

Guide to Minimize Biological Hazards in Ready-to-Eat Fresh-Cut Produce: Guidance for Industry

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**U.S. Department of Health and Human Services
Food and Drug Administration
Human Foods Program
August 2026**

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Guide to Minimize Biological Hazards in Ready-to-Eat Fresh-Cut Produce: Guidance for Industry¹

This guidance document represents 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 the FDA staff responsible for this guidance document at the phone number listed on the title page.

I. Introduction

This guidance is intended to help manufacturers/processors of ready-to-eat (RTE) fresh-cut produce that is not a low-moisture food (“you”) ² comply with applicable requirements in 21 CFR part 117 (part 117), titled “Current Good Manufacturing Practice (CGMP), Hazard Analysis, and Risk-Based Preventive Controls for Human Food (PCHF).”³ In this guidance, “fresh-cut produce” means any fresh fruit or vegetable (or combination thereof) that has been physically altered to no longer be in its whole state (e.g., by chopping, dicing, peeling, ricing, shredding, slicing, spiralizing, or tearing) without additional processing (such as blanching, freezing, cooking, canning, or packing in a juice, syrup, or dressing), with or without a wash or other treatment before being distributed in fresh form (e.g., to a consumer, a retail food establishment, or a manufacturing/processing facility). Fresh-cut produce is a processed food that can be a single produce commodity (such as cut lettuce, sliced cantaloupe, diced celery, diced onions, and shredded carrots) or two or more produce commodities mixed in the same package (such as coleslaw mix and a fruit salad that contains a variety of cut melons).

The recommendations in this guidance are tailored to apply to the control of known or reasonably foreseeable (“potential”) biological hazards⁴ in fresh-cut produce that:

- Is ready-to-eat. Part 117 defines “ready-to-eat food” as “any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably

¹ This guidance has been prepared by the Office of Microbiological Food Safety, Office of Produce Safety, in the Human Foods Program at the U.S. Food and Drug Administration.

² For purposes of this guidance, “you” refers to entities that manufacture/process, as defined in 21 CFR 1.227, RTE fresh-cut produce that is not a low-moisture food.

³ For information about the regulatory framework and applicability of part 117, including exemptions that might apply to you, see section III and Appendix 2.

⁴ For discussion on control of chemical (including radiological) or physical hazards, please refer to the Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance. When finalized, this guidance will represent FDA’s current thinking on this topic.

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foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards” (21 CFR 117.3).

- Exhibits a water activity above 0.85. Almonds, walnuts, pistachios, pecans, macadamias, and peanuts are examples of produce commodities with a water activity below 0.85 and therefore would not be covered by this guidance.

In the remainder of this guidance, we refer to the food that is the subject of this guidance as “RTE fresh-cut produce” without specifying each time that this RTE fresh-cut produce exhibits a water activity above 0.85.⁵

This guidance is intended for fresh-cut produce processing activities that take place on farm mixed-type facilities (i.e., an establishment that is both a farm as defined in 21 CFR 1.227 and a food facility required to register with FDA). This guidance is not intended for farms. Manufacturers/processors of RTE foods (such as frozen, cut fruit) that are not fresh-cut produce as that term is defined in this guidance, but include steps such as cutting produce raw agricultural commodities (RACs) or washing cut produce in the production of RTE foods, might find this guidance useful for their operations, particularly with respect to control measures for washing cut produce.

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

RTE fresh-cut produce that has been contaminated with pathogens (such as *Escherichia coli* O157:H7, *Salmonella* spp., *Listeria monocytogenes*, and *Cyclospora cayetanensis*) has been associated with numerous foodborne illness outbreaks. Examples of RTE fresh-cut produce commodities that have been associated with foodborne illness are melons, leafy greens, onions, and mixed vegetable trays (Ref. 1-4). However, any RTE fresh-cut produce commodity contaminated with a pathogen could potentially cause an outbreak of foodborne illness. You can review FDA’s Coordinated Outbreak Response & Evaluation (CORE) Network Annual Reports to learn about recent outbreaks associated with fresh-cut produce (Ref. 5). Contamination can occur on-farm (Ref. 6) or in a fresh-cut processing plant (Ref. 7 and Ref. 8).

Produce RACs can be contaminated by pathogens such as *E. coli* O157:H7 and *Salmonella* spp. during growing, harvesting, packing, or holding on farms. These pathogens may contaminate the food through routes such as contaminated agricultural water, improperly applied biological soil

⁵ Please note additional discussion for processors of low moisture RTE foods are contained in FDA’s draft guidance, “Draft Guidance for Industry: Establishing Sanitation Programs for Low-Moisture Ready-to-Eat Human Foods and Taking Corrective Actions Following a Pathogen Contamination Event.” When finalized, this guidance will represent FDA’s current thinking on this topic.

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amendments of animal origin, and poor farm worker hygienic practices. When incoming produce RACs have been contaminated on-farm, processing produce RACs into fresh-cut produce 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 cut, 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 can spread.

Even if incoming produce RACs have not been contaminated on-farm, fresh-cut produce can be contaminated at a fresh-cut processing plant by pathogens as a result of cross-contamination (such as a result of washing). Handling practices that are common at fresh-cut processing establishments (such as mixing large batches of produce) have the potential to spread low-level, sporadic contamination across a larger volume of product (Ref. 10).

Pathogens can also contaminate food as a result of poor employee hygienic practices during manufacturing/processing and storage of fresh-cut produce (i.e., through the “fecal-oral route”). The potential for their introduction into fresh-cut produce in the processing plant can be addressed through the implementation of personnel hygienic practices such as those required by the CGMP requirements at 21 CFR 117.10 (e.g., disease control, cleanliness, handwashing).

An environmental pathogen is a pathogen capable of surviving and persisting within 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 (§ 117.3). These pathogens can be introduced into a food processing plant. Environmental pathogens that are not removed through routine cleaning and sanitizing and become established in a food processing plant (either in processing equipment and/or parts of the facility infrastructure) are referred to as “resident strains.”⁶ *L. monocytogenes* is an example of an environmental pathogen that can contaminate RTE foods and cause foodborne illness (Ref. 12 and Ref. 13). For comprehensive recommendations regarding control of *L. monocytogenes* in RTE foods, see our draft guidance for the control of *L. monocytogenes* in RTE foods (the *Listeria* draft guidance) (Ref. 14).⁷

The potential for pathogens to survive or grow in RTE fresh-cut produce 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).

⁶ A “resident strain” (also referred to as a “persistent strain”) of an environmental pathogen is a strain that becomes established in a food processing plant (e.g., in processing equipment and/or parts of the facility infrastructure) and is not removed through routine cleaning and sanitizing. It can be repeatedly isolated over an extended period of time (months or even years), despite frequent cleaning and sanitizing (Ref. 11).

⁷ In January 2017, we issued the draft guidance titled “Control of *Listeria monocytogenes* in Ready-to-Eat Foods” (Ref. 14). When finalized, this guidance will reflect FDA’s current thinking on this topic. In this document, we refer to that guidance as “the *Listeria* draft guidance.”

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

Part 117 covers the manufacturing, processing, packing, and holding of human food. Part 117 contains 7 subparts (subparts A through G) that each have a specific focus. Some of the requirements of part 117 address CGMPs for human food (“CGMP requirements”). The CGMP requirements are primarily in subpart B, with associated requirements in subparts A and F. With some exceptions (such as for farms),⁸ the part 117 CGMP requirements apply to all persons who manufacture, process, pack, or hold human food,⁹ including manufacturers of fresh-cut produce.

Other requirements of part 117 address “hazard analysis and risk-based preventive controls for human food” (“PCHF requirements”). The PCHF requirements are primarily in subparts C and G, with associated requirements in subparts A, D, E, and F. The PCHF requirements largely reflect a sequence of activities. For example, the requirement for hazard analysis leads a facility to determine which hazards require a preventive control. The facility then identifies and implements appropriate preventive controls, together with appropriate “preventive control management components” (i.e., monitoring, verification, corrective actions and corrections, and associated records) for each preventive control. With some exceptions,¹⁰ the PCHF requirements generally apply to the owner, operator, or agent in charge of those domestic and foreign facilities that manufacture, process, pack, or hold human food and are required to register as a food “facility.”¹¹ The exception that is most relevant to the production of fresh-cut produce is the exemption for “qualified facilities” (e.g., facilities that are a very small business as defined in § 117.3; see the exemption in § 117.5(a)). A “qualified facility” is subject to the CGMP requirements but is exempt from the PCHF requirements in subpart C (Hazard Analysis and Risk-Based Preventive Controls) and subpart G (Supply-Chain Program) and is instead subject to modified PCHF requirements in § 117.201.

In this guidance, we identify CGMP and PCHF requirements that are most relevant to fresh-cut processing establishments, and provide specific recommendations related to those requirements. 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

⁸ See [§ 117.5\(k\)](#) for a complete list of exemptions from the CGMP requirements.

⁹ A restaurant or retail food establishment (as defined in § 1.227) is not required to register as a food facility (see [§ 1.226](#)). These establishments generally are inspected by State or local regulatory agencies, often under State or local laws and regulations based on FDA’s Food Code (Ref. 15). FDA’s Food Code is a model that assists food control jurisdictions at all levels of government by providing a scientifically sound technical and legal basis for regulating the retail and foodservice segment of the industry (e.g., restaurants, grocery stores, and institutions such as nursing homes). Food control jurisdictions (e.g., at the local, State, and tribal level) use the FDA Food Code as a model to develop or update their own food safety rules and to be consistent with national food regulatory policy.

¹⁰ See [§ 117.5](#) for a complete list of exemptions from the PCHF requirements.

¹¹ Under section 415 of the FD&C Act (21 U.S.C. 350d), the requirement to register as a food facility applies to facilities engaged in the manufacturing/processing, packing, or holding of food for consumption in the United States. (See [21 CFR part 1, subpart H](#).) Under section 415 of the FD&C Act, FDA may suspend registration of a facility if FDA determines that the food poses a reasonable probability of serious adverse health consequences or death. A facility that is under suspension is prohibited from distributing food.

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associated with PCHF requirements. For more information about the regulatory framework and applicability of part 117, see Appendix 2.

Beginning in 2016, we have announced the availability for public comment of several chapters of a multi-chapter draft guidance for industry entitled “Hazard Analysis and Risk-Based Preventive Controls for Human Food: Guidance for Industry” (81 FR 57816, August 24, 2016; 82 FR 41364, August 31, 2017; 83 FR 3449, January 25, 2018; 84 FR 53347, October 7, 2019; 88 FR 66457, September 27, 2023; and 89 FR 7315, February 02, 2024). This multi-chapter draft guidance (Ref. 16) provides information on how to comply with the PCHF requirements. We intend to announce the availability for public comment of additional chapters of the draft guidance as we complete them. When finalized, this multi-chapter guidance will reflect FDA’s current thinking on this topic. We often refer you to the PCHF draft guidance rather than repeat the comprehensive discussion included in the draft guidance.

