used for cleaning and sanitizing; and Specific steps for cleaning and sanitizing equipment and areas of the plant.
Trash removal	The potential for cross-contamination when personnel transition from handling trash and waste containers to handling raw and processed produce and FCSs

D. Delivery of Training

You have flexibility to design and deliver training in a manner that suits your operations and enables your personnel to understand why food hygiene and food safety practices are important, what you expect of them, and when and how they should perform specific tasks. For example, you have flexibility with respect to:

- The method of delivery – e.g., classroom training, online training, or hands-on training;

- The time allotted to a training session – e.g., short training sessions on specific topics or longer training sessions covering multiple training topics;

- Supporting audiovisual materials – e.g., pictures, graphics, and portable visual aids used in specific training, and signs posted throughout the plant as a reminder of food hygiene and food safety practices on an ongoing basis; and

- How to effectively communicate training to all personnel regardless of language – e.g., through use of multi-lingual signs.

See Appendix 3 for an example of a training aid that could be used to instruct personnel on the proper technique to use in washing hands.

See Appendix 4 for an example of a training aid that could be used to instruct personnel with responsibility for cleaning and sanitizing equipment and areas of the plant.

For additional training resources, see the FSPCA website at https://www.ifsh.iit.edu/fspca.

E. Records of Training

You must establish and maintain records that document the required training in the principles of food hygiene and food safety (21 CFR 117.4(d)). For more information about establishing and maintaining records, see section XVIII.

XX. Glossary of Terms Used in This Guidance

A. Terms Defined in 21 CFR part 117

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

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

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

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

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 FD&C 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 FD&C Act, in accordance with the requirements of 21 CFR part 1, subpart H.

Food: Food as defined in section 201(f) of the FD&C Act and includes raw materials and ingredients.

Food allergen: A major food allergen as defined in section 201(qq) of the FD&C Act.[22]

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

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

Hazard requiring a preventive control: A known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls) establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility and the nature of the preventive control and its role in the facility's food safety system.

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

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

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

[22] Section 201(qq) of the FD&C Act defines the term ''major food allergen'' 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, and soybeans, or a food ingredient that contains protein derived from one of these foods, with certain exceptions with respect to highly refined oils.

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

Pathogen: A microorganism of public health significance.

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

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, packing, 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 part 117 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 21 CFR part 1, subpart M.

Qualified facility: A 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) that is a very small business, 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 part 117) 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 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.

Raw agricultural commodity (RAC): Has the meaning in section 201(r) of the FD&C Act.[23]

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 part 117 and that manufactures/processes a raw material or other ingredient that it receives from a supplier.

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.

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.

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

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

Very small business: 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).

B. Terms Defined in 21 CFR part 112

Produce: Any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the

[23] Section 201(r) of the FD&C Act defines the term "raw agricultural commodity" to mean 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.

harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (*e.g.*, cotton seed, flax seed, rapeseed, soybean, and sunflower seed).

C. Terms Defined for Use in This Guidance

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

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

Fresh-cut produce: Any fresh fruit or vegetable or combination thereof that has been physically altered from its whole state after being harvested from the field (e.g., by chopping, dicing, peeling, ricing, shredding, slicing, spiralizing, or tearing) without additional processing (such as blanching or cooking).

Infiltration: Movement of water containing pathogenic microorganisms from the surface of produce into the internal tissues of the produce.

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

Preventive control management components (PC management components): Monitoring, corrective actions and corrections, and verification (with associated records) as required by 21 CFR 117.140.

Target pathogen: A known or reasonably foreseeable pathogenic contaminant with the greatest resistance to a process control that is being validated.