CGMP requirements are sometimes called a “prerequisite program” (Ref. 17) to signify that the measures that you take to comply with the CGMP requirements should be in place before you conduct your hazard analysis and identify risk-based preventive controls to address specific hazards. The preventive controls that you establish and implement should complement and enhance the measures you have in place to comply with the CGMP requirements to prevent allergen cross-contact and contamination of food. CGMP measures can be adapted to be preventive controls by applying preventive control management components. We intend to discuss broad considerations associated with determining which hazards can be effectively addressed through the application of CGMPs alone, and which require the implementation of preventive controls, in the PCHF draft guidance. In this guidance, we discuss examples of how consideration may be given as to when to address a hazard through CGMPs, or through preventive controls, in the context of specific controls related to fresh-cut produce.

IV. CGMP Requirements Regarding Personnel (21 CFR 117.10)

The CGMP requirements regarding personnel¹² address 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. Personnel include persons with a broad range of assigned duties, including food production, maintenance, and clerical duties.

A. Disease Control

The principal goal of the CGMP requirements for disease control 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, including through transfer to food-contact surfaces (FCSs) or food-packaging materials.

¹² Personnel do not include visitors who have no assigned duties. We recommend that you limit access of visitors to food production areas of your plant and inform them of appropriate hygiene practices during their visit. Visitors with a regulatory function (e.g., persons inspecting your plant) are aware of appropriate hygiene practices.

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Many symptoms (e.g., vomiting, diarrhea, abdominal cramps, fever, and jaundice) associated with illnesses (particularly communicable illnesses) that warrant exclusion of an ill person from food production operations would be obvious to affected and supervisory personnel, and symptoms such as uncovered lesions often would be obvious to such personnel as well. You should take steps to ensure that all personnel are aware of the importance of reporting applicable illnesses and staying out of operations or areas of the plant where they could contaminate food, FCSs, or food-packaging materials. One way to do so 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(b)(2)). Other examples of such steps are:

- Reassign any worker who has an infected wound or open lesion to duties that are unlikely to lead to contamination of food, FCSs, or food-packaging materials, such as clerical duties, until the wound can be adequately covered.
- 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 on their behalf during the illness.

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 properly 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. You should take steps to ensure that supervisors are aware of this role. 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(b)(2)). Other examples of such steps are:

- Advise supervisors to be aware of obvious symptoms of an applicable health condition in personnel (e.g., frequent or extended trips to the toilet facilities) and take necessary action to protect against contamination.
- Use signage and visual aids, such as posters, to remind employees to report applicable health conditions to supervisory personnel.

B. Cleanliness (Hygienic Practices)

The CGMP requirements for cleanliness address hygienic practices such as wearing suitable outer garments; washing and, when applicable, sanitizing hands; properly 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)). In the

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remainder of this section, we provide recommendations for complying with the CGMP requirements applicable to clothing, handwashing, gloves, eating, chewing gum, drinking beverages, and using tobacco.

1. Clothing

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 the use of 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 worn or damaged or can otherwise no longer be cleaned.

2. Washing Hands

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, brooms, shovels, and the bottom of buckets) that have been in contact with the floor). The CGMP requirements specify that personnel who work in direct contact with food, FCSs, or food-packaging materials must wash their hands at any time when the hands may have become soiled or contaminated. See Appendix 3 for an example of a training aid to instruct personnel on adequate handwashing procedures.

3. Maintaining gloves

You should choose the type of gloves that work best for your operations. Disposable gloves should be disposed after single use, whenever they become soiled or may otherwise cause food contamination, and when they become visibly worn with holes or tears. You should also 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, or food-packaging materials.

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

You should confine these activities to designated areas (e.g., break rooms, designated smoking areas, and lunchrooms) and locate those areas at a sufficient distance from fresh-cut produce processing operations, FCSs, or food-packaging materials to ensure the safety of the fresh-cut produce and minimize the possibility of contaminating the fresh-cut produce. Locating these designated areas near handwashing facilities may help to facilitate handwashing after engaging in these activities. Your supervisors should also observe that your personnel follow the required practices and be prepared to address observations of unhygienic practices.

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 serving as a source of contamination for food, FCSs, or food-packaging materials.

A. Grounds

Examples of steps you can take to comply with the CGMP requirements in 21 CFR 117.20(a) regarding grounds are:

- Adequately remove debris, unused equipment, and vegetation within the immediate vicinity of the plant; and
- Adequately drain grounds.

B. Plant Construction and Design

Examples of steps you can take to comply with the CGMP requirements in 21 CFR 117.20(b) regarding plant construction and design are:

- Properly construct buildings to help protect against potential sources of external contaminants (e.g., airborne contamination and pests) that may compromise the safety of food;
- Close all exterior doors and entrances when not in use, and ensure that there is an adequate seal when exterior doors are closed, to prevent entry by pests (Ref. 18);
- Fit floor drains with seals and grates adequate to prevent pest entry;
- Design product areas to have traffic and air flow patterns that separate intact RACs and finished product from each other using either linear product flow (i.e., flow of materials in one direction, from intact RACs to finished product) and reverse air flow (i.e., flow of air in the opposite direction), or physical partition (Ref. 14), and use positive air pressure in the fresh-cut processing area (Ref. 14, Ref. 19, and Ref. 20). See Figure 3 in Ref. 20 for an example of suitable product and personnel flow patterns in a fresh-cut processing plant;
- Use construction material that is smooth (Ref. 21) and easily cleanable, such as stainless steel or plastic, whenever practical for constructing walls and ceilings in 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; and
- When applicable, locate any microbiology laboratory as far away as practical from the processing area to minimize potential for contamination, 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, FCSs, or food-packaging materials will be exposed to the environment. For example, new construction and renovations

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could cause significant disruption to air patterns because walls, ceilings, or floors that ordinarily act as a barrier to reduce the potential for cross-contamination of food, FCS, non-FCS, or food-packaging materials may not be present to serve that function. Actions you should take depend on the type of construction activity and the potential for contamination.

The *Listeria* draft guidance (Ref. 14) has discussion on the types of actions that you could take regarding plant and grounds to reduce the potential for *L. monocytogenes* to contaminate food, FCSs, or food-packaging material. Examples that could apply to a fresh-cut produce processing establishment are:

- 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 *L. monocytogenes*.

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

The CGMP requirements for sanitary operations (21 CFR 117.35) 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.

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

- Use a stepwise process for cleaning and sanitizing. For example, the following steps are an example of a typical wet cleaning and sanitizing procedure (Ref. 23 and Ref. 24). Some steps may not be applicable to your operation or could be modified (Ref. 23 and Ref. 25):
 1. Pre-Clean: personnel use tools such as brushes, brooms, scrapers, and collection pans to remove heavy residue, plant material, or debris from the equipment or tools.
 2. Initial Rinse: personnel rinse the equipment or tools from the top down with water to remove additional organic material and residue that was loosened during the pre-clean step; scrubbing could be necessary during this step.

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3. Washing with Cleaning Agent and Mechanical Action: personnel apply a cleaning agent in one of several forms, such as by spray or foam; personnel should ensure full coverage of the relevant surface with the cleaning agent for the time and at the temperature specified by the cleaning agent manufacturer; small equipment or tools or components of these can be washed in sinks or tanks containing a solution of the cleaning agent; mechanical action (e.g., scrubbing) ordinarily should be applied, using tools such as brushes or scouring pads, in order to fully remove organic material and residues.
 4. Post-Rinse: personnel apply water to remove loosened soil and debris along with the cleaning agent; after the post-rinse the equipment and tools could be allowed to dry prior to further activities.
 5. Inspection: personnel check the equipment or tools for any remaining soil or residue.
- Sanitize: when necessary and appropriate, personnel treat clean, rinsed surfaces with a sanitizer. You should consult the instructions provided by the manufacturer of the sanitizer.¹³ Sanitizing is generally not effective unless it is preceded by a cleaning step, because residual organic material can protect pathogens from the action of the sanitizing treatment (Ref. 23 and Ref. 25 through Ref. 28). Sanitizers should be applied so that the treatment contacts all areas of the FCS. Care should be taken to ensure contact of the treatment with hard-to-reach places (e.g., edges of interlocking conveyor systems, gears and sprockets that contact food, and the undersides of guards, covers, and ceilings, from which moisture could drip or drain onto the food). This could be done by immersion (e.g., for small equipment and tools and their components), spraying, or flushing (e.g., for stationary equipment). In some instances, antimicrobial treatments should be followed by rinsing.
 - Understand the factors that influence the effectiveness of cleaning procedures. These factors include:
 - o How well organic matter, food, and other debris is removed from the equipment, through physical removal and/or rinsing.
 - o The type and strength of the cleaning agent/detergent.
 - o The surface material (e.g., plastic, stainless steel, concrete) to be cleaned and its condition. You should consider the surface material to be cleaned when selecting cleaning agents/detergents.
 - o Contact time of the cleaning agent/detergent with the surface(s) being cleaned.
 - o The duration and force of physical scrubbing.
 - Inspect flumes, piping, fittings, flanges, and rubber rings regularly to ensure the absence of residue and scale (e.g., mineral deposits).
 - Inspect cutting blades and belts frequently during processing operations for build-up of food residue or cleaning needs.

¹³ Sanitizers are subject to registration as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which is administered by the U.S. Environmental Protection Agency. You should use sanitizing solutions in accordance with the conditions of use authorized under FIFRA, which are generally on the product label.

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- Examine the interiors of ice machines and ice storage bins to ensure that they are clean; do not store utensils (such as scoops or cups) in the same containers as the ice.
- Identify factors that could impact the frequency of cleaning and sanitizing (e.g., commodity type(s), organic load, product volume, duration of the production cycle (e.g., 4, 8, 12 hours)).
- In general, clean and sanitize FCSs (e.g., knives, cutting boards):
 - o At least daily;
 - o When switching between produce types to limit the potential for cross-contamination and to properly establish a designated lot (Ref. 29);
 - o Prior to resuming production after more than a day of those FCSs not being used; and
 - o After equipment maintenance and repairs (Ref. 14).
- Consider the following when selecting sanitizing agents:
 - o the material of the surface that is to be sanitized;
 - o characteristics of water (e.g., hardness, pH, temperature) used to prepare the sanitizing agent; and
 - o the compatibility of the sanitizing agent with the cleaning chemical(s).
- Consult with vendors of cleaning and/or sanitizing agents (and, when applicable, providers of food hygiene services) to help you select the products that are best suited for your operation.
- Store chemicals used at the plant in a secure and designated area.
- If you purchase equipment that has been previously used to produce food by another company, we recommend that you conduct appropriate activities to ensure it does not become a source of contamination in your facility, e.g., determine what commodities the equipment was used to produce, ask if the equipment has been associated with any *Listeria* positive samples, and break it down for a deep clean and sanitize before using it in your firm;
- Designate equipment and tools used for cleaning and sanitizing procedures (Ref. 22) to specific zones to reduce the likelihood of such tools or equipment transferring contamination from one area of the facility to equipment and tools used for food production in another area of the facility;
- Establish controls to maintain sanitary operations during construction, when applicable;
- Establish a pest control program that includes:
 - o Regularly inspecting your entire facility, including areas used for the receiving, processing, holding, and storage of food and food packaging materials, employee break areas, offices, food waste storage, and the surrounding area to monitor for evidence of pests (e.g., by focusing on the perimeters of the building, looking for unprotected pest entry points and potential pest harborage sites, and signs of potential contamination (e.g., stains, live or dead pests, feathers, urine, feces (rodent pellets), urine (e.g., using a black light), or foreign material));
 - o Seeking advice from a vendor specializing in pest control on implementing pest control measures under conditions that will protect against the contamination of food, FCSs, and food-packaging materials; and

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- o Arranging for pesticides to be applied only by persons who are qualified to do so by education, training, or experience (or a combination thereof).

The *Listeria* draft guidance (Ref. 14) provides information regarding sanitation programs to control *L. 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 (21 CFR 117.37(a)), plumbing and sewage disposal (21 CFR 117.37(b) and (c)), toilet and handwashing facilities (21 CFR 117.37(d) and (e)), and rubbish and offal disposal (21 CFR 117.37(f)).

A. Water Supply

Adequate water quality is critical in fresh-cut processing due to the potential for pathogen infiltration into cut or sliced produce, and the absence of a “kill step” (i.e., lethality processing that significantly minimizes pathogens in a food). Any water that contacts food, FCSs, or food-packaging materials must be safe and of adequate sanitary quality, i.e., potable.¹⁴

B. Plumbing and Sewage Disposal

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

- Sloping floors to drains (e.g., 1/4 inch per foot) to provide adequate drainage, 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;
- Use solid sanitizers (e.g., blocks, rings) approved for your intended use in drains to minimize the potential for them to become a source of contamination;
- Separate floor flumes in the produce cooling and packing operation from the flumes in fresh-cut produce operations whenever practical. Floor flumes present a potential for water aerosol contamination of the fresh-cut produce room air and nearby equipment surfaces;

¹⁴ You are required to ensure that water is safe and of adequate sanitary quality for the operations intended (21 CFR 117.37(a)). As an example, you may ensure that your water meets these standards by obtaining it from a municipal source or using a water treatment system and monitoring the process to ensure that it is safe and of adequate sanitary quality for its intended use. A facility may reference the standards in EPA’s National Primary Drinking Water (NPDW) regulations (40 CFR part 141) to ensure that its water supply is safe and of adequate sanitary quality. These water standards, directed to drinking water for household use, provides adequate standards for water used in the manufacturing/production of fresh-cut produce.

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- Plumb flume wastewater to a floor drain (rather than to the floor) with a backflow preventer (Ref. 30), if possible. One example of a backflow preventer is an air gap. Give special attention to standing water (Ref. 14) 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, FCSs, or food-packaging material. 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;
- Design drains with sufficient capacity to be adequate to handle increased water flow without drain back-ups, during periods of high production; and
- Sewage disposal systems (e.g., septic tanks, waste lines to municipal sewage systems) should be constructed according to design specifications, in good working order, and properly maintained.

C. Toilet Facilities

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

- Provide self-closing doors and/or 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 sets of doors or positive air-flow systems);
- Ensure that toilet facilities are constructed and installed appropriately, including with adequate backflow prevention (Ref. 21); and
- Ensure that toilet facilities are maintained and kept in good repair, including that there are no leaks from the toilet to the restroom floor.

D. Handwashing Facilities

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, elbow, or automatic sensor faucet controls) to protect against recontamination of clean, sanitized hands;
- Provide adequate supplies of soap, single service towels, and a covered waste receptacle;
- Provide running water at a suitable temperature; and
- Ensure that handwashing facilities are maintained, cleaned, and kept in good repair.

E. Waste Disposal

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.

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

The CGMP requirements regarding equipment and utensils address the design, construction, installation, use and maintenance of equipment and utensils (21 CFR 117.40). Examples of steps you can take to comply with these CGMP requirements are:

- Design equipment with surfaces that are smooth, non-absorbent, sealed, and sloped (e.g., without edges that would prevent drainage), where feasible, in order to drain freely;
- Cover junctures in FCSs;
- Apply an established equipment design standard to existing and new equipment containing FCSs, such as the sanitary standards inventoried by 3-A Sanitary Standards, Inc. (Ref. 31).¹⁵ Review the cleanability of equipment surfaces prior to purchase and installation;
- If possible, utilize open framing in the construction of food processing equipment. Avoid the use of hollow tube framing;
- Construct work surfaces such as tables, counters, and cutting boards from stainless steel or similar smooth, durable, nonporous materials with curved edges, when doing so is practical for your operation. When this is not possible, you should give special attention to these surfaces in your sanitation operations (see section VI);
- Regularly inspect cutting boards to ensure surfaces are smooth, non-pitted, and do not exhibit knife cuts or excessive wear;
- Install equipment so that there is a walkway around its perimeter (e.g., not directly against a wall) to enable easy access to all FCSs for cleaning and to all parts that must be removed for cleaning and maintenance);
- Install flumes, piping, fittings, flanges, and rubber seals so that they are accessible for inspection and sanitation and inspect them regularly to ensure the absence of cracks that could be a contamination source;
- Inspect knives, cutting blades and belts frequently during processing operations for damage, and replace knives, cutting blades, and belts that are damaged or cannot be

¹⁵ 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.

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maintained in a sanitary condition. Take any necessary measures to ensure that product is not contaminated with metal fragments;

- Use ice machines and ice storage bins that are constructed of food-grade materials; and
- Use smooth conveyor belts rather than grip-tread or textured belts, because smooth conveyor belts are easier to clean and do not have indentations that can be a source of significant bacterial contamination (Ref. 32).

We recommend that you locate the indicating thermometer, temperature-measuring device, or temperature-recording device (which is required by 21 CFR 117.40(e)) to show the temperature of a freezer or cold storage compartment used to store or hold food capable of supporting growth of microorganisms in an area of the unit that is likely to be the warmest (e.g., near the door, on the cooler/refrigerator wall). Although this placement may not result in temperature readings reflecting 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.

We recommend that you calibrate 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 (such as instruments and controls used in association with washing fresh-cut produce) according to the manufacturer's instructions.

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 include general requirements applicable to conducting operations in a sanitary manner, using appropriate quality control procedures, supervision for sanitation of the plant, precautions to prevent production procedures from contributing to allergen cross-contact or contamination, using testing procedures where necessary to identify problems with sanitation or allergen cross-contact, and appropriately disposing of food that has become contaminated or treating it to eliminate the contamination (21 CFR 117.80(a)).

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

- Restrict and control the movement of lift trucks, bins, totes, maintenance tools, cleaning implements, clothing, and personnel from receiving and storage zones to processing and packaging areas;
- When appropriate, use testing procedures, such as rapid Adenosine Triphosphate (ATP) swabs as an indicator of microbial or food residue contamination, to verify cleaning (Ref. 33; see also 80 FR 55908 at 56010, comment/response 317); and
- Limit access to the plant and to its processing areas to individuals who have a legitimate business need to access those areas.

B. Raw Materials and Other Ingredients

The CGMP requirements regarding processes and controls include specific requirements applicable to raw materials and other ingredients (21 CFR 117.80(b)). Examples of steps you can take to comply with the CGMP requirements applicable to raw materials and other 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, and nails or wires from crates)), either visually or by using detectors (such as metal detectors) and remove 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, if appropriate, or reject it.

C. Manufacturing Operations

The CGMP requirements regarding processes and controls include specific requirements applicable to manufacturing operations (21 CFR 117.80(c)). Examples of steps you can take to comply with the CGMP requirements applicable to manufacturing operations are:

- Give special attention to cleaning procedures for containers (e.g., wooden bins) that cannot be sanitized (see 21 CFR 117.80(c)(1));
- For fresh-cut produce that can support the rapid growth of undesirable microorganisms, minimize exposure of in-process products, rework, and finished product to unrefrigerated conditions (see 21 CFR 117.80(c)(3));¹⁶
- Use equipment such as sieves, traps, magnets, and metal detectors to prevent inclusion of metal and extraneous material in food, or to detect metal if such contamination does occur (see 21 CFR 117.80(c)(8));
- Wash RACs and fresh-cut produce using procedures (see 21 CFR 117.80(c)(10)) such as:
 - o Conducting an initial wash to remove dirt and debris where practicable;

¹⁶ We note that the FDA Food Code, which has been widely adopted in state laws, recommends holding most “Time/Temperature Control for Safety foods” (TCS foods) at 41°F (5°C) or lower (Ref. 15). The Food Code defines TCS food to mean a food that requires time/temperature control to limit pathogenic microorganism growth or toxin formation. 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. 15).

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- o Using antimicrobial chemicals¹⁷ in wash water, including water used in single-pass spray systems, to minimize the potential cross-contamination of RACs and processed produce;¹⁸
- o Where water is reused in a series of processes, arranging water flow to be counter to the movement of produce, with the result that as produce is further processed, it is exposed to the cleaner water; and
- o 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.

X. CGMP Requirements Regarding Warehousing and Distribution (21 CFR 117.93)

Part 117 includes CGMP requirements for the storage and transportation of food under conditions that will protect against allergen cross-contact, contamination of food, and deterioration of the food and the container (21 CFR 117.93).

We recommend holding fresh-cut produce that can support the rapid growth of undesirable microorganisms under refrigerated conditions.

The regulation titled “Sanitary Transportation of Human and Animal Food” (21 CFR part 1, subpart O (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 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.

¹⁷ 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.

¹⁸ For a comprehensive discussion of factors to consider in the design and implementation of antimicrobial substances in wash water, see section XV.