XXI. Abbreviations Used in This Document

Abbreviation	What It Means
CFR	Code of Federal Regulations
CGMP	Current good manufacturing practice
FCN	Food Contact Substance Notification

Abbreviation	What It Means
FCS	Food-contact surface
FDA	U.S. Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FSPCA	Food Safety Preventive Controls Alliance
HACCP	Hazard Analysis and Critical Control Point
N/A	Not applicable
NRTE	Not ready-to-eat
Part 117	Our regulation, established in 21 CFR 117, entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food"
PCHF	Preventive Controls for Human Food
PCHF requirements, human food preventive controls requirements	Requirements, in subparts A, C, D, E, F, and G of 21 CFR part 117, to establish and implement hazard analysis and risk-based preventive controls for human food
PC management components	Monitoring, corrective actions and corrections, and verification (with associated records) as required by 21 CFR 117.140
Produce safety regulation	Our regulation, established in 21 CFR part 112, entitled "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption"
QA	Quality Assurance
RAC	Raw agricultural commodity
RTE	Ready-to-eat
TCS	Time/temperature control for safety
TCS food	A food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation.

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Appendix 1. Example of a Sanitation Master Schedule

The table in this Appendix is an example of a Sanitation Master Schedule for periodic infrastructure cleaning and periodic equipment cleaning. For each area to be cleaned, the example Master Sanitation Schedule lists the cleaning method, the tools used, the cleaning and sanitizing materials, and the frequency of cleaning and sanitizing. We developed this example sanitation master schedule from publications in the scientific literature (Ref. 32 through Ref. 36), publicly availably documents from academic institutions (Ref. 37 and Ref. 38), and our *Listeria* guidance (Ref. 11).

The table in this Appendix is a resource for you to see at a glance what a Sanitation Master Schedule could address; how certain methods, tools, and cleaning and sanitizing materials could be used in specific areas of your plant; and how the frequency of cleaning and sanitizing could vary depending on the area. You have flexibility to use different methods, tools, cleaning and sanitizing materials, and frequency of cleaning.

In selecting products for your sanitation program, you should carefully review the product label and other information from the manufacturer to determine whether the product is intended for use as a cleaning compound or as a sanitizer. One way to distinguish a cleaning compound from a sanitizer is to look for information about the effectiveness of the product against specific microorganisms. The oversight by the U.S. Environmental Protection Agency (EPA) of sanitizers used for FCSs and non-FCSs includes a registration process in which the label of the EPA-registered product lists the microorganisms for which the sanitizer is effective.

When selecting a cleaning compound, you should consider the manufacturer's information regarding the compatibility of the cleaning compound with the objects on which the compound will be used.

When selecting a sanitizer, you should consider the manufacturer's information regarding:

- The intended use of the sanitizer– e.g., for use on FCSs, non FCSs, or both;
- The compatibility of the sanitizer with the objects on which the sanitizer will be used;
- The impact of soil on the sanitizer efficacy;
- The ability of the sanitizer to effectively penetrate the extracellular material of the biofilm; and
- The efficacy of the sanitizer:
    - In significantly minimizing pathogens that are reasonably foreseeable for your food products; and
    - Under your conditions of use (e.g., concentration, temperature, pH, and water hardness).

Example of a Sanitation Master Schedule

Area	Cleaning/Sanitation Method	Tools	Cleaning and Sanitizing Materials	Frequency
Walls	Foam, brush, rinse	Soft nylon brush and medium pressure hose (when appropriate)	Chlorine-Quaternary ammonium ("quat")-based cleaner and sanitize	Once/Month (walls adjacent to processing equipment should be cleaned daily)
Ceiling	Foam, brush, rinse	Nylon brush, medium pressure machine	Chlorine-quat-based cleaner and sanitize	Once/Month
Floors	Foam, scrub, rinse	Hard bristle broom (not straw), floor scrubbers, low pressure hose	Chlorine-quat-based cleaner and sanitize	Daily
Doors	Foam, scrub, rinse	Scouring pad	Chlorine-quat-based cleaner and sanitize	Once/Week
Handwashing station	Foam, scrub, rinse	Scoring pad	Chlorine-quat-based cleaner and sanitize	Daily
Pallet jacks/forklift (forks and wheels)	Foam, scrub, rinse	Nylon brushes	Chlorine-quat-based cleaner and sanitize	Weekly
Plastic curtains	Foam, scrub, rinse	Nylon brush or scouring pad	Chlorine-quat-based cleaner and sanitize	Once/Week (adjacent to processing equipment should be cleaned daily)
Drains and covers	Foam, brush, rinse	Drain brush	Chlorine-quat-based cleaner and sanitize	Daily
Evaporator plates of cooling units	Foam, brush, rinse	Nylon brush	Chlorine-quat-based cleaner and sanitize	Quarterly if using quaternary rings in the drip pans.
Overhead pipes, electrical conduits, structural beams	Foam, brush, rinse	Brush with bucket, or med water pressure	Chlorine-quat-based cleaner and sanitize	Once/Month
Hoist fixtures	Foam, brush, rinse	Cleaning pad	Chlorine-quat-based cleaner and sanitize	Once/Month
Light fixtures	Brush and rinse	Brush or wipes	Chlorine-quat-based cleaner and sanitize	Monthly or as needed
Platform “standing” grids	Foam, brush, rinse	Nylon brush	Chlorine-quat-based cleaner and sanitize	Daily
Waste, dumpster areas	Foam, brush, rinse	Nylon brush	Heavy duty degreaser, Chlorine-quat-based cleaner and sanitize	Weekly or as needed
Employee break rooms/bathrooms	Sweep, Wash and Sanitize	Designated bathroom brushes and tools	Chlorine-quat-based cleaner and sanitize	Frequently throughout the day
Shipping warehouse	Sweeping Foam, scrub, rinse	Designated Broom and Brushes	Chlorine-quat-based cleaner and sanitize	Daily Quarterly