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

Part 117 includes CGMP requirements applicable to the holding and distribution of human food by-products for use as animal food (21 CFR 117.95). These requirements apply to practices such as sending by-products from a fresh-cut processing facility to local farmers or animal food manufacturers for use as animal food. Because human food by-products used for animal food must be safe for their intended use, fresh-cut processing facilities that distribute a by-product for use as animal food should know whether their by-product can or will be used for animal food and whether it is suitable for use in animal food.

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 titled “Human Food By-Products For Use As Animal Food” (Ref. 34 and 81 FR 58521, August 25, 2016). FDA issued additional guidance on certain manufacturing activities conducted on human food by-products in section III.D. (pages 19-20) of a guidance for industry titled “Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs” (Ref. 35 and 83 FR 598, January 5, 2018). If you distribute human food products for use in animal food, we recommend that you consult currently available guidance documents such as these and check our website for updates to these guidances.¹⁹

XII. 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

¹⁹ An additional resource for you is a fact sheet on food waste, “At a Glance: Safely distributing unused human food for use as animal food” (available at <https://www.fda.gov/media/136521/download>).

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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)).

Chapters 2 and 3 of the PCHF draft guidance (Ref. 16) provide information for conducting a hazard analysis and describe hazards relevant to food safety. Appendix 1 of the PCHF draft guidance (Ref. 16) provides information on known or reasonably foreseeable (“potential”) biological and chemical hazards in several food categories; known or reasonably foreseeable (“potential”) biological and chemical hazards for fresh-cut produce are addressed within the food category “Fruits and Vegetables.” We recommend that you check our website for the most recent edition of Appendix 1 of the PCHF draft guidance.

Produce RACs could be contaminated with multiple known or reasonably foreseeable (“potential”) biological hazards. In conducting a hazard analysis for RTE fresh-cut produce, we recommend that your hazard evaluation consider whether pathogens such as *Salmonella*, *L. monocytogenes*, and pathogenic *E. coli* are hazards requiring one or more preventive controls. A hazard analysis is conducted to identify and evaluate the pathogens relevant to each type of food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control. In many cases, but not all, establishing one or more preventive controls for the pathogens listed above would also control pathogens that are less common, such as those identified for fresh-cut produce in Appendix 1 of the PCHF draft guidance.

Cyclospora cayetanensis is recognized as a known or reasonably foreseeable (“potential”) biological hazard in berries (and berry-containing products), fresh basil, fresh cilantro, and fresh salad mixes, including salad mixes that contain lettuce and carrots (Ref. 36). *C. cayetanensis* has also been linked to vegetable trays (Ref. 36). As of the date of this guidance, research to elucidate the routes by which fresh produce becomes contaminated with *Cyclospora* is ongoing. However, fecally contaminated agricultural water and contaminated fecal deposits from infected field workers on or in the direct vicinity of harvested product are currently considered to be reasonable routes of transfer (Ref. 36). We recommend that you assess the available information regarding whether *C. cayetanensis* is a known or reasonably foreseeable (“potential”) hazard that could require a preventive control (such as a supply-chain control) for your particular fresh-cut product(s).

Clostridium botulinum is commonly found on fruits and vegetables but is principally a concern for produce packaged using reduced oxygen packaging, which is sometimes used for products such as fresh-cut leafy greens. In numerous studies on the growth and toxin production of *C. botulinum* in produce packaged in modified atmospheres, most often the product (including leafy greens) was grossly spoiled before significant toxin production was detected (Ref. 37). However, toxin production by *C. botulinum* has occurred prior to spoilage for some produce (e.g., mushrooms, potatoes, butternut squash, onions, cabbage), and packaged shredded cabbage in a modified atmosphere was the suspected source of a 1987 botulism outbreak from coleslaw (Ref.

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38). Many factors, including water activity, pH, respiration rate, initial spore levels, and indigenous microflora, play a role in the growth and toxin production by *C. botulinum* on produce packaged in modified atmospheres. For a comprehensive review of the microbiological safety of controlled and modified atmosphere packaging of fresh-cut produce, see Ref. 37.

This guidance focuses on biological hazards. For additional information about chemical and physical hazards and preventive controls for chemical and physical hazards, see the PCHF draft guidance (Ref. 16).

Appendix 2 of the PCHF draft guidance (Ref. 16) includes worksheets, modified from those developed by the Food Safety Preventive Controls Alliance (FSPCA), for you to use in conducting a hazard analysis.

XIII. PCHF Requirements for Preventive Controls (21 CFR 117.135) and Associated Preventive Control Management Components (21 CFR 117.140)

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 (21 CFR 117.135(a)). Preventive controls must be written (21 CFR 117.135(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)).

A. 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. An example of a process control applicable to fresh-cut produce is the use of an antimicrobial substance added to wash water (see section XV). 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

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- 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.

B. 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.

None of the fresh-cut produce commodities that are the subject of this guidance are food allergens as that term is defined in part 117.²⁰ However, fresh-cut processors might need to establish food allergen controls applicable to food other than the fresh-cut produce commodity in certain instances (e.g., if the fresh-cut produce will be packaged with a dressing that includes a food allergen).

C. 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. Sanitation controls 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 environmental pathogens) that would significantly minimize environmental pathogens. It is important to note that the term “environmental pathogen” as defined in part 117 refers to a pathogen capable of surviving and persisting within the food processing environment. Such pathogens may also be introduced into the facility through incoming produce, i.e., raw agricultural commodities contaminated in the growing environment. You should consider the manufacturing, processing, packing, and holding environment of the food being prepared when you conduct your hazard analysis (21 CFR

²⁰ Part 117 defines “food allergen” as a major food allergen as defined in section 201(qq) of the FD&C Act (i.e., milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, soybeans, and sesame) (21 CFR 117.3).

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117.130). *Salmonella* spp. and *L. monocytogenes* are examples of environmental pathogens that should be considered in your hazard analysis for RTE fresh-cut produce because they can survive and persist within food processing environments and pose risks to RTE fresh-cut produce that lacks a lethal treatment step. *Salmonella* can be present in the growing environment (where it can contaminate food crops) and can establish harborage sites in the food processing environment. *L. monocytogenes* is relevant to many food products because it is ubiquitous in the growing environment (where it can contaminate food crops) and can establish harborage sites in the food processing environment, particularly in wet processing environments. In addition, *L. monocytogenes* can grow (i.e., increase in number) slowly at refrigeration temperatures, including during refrigerated storage and under refrigerated manufacturing conditions. You should evaluate whether your specific processing environment could be the source of other pathogens given the nature of your product and process.

If your hazard analysis identifies *L. monocytogenes* as a hazard requiring a preventive control, you should refer to our *Listeria* draft guidance (Ref. 14) for discussion on sanitation controls and environmental monitoring as verification of sanitation controls.

The potential for biological hazards due to employee handling (i.e., enteric pathogens) during manufacturing/processing and storage of fresh-cut produce should be controlled (i.e., significantly minimized) through the implementation of personnel hygienic practices such as those required by the CGMPs at 21 CFR 117.10 (e.g., disease control, cleanliness, handwashing). You should assess your operations and determine whether there are steps that you are or should be taking to prevent cross-contamination from insanitary objects and from personnel to food, food packaging material, and other FCSs and from raw product to processed product that are critical to the safety of your product and warrant the added assurance of consistent implementation provided by the establishment of a sanitation preventive control. For example, you may determine that proper handwashing before starting work, after each absence from the workstation, and at any other time when the hands may have become soiled or contaminated is critical to the safety of your fresh-cut produce. Based on your history with implementing this control as a CGMP in your facility (e.g., lapses in proper employee practices), you may determine that, in order to achieve consistent compliance, you will need to institute the added steps provided by a sanitation preventive control. Such steps would include: periodic monitoring of employee behavior for consistency with your handwashing policies; verification that such monitoring is being consistently performed and that appropriate corrections or corrective actions are taken when conditions are not consistent with your policies (e.g., record review); and maintaining records of such monitoring and verification (see section XIII.G. PCHF Management Components).

D. Supply-Chain Controls

Part 117 specifies requirements for supply-chain controls in 21 CFR 117.135(c)(4) and subpart G. Examples of activities that can be part of a supply-chain program are onsite audits (conducted by you or a third party) and periodic testing of incoming produce for pathogens (see section XVI. Examples of a Supply-Chain Program).

E. Other Controls

Part 117 requires implementing other controls including other procedures, practices, and processes necessary to provide the assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the food will not be adulterated (21 CFR 117.135(c)(6)). Examples of other controls include hygiene training and other current good manufacturing practices.

F. Control Measures for Different Sources of Contamination

In determining which preventive controls to establish and implement, we recommend that you consider factors that can lead to contamination of RACs and fresh-cut produce and implement appropriate control measures. For example:

- You should control pathogens on incoming produce through your supply-chain program as discussed in section XVI.
- You should significantly minimize or prevent cross-contamination of pathogens that could be present in your incoming produce by adding an antimicrobial substance to water used to wash fresh-cut produce as discussed in section XV.
- You should control pathogens in the production environment through your CGMPs (as discussed in sections IV-XI) and through sanitation preventive controls (as discussed in section XIII) that are verified with an environmental monitoring program (as discussed in section XIII). Also, see the *Listeria* draft guidance (Ref. 14) for discussion on sanitation controls for the environmental pathogen *L. monocytogenes* and environmental monitoring as verification of those sanitation controls.
- You should control pathogen growth in fresh-cut produce through your time-temperature controls (as discussed in section XVII).

G. PCHF Management Components

With some exceptions, the PCHF requirements at 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 (including validation) in accordance with 21 CFR 117.155.

(See 21 CFR 117.160 and 117.165 for specific requirements for validation and verification activities, respectively.)

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

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“verification.” Chapter 5 of the PCHF draft guidance (Ref. 16) provides additional information about PC management components. See section XV of this guidance for specific recommendations for how you can apply the PC management components when adding antimicrobial substances as a process control in wash water.

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 or peroxyacetic acid as a process control in wash water. See Appendices 5 and 6 in this guidance for that worksheet.

XIV. Records (21 CFR 117.126, 21 CFR 117.190, and Part 117, Subpart F)

Part 117 includes PCHF requirements for:

- A written food safety plan (21 CFR 117.126). The contents of a food safety plan (21 CFR 117.126(b)) include, as applicable, a written hazard analysis, written preventive controls, written supply-chain program, written recall plan, written procedures for monitoring the implementation of the preventive controls, written corrective action procedures, and written verification procedures.
- Implementation records (21 CFR 117.190). The implementation records most relevant to the discussions in this guidance are records that document the monitoring of preventive controls, corrective actions, verification activities, and the supply-chain program.²¹
- Recordkeeping (part 117, subpart F), including general requirements applying to records, specific additional requirements applying to the food safety plan, requirements for retention and official review, and disclosure requirements. Part 117, subpart F, also provides flexibility for use of existing records if they contain all the required information and satisfy the requirements of subpart F (21 CFR 117.330). Subpart F requires that records must contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities. Also, subpart F requires that records be created concurrently with performance of the activity documented.

Examples of how to comply with requirements for recording an “actual value” (21 CFR 117.305(b)) are:

- When monitoring temperature, record the actual measured temperature (e.g., “37°F”) rather than simply state whether the measured temperature was within the acceptable operating range (e.g., “< 41°F,” “OK,” “Pass”).
- When monitoring the concentration of free chlorine in wash water, record the actual concentration observed (e.g., “22 ppm”) rather than simply state whether the measured free chlorine was within the acceptable operating range (e.g., “> 20 ppm,” “OK,” “Pass”).

Examples of how to comply with requirements for creating records concurrently with performance of the activity documented (21 CFR 117.305(d)) are:

²¹ See the draft PCHF guidance (Ref. 16) for recommendations on records required under 21 CFR 117.190(a)(1) and (a)(6).

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- The time the values were observed for each measurement should be recorded, and ensure the record also identifies the date and signature or initials of the person performing the activity (e.g., Individual's initials, 02/03/2025, 9:00 AM, 30 ppm; Individual's initials, 02/03/2025, 9:01 AM, pH 6.5).

To comply with requirements for records to be indelible (21 CFR 117.305(c)), you should not erase a mistake or obscure a mistake by completely scratching it out or using liquid correction fluid.

XV. Adding an Antimicrobial Substance to Wash Water as an Example of a Process Control in the Production of Fresh-cut Produce

A. Introduction

1. General

We recommend that you establish and implement a process control and associated preventive control management components for the addition of an antimicrobial substance to wash water used in washing fresh-cut produce in order to prevent the transfer of microbial pathogens from contaminated produce to uncontaminated produce ("wash water process control").²² The purpose of this section is to illustrate how you could establish and implement a process preventive control and associated preventive control 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, this section illustrates the use of antimicrobial substances in recirculated wash water during the production of fresh-cut produce.

Antimicrobials function as a process control to significantly minimize or prevent cross-contamination of fresh-cut produce with pathogens. This section discusses scientific and technical considerations associated with doing so and addresses the following topics:

- The importance of controlling systems used to wash fresh-cut produce;
- Characteristics of antimicrobial substances added to wash water to control biological hazards; and
- Preventive control management components applicable to a wash water process control, including:
 - o Validation of an antimicrobial substance for use as a process control during the washing of fresh-cut produce;
 - o Monitoring the use of an antimicrobial substance for use as a process control during the washing of fresh-cut produce;
 - o Corrective action procedures;

²² For the purposes of this guidance, we use the term "wash water" to mean water used to wash and convey fresh-cut produce (e.g., in flumes, spray systems, or wash tanks).

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- o Verification of implementation and effectiveness of use of an antimicrobial substance as a process control during the washing of fresh-cut produce; and
- o Associated records.

Within each topic, we discuss the topic in general as well as provide two specific examples that illustrate these topics. The antimicrobial substances used in these examples are:

- Sodium hypochlorite (Example 1); and
- Peroxyacetic acid (PAA) (Example 2).

Some features of these examples are the same or similar, whereas other features of these examples are different. For example, in both examples the processor washes the commodity using a single stage recirculating chilled water flume. However, in Example 1 many features of the production system are automatic whereas in Example 2 most features of the production system are manual.

The general discussions and examples are illustrative. You should tailor your use of an antimicrobial as a wash water process control to your products and production operations.

2. Example 1: Use of sodium hypochlorite in wash water for fresh-cut leafy greens

The processor washes fresh-cut romaine of various cut sizes (0.5 inches – 1.5 inches) through a single-stage recirculating chilled water flume, using water from a municipal source. The processor uses an automated system that has sensors to measure the free chlorine concentration²³ and pH, which is adjusted using phosphoric acid. If the free chlorine concentration falls to a specified minimum concentration (which is an operating limit that is set higher than the critical limit), or the pH falls outside a specified range (which is an operating limit that has an upper limit below the maximum critical limit), the system automatically adds liquid sodium hypochlorite or phosphoric acid as applicable. Water automatically replenishes in the recirculation tank where particulates are removed by a separating screen. If the free chlorine concentration drops below the critical limit, or if the pH level exceeds the critical limit, the conveyor feeding the fresh-cut romaine into the flume line stops automatically. Then, the processor removes product from the system, cleans the system, and restarts the system. The processor drains and replaces the flume water every 8 hours of operation or daily, whichever occurs first.

3. Example 2: Use of PAA in wash water for fresh-cut onions

The processor washes fresh-cut red, white, and yellow onions of various sizes (0.25 inches – 0.75 inches) through a single-stage recirculating chilled water flume, using water from a municipal source. The processor manually adds PAA at the beginning of production to achieve

²³ “Free chlorine” (sometimes called “available chlorine” or “active chlorine”) is produced when sodium hypochlorite (or similar chlorine-based chemistries) is added to water. When a chlorine compound such as sodium hypochlorite is added to water, a portion of it becomes bound by substances such as organic material in the water. Only the unbound or “free chlorine” is available for antimicrobial activity. Among other things, free chlorine consists of hypochlorite ions and hypochlorous acid. Free chlorine is readily measured using commercially available sensors.

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the desired concentration, takes water samples every 30 minutes at the end of the flume line, and tests the samples for PAA using a titration method.²⁴ When the test results for PAA demonstrate that the PAA level in the water has dropped to a specified level (which is an operating limit that is set higher than the critical limit), the processor manually adds additional PAA to bring the concentration back within the operating range. If the PAA drops below the critical limit, the processor stops the processing line manually, removes product from the system, cleans the system, and restarts the system. Next, PAA is manually added to the system to achieve the appropriate operating conditions and production of fresh-cut onions begins again. The processor drains and replaces the flume water every 8 hours of operation or daily, whichever occurs first.

B. The Importance of Antimicrobial Use in Fresh-Cut Produce Wash Water

1. General

Wash water systems used in the production of fresh-cut produce can vary greatly depending on the product and the facility and are often complex. If not properly managed, such wash water systems can facilitate the cross-contamination of incoming uncontaminated produce with incoming contaminated produce (i.e., produce that is contaminated with pathogens) due to:

- product-to-product contact;
- contaminated particles that accumulate in the water as cut produce is washed; or
- pathogens that wash off contaminated raw produce.

a. Factors affecting cross-contamination in wash water

The potential for cross-contamination of fresh-cut produce during the wash process depends on a number of factors. These factors include 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 pH²⁵ and temperature of the water; product feed rate into the system; and water agitation. “Organic load” refers to dissolved and suspended solids such as plant particles and exudates. Organic load will accumulate over time in recirculated water and can combine with and deplete an antimicrobial substance, thereby reducing its concentration and effectiveness. In addition to the dynamic characteristics already mentioned, factors such as product type and product cut size can impact the organic load and, thus, the concentration and effectiveness of antimicrobial in your wash water.

As discussed in section XV.D, factors such as these can play a role in your validation of the use of antimicrobial substances added to wash water as a process control. Although the wash water process controls that we discuss in this guidance are used in a recirculating water system, you can adapt them to use in other wash water systems.

²⁴ In fresh-cut produce operations, the most common manual method to measure PAA is titration with a thiosulfate standard and starch-iodine as the visualization agent. Although not applicable to the example in this guidance, automated methods that are specific for PAA utilize a sensor that can be used to drive a pump for dosing on demand.

²⁵ The degree to which pH influences pathogen inactivation in wash water is dependent on the type of antimicrobial substance in the wash water.

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

Water containing an antimicrobial substance can remove some pathogens from the surface of produce, but the antimicrobials do not significantly minimize pathogens that have attached to produce or that have been internalized in the tissue. Thus, a wash water process control is not a “kill step” for pathogens on produce (as would happen during a process such as cooking, boiling, or roasting) (Ref. 39 and Ref. 40). During the washing process, pathogens dislodged from contaminated produce can survive in wash water, and spread to uncontaminated produce that is washed at the same time or subsequently in the same wash water, causing pathogen cross-contamination of a large quantity of produce, if uncontrolled (Ref. 41). Antimicrobials are most effectively used to minimize pathogens that have been washed off produce and that are circulating in wash water in order to prevent transfer of microbial pathogens via wash water to non-contaminated produce (Ref. 39).

2. Example 1: Use of sodium hypochlorite in wash water for fresh-cut leafy greens

The relative proportion of the most active (i.e., most effective) component of free chlorine, hypochlorous acid, is dependent on pH. The proportion of hypochlorous acid is greatest at a pH near 6.0 (with a pH below 7.5 providing sufficient hypochlorous acid to result in effective antimicrobial activity) (Ref. 43). The same free chlorine value (ppm) at a lower pH will have a higher efficacy (greater proportion of hypochlorous acid in the water) than that value (ppm) at a higher pH (lower proportion of hypochlorous acid). As the pH of the wash water increases, a less active form of free chlorine (hypochlorite) predominates, while hypochlorous acid levels decrease (Ref. 39 and Ref. 43). When sodium hypochlorite (pH > 11) is used as an antimicrobial in produce wash water, an acidulant (such as phosphoric acid) should be added in order to maintain adequate levels of hypochlorous acid. At lower pH values, the likelihood of toxic chlorine gases forming increases, so a lower operating limit is set for pH (Ref. 43).

Free chlorine generated from sodium hypochlorite is generally more effective at higher temperatures than at lower temperatures. However, within a typical temperature processing range (33°F (0.5°C) to 40°F (4°C)), this temperature effect is minimal. Organic load will deplete free chlorine, thereby reducing the free chlorine concentration and effectiveness.

3. Example 2: Use of PAA in wash water used for fresh-cut onions

PAA (pH < 3) is in its most active form at a pH level below 7.2, and the acid component of PAA can act as a buffer to maintain a neutral to acidic pH in wash water; the pH of the water will be impacted by the volume of PAA added to the wash water. Addition of another acid is not needed when PAA is added as an antimicrobial substance in produce wash water. PAA is generally more effective at higher temperatures than at lower temperatures. However, within a typical temperature processing range (33°F (0.5°C) to 40°F (4°C)), this temperature effect is minimal. Organic load can deplete PAA, thereby reducing the PAA concentration and effectiveness.