Area	Cleaning/Sanitation Method	Tools	Cleaning and Sanitizing Materials	Frequency
Maintenance areas	Sweeping Scrub, rinse	Designated Broom and brushes	Degreasing agent	Daily Monthly
Receiving warehouse	Sweeping Foam, scrub, rinse	Designated Broom and Brushes	Chlorine-quat-based cleaner and sanitize	Daily Quarterly
Mezzanines above flumes and above filling product	Foam, brush, rinse	Brush	Chlorine-quat-based cleaner and sanitize	Daily
Production processing area	Foam, scrub, rinse	Nylon brushes	Chlorine-quat-based cleaner and sanitize	Daily
Bin dumpers	Foam, scrub, rinse	Nylon brushes	Chlorine-quat-based cleaner and sanitize	Daily
Flumes	Empty flumes, foam, scrub, rinse	Nylon brushes	Chlorine-quat-based cleaner and sanitize (Sanitizer air dry before re-filling flume)	Daily
Chiller plates	Foam, scrub, rinse	Nylon brushes	Chlorine-quat-based cleaner and sanitize	Daily
Spin dryers	Remove basket from dryer, foam, scrub, rinse	Nylon brushes	Chlorine-quat-based cleaner and sanitize	Daily
Spin dryer baskets	Empty basket, foam, scrub, rinse	Nylon brushes	Chlorine-quat-based cleaner and sanitize	Daily
Blades and cutters	Remove, foam, scrub, rinse	Nylon brushes	Chlorine-quat-based cleaner and sanitize	Daily or as needed to prevent cross-contamination during processing
Hoppers	Foam, scrub, rinse	Nylon brushes	Chlorine-quat-based cleaner and sanitize	Daily
Product filling scales	Remove, foam, scrub, rinse	Nylon brushes	Chlorine-quat-based cleaner and sanitize	Daily
Forming tubes at the filler	Foam, scrub, rinse	Nylon brushes	Chlorine-quat-based cleaner and sanitize	Daily
Conveyor belts	Foam, scrub, rinse Remove, foam, scrub, rinse	Nylon brushes	Chlorine-quat-based cleaner and sanitize	Daily Monthly
Food contact knives and tools	Foam, scrub, rinse	Nylon brushes	Chlorine-quat-based cleaner and sanitize	Daily or as needed to prevent cross-contamination during processing
Plastic bins/barrels	Foam, scrub, rinse	Nylon brushes	Chlorine-quat-based cleaner and sanitize	Daily
Injection pump hose	Wipe clean	Single use wipes	Chlorine-quat-based cleaner and sanitize	Daily
Leaker tanks	Empty, foam, scrub, rinse	Nylon brushes	Chlorine-quat-based cleaner and sanitize	Daily

Appendix 2. Summary Process Control Chart for Adding Sodium Hypochlorite to Wash Water as an Example of a Process Preventive Control in the Production of Fresh-cut Leafy Vegetables