C. Regulatory Status and Conditions of Use for Substances Used to Treat Wash Water in Contact with Fresh-cut Produce

1. General

See the PCHF draft guidance (Ref. 16) regarding the regulatory framework applicable to ingredient-related chemical hazards, including the regulatory framework applicable to substances that are directly added to food or are reasonably expected to become a component of food (e.g., when a substance that is added to wash water used during the production of fresh-cut produce migrates into the produce).²⁶ See Appendix 7 for Antimicrobial Substances Authorized for Use in Wash Water for Fresh-Cut Produce. It is your responsibility to use only substances that are lawful under sections 402(a)(2)(C) and 409 of the FD&C Act and to use these substances in accordance with applicable conditions of use (e.g., conditions of use specified in an applicable food additive regulation or an effective food contact notification,²⁷ or associated with a GRAS substance). If you are not familiar with the regulatory status of a substance that you are considering using as a wash water process control, we recommend that you consult the vendor of the substance.

2. Example 1: Use of sodium hypochlorite in wash water for fresh-cut leafy greens

The processor uses sodium hypochlorite to wash fresh-cut leafy greens as authorized by 21 CFR 173.315 in an amount no more than the minimum required to accomplish the intended technical effect. The amount of sodium hypochlorite required to accomplish its intended effect for their particular application was determined by a validation study for that application. See the discussion of validation in section XVI.D. The fresh-cut leafy greens processor uses phosphoric acid to reduce pH in the wash water, which is used in food as a GRAS substance (21 CFR 182.1073).

3. Example 2: Use of PAA in wash water used for fresh-cut onions

The processor uses PAA to wash onions that are not RACs at a level that does not exceed 80 ppm in wash water, as authorized by our regulation in 21 CFR 173.315.

²⁶ 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 (rather than regulated by FDA as a food additive), see our “Guidance for Industry: Antimicrobial Food Additives” (Ref. 42).

²⁷ For information on food contact substance notifications, see our “Guidance for Industry: Antimicrobial Food Additives” (Ref. 42).

D. Validation of a Wash Water Process Control

1. General

a. Approaches to validation of process controls and multi-faceted nature of validation studies

With few exceptions (21 CFR 17.160(c)), 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). There are several approaches, used alone or in combination, for validating process controls (Ref. 44), including:

- historically established process controls;
- reference to scientific or technical information;
- previous validation studies;
- mathematical modeling; and
- scientifically valid experimental data, including collection of data during operating conditions.

The validation process for a process control to significantly minimize or prevent cross-contamination in your wash water system should address the following topics:

- 1) You should determine the commodity that you will use for validation purposes based upon information about the commodities that you process (e.g., organic load associated with incoming produce).
- 2) You should determine the target microorganism for your validation study from those pathogens that you identified in your hazard analysis as requiring a preventive control, considering, to the extent practicable, which pathogen has the greatest resistance to the antimicrobial that you intend to use. You should also determine whether you will use a surrogate for the target pathogen in your studies, and, if so, the appropriate surrogate.
- 3) You should determine the minimum antimicrobial level required to significantly minimize or prevent cross-contamination in wash water (i.e., critical limit). This can be identified through the available scientific literature or as part of a validation study. You should consider information in the scientific literature, guidance provided in the examples in this guidance, as well as studies that you could conduct or have conducted for you;
- 4) You should determine the worst-case operating conditions for organic load (i.e., the conditions under which the organic load in the water accumulates most rapidly and to the greatest level) and the timeframe to reach the greatest organic load under worst-case operating conditions;
- 5) You should determine the location in the wash water system where the antimicrobial concentration is consistently at the lowest level. This should be the location at which the antimicrobial level is monitored and verified; and
- 6) You should determine the frequency of monitoring to ensure the antimicrobial level does not fall below the critical limit throughout production, including under worst-case conditions. You

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should base your decision on how frequently to monitor antimicrobial levels (and pH for chlorine-based systems) on the range of values and the time-period of fluctuations that you observed when you previously measured antimicrobial levels (and pH for chlorine-based systems) when operating under worst-case conditions.

This guidance includes examples in which processors use publicly available scientific or technical information to determine the minimum or maximum values for one or more critical parameters for a wash water process control. The processors then obtain additional scientifically valid data during production demonstrating that its wash water process control can be consistently achieved under its specific operating conditions, including worst-case conditions in the equipment used.

A validation study generally is multi-faceted so that it can address several process parameters. The multi-faceted nature of most validation studies is a key reason for repeating experiments conducted as part of the validation process to have confidence in the accuracy of the results. In Example 1 and Example 2 below, the PCQI adapts the validation procedure from a procedure published in the scientific literature (Ref. 39).

For each process parameter that you address in a validation study, you should identify the range of values that could occur during processing and select the conditions under which you will perform your validation study accordingly. If you use studies from the scientific literature to help establish critical limits applicable to your process parameters, those studies should be consistent with the range of values for each of the process parameters that apply to your product and facility. You should confirm the applicability of those process parameters during representative production runs.

The conditions under which you perform a validation study will establish the operating conditions for which an antimicrobial has been validated for use as a wash water process control and identify the maximum or minimum values (i.e., critical limits) that, if not met during production, would lead to corrective actions (see 21 CFR 117.150). Changes to your process conditions that fall outside those used in the study would be considered conditions that have not been validated; these should be validated prior to use. Note that some process parameters are (or can be) fixed, such as dimensions of the flume, flume water depth, and water temperature. Process parameters that could vary during production could be fixed for the purposes of your validation study (e.g., product cut size, product flow rate, water flow rate, water agitation, water replenishment rate).

The conditions you evaluate in a validation study should address the reasonably foreseeable conditions that provide the greatest challenge to the effectiveness of the added antimicrobial, i.e., the worst-case conditions that are likely to occur for process parameters that could vary during processing. For example, if a process parameter such as water flow rate, product cut size, product flow rate, water replenishment rate, or product feed rate can impact the outcome of the study, then you could design a study where those parameters are fixed to account for the worst-case condition for that parameter (e.g., the fastest water flow rate, the smallest cut size that you expect to use, the fastest product flow rate, the lowest water replenishment rate, and the fastest product feed rate that you expect to use).

If needed to help identify the ranges for the variation of process parameters, you should conduct a representative product run in advance of the validation study.

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b. Example 1: Use of sodium hypochlorite in wash water for fresh-cut leafy greens

The PCQI for the fresh-cut leafy greens processor approached process validation for its wash water process control as follows:

- Determine the commodity for validation based on information about the commodities that are processed;
- Determine the target pathogen for validation from among the pathogens that the PCQI identified in the hazard analysis as requiring a preventive control, including determining, to the extent practicable, which pathogen has the greatest resistance to sodium hypochlorite;
- Use scientific literature to determine critical limits for the concentration of free chlorine and for pH and confirm those critical limits can be maintained in wash water during a representative production run;
- Conduct studies to determine the timeframe for greatest organic load to be reached under worst-case operating conditions; and
- Conduct studies to determine the location in the processing line to place sensors that automatically monitor free chlorine and pH during production.

c. Example 2: Use of PAA in wash water used for fresh-cut onions

The PCQI for the fresh-cut onions processor approached process validation for its wash water process control as follows:

- Determine the commodity for validation based on information about the commodities that are processed;
- Determine the target pathogen for validation from among the pathogens that the PCQI identified in the hazard analysis as requiring a preventive control, including determining, to the extent practicable, which pathogen has the greatest resistance to PAA, as well as identifying a suitable surrogate for in-plant studies;
- Conduct studies to determine critical limits for the concentration of PAA;
- Conduct studies to determine the timeframe for greatest organic load to be reached under worst-case operating conditions; and
- Conduct studies to determine the location in the processing line to monitor PAA during production and the frequency of monitoring by manually collecting samples of wash water and measuring them for the concentration of PAA.

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

a. General

If you process multiple fresh-cut produce commodities, you can often choose a single commodity for the validation study rather than conduct validation studies for each commodity. How you choose the commodity depends on the information that you have about the commodities. For example, you could choose your commodity based on considering the following:

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- Because the type and amount of soil on the surface of the commodity significantly affects the effectiveness of antimicrobial substances, you could rely on information about the relative organic load associated with the incoming produce RACs (e.g., type and amount of soil on the surface of the commodity), as well as the amount and type of organic load a commodity releases into a wash system as a result of being altered from its whole state. For example, if you are processing both leaf lettuce and iceberg lettuce, you could decide to conduct a validation study for antimicrobial efficacy using leaf lettuce, because the loose lettuce leaves are more likely to retain soil splashed onto the plants by rain than the tighter iceberg lettuce leaves.
- If there is little difference in the organic load for your commodities, you could consider the extent to which a commodity has been associated with foodborne illness. For example, if you are processing multiple types of leafy greens, you could decide to conduct a validation study for antimicrobial efficacy using the leafy green most often associated with foodborne illness.
- If considerations such as organic load and association with foodborne illness are similar for all your commodities, you could choose the commodity that you process the most.

b. Example 1: Use of sodium hypochlorite in wash water for fresh-cut leafy greens

In this example, romaine lettuce was among the lettuce commodities processed by the leafy greens processor in the system being validated. The PCQI consulted with cooperative extension services to help determine which leafy green to use for validation. The PCQI and cooperative extension services determined that romaine would be an appropriate commodity to use in validation studies because its release of substantial organic material when cut, and because it has been the confirmed vehicle in several foodborne outbreaks. Another factor the PCQI and cooperative extension services considered before choosing romaine was the growing region from which the romaine lettuce was sourced because of previously noted high accompanying soil load due to extrinsic factors (e.g., weather events, soil type).

c. Example 2: Use of PAA in wash water used for fresh-cut onions

The PCQI was not aware of any information documenting any meaningful difference in accumulation of organic load in the wash water based on the onion variety. Thus, when a study was conducted with a single onion variety (e.g., for validation of the wash water treatment under worst-case organic load) the PCQI chose yellow onions (rather than red or white onions) because the processor processes more yellow onions than red or white onions. When the processor conducted a study to determine the level of PAA to control cross-contamination, two varieties of onions were chosen (i.e., diced red onions inoculated with a surrogate microorganism were washed together with uninoculated diced yellow onions).

3. Identify the target microorganism for your validation study

a. General

A target microorganism is the pertinent pathogen (or a surrogate) that will be evaluated in a validation study. The first step in identifying the target microorganism is to consider the outcome of your hazard analysis, in which you determined those known or reasonably foreseeable pathogens that require a preventive control for each commodity that you process. The generally

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accepted approach for selecting a target microorganism from among the pathogens identified as requiring a preventive control is to choose the pathogen that has the greatest resistance to the process control. If the other relevant pathogens have less resistance to the process control, it is generally accepted that you can assume that they will also be controlled. In general, studies performed to evaluate the efficacy of specific antimicrobials in fresh-cut produce have focused on the pathogens of greatest public health concern in association with a particular produce commodity, especially *E. coli* O157:H7 and *Salmonella* spp., because of their history of foodborne illness attributed to consumption of that commodity, as well as *L. monocytogenes* (likely to be identified in your hazard analysis as a hazard requiring a preventive control). In many cases you can assume that these bacterial pathogens have similar resistance to the antimicrobials currently in use in fresh-cut wash water (e.g., PAA, sodium hypochlorite) (Ref. 45). As such, a study performed to validate PAA or sodium hypochlorite as an antimicrobial in wash water using one of these three pathogens should generally be suitable to validate the efficacy of the antimicrobial against all three of these pathogens, as well as other pathogens with similar resistance to the antimicrobial of interest.

However, the pathogens discussed above might not be the most resistant of the relevant pathogens to the tested antimicrobial. For example, we are not currently aware of any antimicrobial that would significantly minimize or prevent *Cyclospora* cross-contamination and be suitable for use on fresh-cut produce. While your goal should be that your wash water antimicrobial be effective against all pathogens that you have identified in your hazard analysis as requiring a preventive control, we recognize that validating such control at this time for all pathogens could be beyond the scope of current science. In such circumstances, you should identify a bacterial pathogen to validate the efficacy of the antimicrobial in wash water and address hazards not controlled by antimicrobial use with another preventive control, i.e., supply-chain controls (see section XVI for examples of supply-chain programs).

A surrogate is a non-pathogenic microorganism that has survival and/or growth capabilities that are similar to, or more robust than, the pertinent pathogen under the conditions being evaluated. A surrogate microorganism is useful when conducting an in-plant validation study because introducing a pathogen into your production facility could pose an unacceptable risk.

b. Example 1: Use of sodium hypochlorite in wash water for fresh-cut leafy greens

The processor's PCQI identified *E. coli* O157:H7 as the target microorganism²⁸ based on:

- the history of occurrence of *E. coli* O157:H7 in lettuce in the suppliers' growing regions;
- the history of outbreaks linked to contamination of lettuce with *E. coli* O157:H7;
- the severity of illness associated with *E. coli* O157:H7 infection;
- a review of the literature that indicates that existing cross-contamination studies with lettuce have focused on *E. coli* O157:H7 as the target pathogen; and

²⁸ Although the PCQI identified a target pathogen, see section XV.D.6.b in which the PCQI determined that validation studies (with a pathogen or a surrogate) were not needed because the studies in the scientific literature specifically addressed the efficacy of hypochlorite on *E. coli* O157:H7 to prevent cross-contamination of leafy greens.

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- a review of the literature that indicates that *E. coli* O157:H7 has similar resistance to sodium hypochlorite as the other bacterial pathogens identified by the hazard analysis.

c. Example 2: Use of PAA in wash water used for fresh-cut onions

The processor's PCQI identified *Salmonella* as the target microorganism based on:

- the history of occurrence of *Salmonella* in onions in the suppliers' growing regions;
- the history of outbreaks linked to contamination of onions with *Salmonella*;
- the severity of illness associated with *Salmonella* infection;
- a review of the literature that indicates that existing cross-contamination studies with onions have focused on *Salmonella* as the target pathogen; and
- a review of the literature that indicates that *Salmonella* has similar resistance to PAA as do the other bacterial pathogens identified by the hazard analysis.

The PCQI considered the following scientific literature and concluded that *Enterococcus faecium* NRRL B-2354 can be used as a surrogate for *Salmonella* during an in-plant validation study:

- The PCQI considered a study reporting that *E. faecium* NRRL B-2354 performed similarly to a *Salmonella* strain when evaluating cross-contamination during triple-washing of butternut squash using a hydrogen peroxide-PAA mixture (Ref. 46). The authors of that study concluded that *E. faecium* is an appropriate surrogate for *Salmonella* during post-harvest produce washing challenge studies (Ref. 46). The PCQI noted that the only meaningful difference between the hydrogen peroxide-PAA solution used in the study and the antimicrobial solution they were using for validation was the proportion of the hydrogen peroxide to PAA. Because the main components of the antimicrobial solutions (acetic acid, hydrogen peroxide, and peroxyacetic acid) are the same, the PCQI expected that the surrogate would perform similarly to the pathogen for each respective antimicrobial solution. Additionally, the PCQI found another study using PAA in an apple dump tank in which *E. faecium* NRRL B-2354 was found to be an appropriate surrogate for *L. monocytogenes* (Ref. 47) and a study showing that *L. monocytogenes* is more resistant than *Salmonella* to PAA (Ref. 48), but could not find anything to indicate that the antimicrobial solution used in their wash water, with its higher concentration of PAA, would function differently than the hydrogen peroxide-PAA mixture used in the study. Thus, the PCQI concluded that *E. faecium* would be an appropriate surrogate for *Salmonella* for their substance as well.

4. Establishing fixed process parameters for your validation study

a. General

As noted previously, some process parameters are (or can be) fixed, such as dimensions of the flume, water flow rate (if there is only one operating water flow rate), water agitation (which generally is linked to water flow rate), flume water depth, and water temperature. Once you identify process parameters that are fixed (or that you choose to fix), you should set these process parameters to be the same in all your validation studies. If they are set at the rate that presents the greatest challenge to antimicrobial efficacy (i.e., most likely to allow microbial

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survival), these are not processing parameters that require control in accordance with 21 CFR 117.135(c)(1) (because if these parameters were to change during production this would not reduce antimicrobial efficacy), and do not need further consideration for the validation study. You should establish which process parameters are fixed when validating your process control under worst-case conditions.

b. Example 1: Use of sodium hypochlorite in wash water for fresh-cut leafy greens

The PCQI:

- considered water hardness to be a fixed process parameter because it would always be approximately the same in the geographic location of the plant;
- decided to make the water flow rate and product flow rate fixed process parameters, both set at the fastest flow rates;
- decided to make product cut size a fixed process parameter, set at the smallest cut size (0.5 inches);
- considered flume dimensions to be a fixed process parameter because the equipment used does not change;
- considered water agitation as a fixed process parameter because it is determined by water flow rate in this wash system (which is fixed); and
- decided to make water temperature (chilled for product quality by the application of refrigeration to the intake water) a fixed process parameter. During a representative run using sodium hypochlorite as the antimicrobial, the PCQI confirmed water temperature as a fixed process parameter by observing that the temperature of the water stayed within the range of 34°F (1°C) – 36°F (2°C) by the application of refrigeration to the intake water.

c. Example 2: Use of PAA in wash water used for fresh-cut onions

The PCQI:

- considered water hardness to be a fixed process parameter because it would always be approximately the same in the geographic location of the plant;
- decided to make the water flow rate and product flow rate fixed process parameters, both set at the fastest flow rates;
- decided to make product cut size a fixed process parameter, set at the smallest cut size (0.25 inches);
- considered flume dimensions to be a fixed process parameter because the equipment used does not change;
- considered water agitation as a fixed process parameter because it is determined by water flow rate in this wash system (which is fixed); and
- decided to make water temperature (chilled for product quality by the application of refrigeration to the intake water) a fixed process parameter. During a representative run using PAA as the antimicrobial, the PCQI confirmed water temperature as a fixed process parameter by observing that the temperature of the water stayed within the range of 34°F (1°C) – 36°F (2°C) by the application of refrigeration to the intake water.

5. Determine the process parameters to evaluate through the validation study

a. General

There are some parameters in your wash system that you have control over, and which are expected to change throughout production (e.g., antimicrobial concentration, pH). There may be other parameters in your wash system that are also expected to change throughout production, but that you have less control over (e.g., accumulation of organic load). To ensure that you have an adequate understanding and control of your system, you should evaluate these parameters during your validation study.

Examples of process parameters to evaluate in a validation study for a wash water process control are:

- the concentration of your antimicrobial substance;
- pH (when pH impacts the effectiveness of the selected antimicrobial substance); and
- the organic load in the wash water (when organic load impacts antimicrobial concentration).

b. Example 1: Use of sodium hypochlorite in wash water for fresh-cut leafy greens

The PCQI determined that the process parameters to evaluate during validation are concentration of free chlorine, pH, and organic load.

c. Example 2: Use of PAA in wash water used for fresh-cut onions

The PCQI determined that the process parameters to evaluate during validation are concentration of PAA and organic load; it was determined that pH would not need to be evaluated (see XV.B.5).

6. Determine the critical limits for concentration of antimicrobial substance

a. General

You have flexibility to determine critical limits for the concentration of an antimicrobial substance:

- solely through your own validation study(ies) using
 - o the produce washing equipment in your commercial processing line; or
 - o a suitable laboratory-scale or pilot-scale processing line (i.e., one that simulates your processing line). You should use a laboratory-scale or pilot-scale processing line if your target microorganism for validation is a pathogen rather than a surrogate microorganism;
- using publicly available scientific or technical information; or
- through a combination of your own validation study(ies) and other information (such as information about historically established process controls, scientific/technical information, or previous validation studies).

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If you are conducting your own scientific study, you could determine the minimum effective concentration of your antimicrobial substance under the worst-case conditions using your washing equipment and a surrogate microorganism. Alternatively, you could determine the minimum effective concentration, under the worst-case conditions identified for your processing line, using a suitable laboratory-scale or pilot-scale processing line (i.e., one that simulates your processing line), rather than your production processing line. In that case, you could use either a surrogate microorganism or the target pathogen. Although you should not introduce a pathogen to your production processing line even for a validation study (because of the potential for residual pathogen to contaminate your product), this concern does not impact studies done in a laboratory or pilot plant as long as you do not distribute food produced in these settings.

To the extent that you use studies from the scientific literature to help establish your critical limits, those studies should be compatible with the range of values for each of the process parameters that apply to your product and facility.

b. Example 1: Use of sodium hypochlorite in wash water for fresh-cut leafy greens

Using scientific literature, the PCQI identified a minimum concentration (i.e., critical limit) of 10 ppm free chlorine based on:

- A published scientific study evaluating the effectiveness of sodium hypochlorite as an antimicrobial in wash water during the production of fresh-cut romaine (Ref. 40), which was supported by other published scientific studies (Ref. 39, and Ref. 41); and
- A risk assessment that characterized cross-contamination of *E. coli* O157:H7 in fresh-cut lettuce using a model that predicted the need for free chlorine levels of at least 10 ppm to prevent significant increases in predicted contamination prevalence due to washing (Ref. 49).

Considering the strength of the available scientific literature relevant to their product and facility, the PCQI determined that there was no need for studies to validate the critical limit (other than to determine that the washing system could consistently deliver sodium hypochlorite that achieves the minimum free chlorine concentration). The PCQI determined that setting a minimum operating limit of 20 ppm of free chlorine in wash water, and an operating range of 25 ± 5 ppm of free chlorine, would provide assurance that the concentration of free chlorine would be achieved and maintained above the critical limit of 10 ppm.