FORM 2-C (Modified)[24] PROCESS CONTROLS

PAGE _____

PRODUCTS: Fresh-cut romaine lettuce
PLANT NAME: Fresh-cut Operation A **ADDRESS:** 123 Main Street, Anytown, State, Zip
ISSUE DATE: (mm/dd/yy) 12/15/17 **SUPERSEDES:** (mm/dd/yy) 12/13/16
PROCESS CONTROL STEP: Chlorine added to wash water
HAZARD(S): *E. coli* O157:H7

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action/Correction	Verification	Records[25]
Minimum concentration of free chlorine is 10 ppm	Concentra-tion of free chlorine in the wash water	• Automated sensor • Visual observation of the reading on the automated sensor by the QA Technician	• Continuous (automated sensor) • Twice per shift (QA Technician)	• The automated sensor • The QA Technician	• Empty the processing line and discard the product back to the last time the monitored parameters were within the critical limits • Clean and sanitize all affected post-wash FCSs • The PCQI takes steps to determining (if possible) what caused the free chlorine concentration to drop below the critical limit so that actions can be taken to prevent such occurrences from happening in the future • Replace non-functioning sensor(s) when applicable	• Weekly calibration of sensors used for monitoring free chlorine • Twice per shift verification of free chlorine concentration using a titration test kit • Records review by PCQI within 7 days of record creation (batch records documenting the free chlorine concentrations, calibration of sensors, corrective action records)	• Accuracy checks and calibration records • Free chlorine titration test records • Process logs documenting the concentrations of free chlorine observed by the QA Technician from the readings on the automated sensor • Corrective action records

[24] Modified from Form 2-C in Appendix 2 to address a single process control step. Form 2-C in Appendix 2 can be used to list multiple process control steps.
[25] Records include the date and initials of the PCQI (or designee) as verification.

Appendix 3. Example of a Training Aid to Instruct Personnel on Adequate Handwashing Procedures

We recommend that you train your employees on how, when, and why they must adequately wash (and, when applicable, sanitize) their hands and exposed portions of their arms (e.g., before entering areas where fresh or fresh-cut produce is processed or exposed). Below, we provide an example of a training aid that you could use to train employees on adequate handwashing procedures.[26]

Example Training Aid on Adequate Handwashing Procedure:

Soap combined with scrubbing helps dislodge and remove dirt and germs. Wash your hands following the steps below before entering any area where produce is processed or exposed:

- Step 1: Use soap and warm running water.
- Step 2: Wet hands.
- Step 3: Apply soap.
- Step 4: Vigorously rub hands up to elbows for 20 seconds.
- Step 5: Rinse Hands.
- Step 6: Turn off running water with a paper towel, not bare hands.
- Step 7: Dry hands with a paper towel or air dry. Do not share towels.

[26] This training aid would be used during a demonstration of the 7 steps of how to wash hands. It can be modified as appropriate to the hand-washing facilities used in your plants, e.g., to be specific to the use of knee-operated controls.

Appendix 4. Example of a Training Aid to Instruct Personnel Who Have Responsibility for Cleaning and Sanitizing

[Insert one or more pictures of the equipment or infrastructure to be cleaned]

- Tools [provide a list of tools that will be used to clean the equipment or infrastructure in the picture]
    - Hose
    - Brush (including color when applicable for color-coded brushes)
    - Other
- Safety Requirements (As Applicable)
    - Goggles/safety glasses
    - Gloves
    - Sanitation Rain Suit
    - Other

Cleaning chemicals and sanitizers

Procedural Step	Explanation of the Actions to Be Performed
Step 1	Explanation of how to Dry Clean this equipment
Step 2	Explanation of how to Pre-Rinse this equipment
Step 3	Explanation of how to Soap and Scour this equipment
Step 4	Explanation of how to Post-Rinse this equipment
Step 5	Explanation of how to Prepare this equipment for Inspection
Step 6	Explanation of how to perform the Pre-Op Inspection on this equipment and explanation of an acceptable Pre-op Inspection.
Step 7	Explanation of how to Sanitize this equipment including acceptable levels of sanitizer ppm concentration.