Using scientific literature, the PCQI determined that the critical limit for pH was below 7.5 (Ref. 43), because this pH range provides for the most active form of free chlorine (i.e., hypochlorous acid) to predominate over less active forms as sodium hypochlorite is added to the wash water.²⁹ The PCQI determined that setting pH operating limits of 4.0 (minimum)³⁰ and 7.2 (maximum) would provide assurance that the pH would be achieved and maintained below the critical limit for pH of 7.5. Table 1 summarizes the approach of the PCQI to use operating limits as a

²⁹ The same free chlorine value (ppm) at a lower pH will have a higher efficacy (greater proportion of hypochlorous acid) than that value (ppm) at a higher pH (lower proportion of hypochlorous acid).

³⁰ A lower operating limit for pH was set for employee safety (and not food safety), and while unlikely to occur based on the automated continuous monitoring system setup, an adjustment could be made by the PCQI in the event that the pH drops below the operating limit of 4.0.

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mechanism to provide assurance that critical limits identified through scientific literature will be achieved and maintained during production.

Table 1. Free chlorine and pH values established by the PCQI

	Free Chlorine	pH
Operating limit	Minimum 20 ppm	Minimum 4.0 and maximum 7.2
Critical limit	Minimum 10 ppm	Maximum 7.5

c. Example 2: Use of PAA in wash water used for fresh-cut onions

The PCQI reviewed the manufacturer's instructions for use of PAA. These instructions provide a concentration range and contact time that achieve a specific log reduction of certain pathogens (including *Salmonella* spp.) in produce wash water. However, neither the manufacturer's instructions nor scientific literature specifically address a concentration range that significantly minimizes or prevents pathogen cross-contamination during washing of fresh-cut onions. The PCQI decided to perform a study to identify a minimum concentration of PAA to use as a wash water process control during the production of fresh-cut onions.

Based upon use-level information in the manufacturer's instructions, the PCQI designed a validation study to assess the efficacy of 30 ppm and 50 ppm PAA to significantly minimize or prevent cross-contamination of fresh-cut onions during washing under worst-case conditions as follows:

- Four PAA concentrations were evaluated:
 - 0 ppm PAA (positive control, cross-contamination expected);
 - 30 ppm (target level);
 - 50 ppm (alternative target level); and
 - 300 ppm (negative control, cross-contamination not expected).³¹
- Initial studies were conducted to determine how much PAA should be added to the flume containing fresh-cut yellow onions to achieve the desired PAA concentration in the wash water.
- Following the initial studies, three trials were performed at each PAA concentration (i.e., 0, 30, 50, 300 ppm) under the conditions that would likely contribute the most to pathogen cross-contamination (e.g., maximum product to water ratio, maximum product feed rate). To determine whether cross-contamination occurred, fresh-cut red onions inoculated with *E. faecium* NRRL B-2354 were washed with uninoculated fresh-cut yellow onions. For the three trials at each PAA concentration, once the system was fully loaded with product, samples of yellow onions were processed to determine the presence of *E. faecium* NRRL B-2354. These sample results indicated whether cross-

³¹ 21 CFR 173.315(a)(5) states that peroxyacetic acid concentrations for use on fruit and vegetables that are not RACs are not to exceed 80 ppm in wash water. However, the specific wash water antimicrobial this facility is using has a food contact substance notification that allows for a concentration of up to 300 ppm in their application. For information on food contact substance notifications, see our "Guidance for Industry: Antimicrobial Food Additives" (Ref. 42).

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contamination from inoculated fresh-cut red onions to uninoculated fresh-cut yellow onions had occurred.

Upon completion of the experiment, the PCQI determined that:

- Each positive and negative control performed as expected:
 - o In all three trials performed at 0 ppm PAA (positive control), cross-contamination from inoculated fresh-cut red onions to uninoculated fresh-cut yellow onions was observed; and
 - o In all three trials performed at 300 ppm PAA (negative control), no such cross-contamination was observed.
- In one of three trials performed at 30 ppm PAA, cross-contamination from inoculated fresh-cut red onions to uninoculated fresh-cut yellow onions was observed.
- In all three trials performed at 50 ppm PAA, no cross-contamination from inoculated fresh-cut red onions to uninoculated fresh-cut yellow onions was observed.

Because cross-contamination was observed in one trial using 30 ppm but was not observed during any of the three 50 ppm PAA trials, the PCQI determined that a concentration above 30 ppm, and possibly as high as 50 ppm, was necessary for their specific operation. Rather than conduct additional studies to determine whether a concentration between 30 ppm and 50 ppm would be adequate for their operation, the PCQI established a minimum concentration of 50 ppm PAA as the critical limit for their system.

The PCQI determined that targeting an operating range of 60 to 80 ppm PAA in wash water would provide assurance that the concentration of PAA would be achieved and maintained above the critical limit of 50 ppm.

7. Determining the worst-case conditions for organic load in the wash system

a. General

Because organic load can negatively impact the concentration of an antimicrobial in the wash water, your validation process should:

- determine the worst-case operating conditions for organic load (i.e., the conditions under which the organic load in the water accumulated most rapidly and to the greatest level); and
- determine the timeframe to reach the greatest organic load under worst-case operating conditions.

b. Example 1: Use of sodium hypochlorite in wash water for fresh-cut leafy greens

The PCQI determined that product feed rate and product cut size were process parameters that would impact the rate of accumulation of organic load and the maximum level of organic load in the flume water. Based on information in the scientific literature (Ref. 39), the PCQI hypothesized that using the fastest feed rate and the smallest cut size would result in worst-case conditions for organic load. By using worst-case conditions for these parameters in validation studies, the PCQI made sure that these parameters would not need to be controlled during production.

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The PCQI conducted a study to determine when organic load reached its greatest level. The PCQI set the speed of the conveyor feeding product into the shredder at the maximum speed used (6,000 pounds/hour) and set the shredder to the smallest product cut size used (0.5 inches) during a four-hour study in which organic load was measured using chemical oxygen demand. The findings of this study demonstrated that the organic load that accumulated in the water plateaued at a chemical oxygen demand of 2,100 mg O₂/L after 2 hours of processing.

c. Example 2: Use of PAA in wash water used for fresh-cut onions

Based on the scientific literature, the PCQI found that PAA is only marginally sensitive to most organic loads present in the water, but it is more sensitive to an organic load associated with sulfur-rich produce (such as onions) (Ref. 39).

The PCQI determined that product feed rate and produce cut size were process parameters that would impact the rate of accumulation of organic load and the maximum level of organic load in the flume water. Based on information in the scientific literature (Ref. 39), the PCQI hypothesized that using the fastest feed rate and the smallest cut size would result in worst-case conditions for organic load. By using worst-case conditions for these parameters in validation studies, these parameters would not need to be controlled during production.

The PCQI conducted a study to determine when organic load reached its greatest level. The PCQI set the speed of the conveyor feeding product into the dicer at the maximum speed used (2,200 pounds/hour) and set the dicer to the smallest product cut size used (0.25 inches) during a four-hour study in which organic load was measured using chemical oxygen demand. During this study, PAA was manually dosed into the wash water to achieve a level of 300 ppm, with the PAA concentration measured by titration every 30 minutes. The PCQI decided to dose the wash water with PAA during this evaluation of a worst-case scenario to account for the expected increase in chemical oxygen demand following the addition of PAA to wash water based on the scientific literature (Ref. 50). The findings of this study demonstrated that the organic load that accumulated in the water plateaued at a chemical oxygen demand of 1,100 mg O₂/L after 1.5 hours of processing.

8. Determining the location and frequency for monitoring the concentration of an antimicrobial substance

a. General

In general, a wash water process control relies on measurement of the level of the antimicrobial substance in the wash water (e.g., by using automatic sensors or by manually sampling and testing) during production runs. Your validation process should provide information that enables you to determine the appropriate frequency of monitoring to obtain such measurements and the appropriate location within the wash water system where you will conduct the monitoring.

- If monitoring will be continuous (e.g., through sensors placed in the wash water system) rather than be performed by manually collecting samples and testing them, it is not necessary to determine the appropriate frequency of monitoring during the validation process.
- If monitoring will be performed manually, you should determine the minimum frequency of monitoring as part of your validation process. We recommend that you monitor more frequently than the minimum frequency determined during process validation in order to

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provide additional assurance that antimicrobial levels do not fall below critical limits in the time period between sampling events. To determine the adequate frequency of monitoring, you could determine the rate of degradation of the antimicrobial; a higher antimicrobial degradation rate can be expected to correspond to an increased monitoring frequency.

Your validation process should address the location for monitoring. In general, this location is where the antimicrobial will be at its lowest level (often at the end of the line where flume water is returned to the recirculation tank, because this is the farthest point from where the antimicrobial is added, and the antimicrobial will have been exposed to organic material in the wash water for the longest time). One way to determine this location is to conduct a validation study that measures the antimicrobial concentration at various points in the system, along with measuring other factors (e.g., organic load) that could impact the level of the antimicrobial and help you understand how the system is operating.

b. Example 1: Use of sodium hypochlorite in wash water for fresh-cut leafy greens

During the production process, the concentration of free chlorine and the pH will be continuously monitored by sensors as part of an automated system that adds additional hypochlorite or phosphoric acid when the concentration of free chlorine or the pH fall outside specified operating limits. Therefore, the PCQI decided that it was not necessary to evaluate the frequency of monitoring as part of the validation process.

To determine the location for the automated system sensors used to continuously monitor the concentration of free chlorine and the pH, the PCQI decided to conduct a validation study at the critical limit of 10 ± 5 ppm rather than the normal operating level of 25 ± 5 ppm. During the study, the pH was allowed to vary with an upper critical limit of 7.5. The PCQI repeated the trial three times to determine the best location for the automated system as follows:

- The wash water system was mapped using as many calibrated sensors as possible throughout the water system to measure free chlorine, pH, and temperature. One set of sensors was part of the automatic monitoring system that will operate during normal operating conditions. Additional sets of sensors were temporary units used only for this study. The PCQI hypothesized that the end of the production line would be the location where the free chlorine would be the lowest and pH would diverge the most from the desired pH. Accordingly, the PCQI placed the automatic monitoring system sensors at the end of the flume line. The PCQI selected areas of minimal water movement (where water and the added substances are not replenished as often) for additional measurements with the temporary sensors to compare these readings with the automated sensor readings at the end of the flume line.
- The system was started with sodium hypochlorite being fed until all free chlorine sensors were reading no lower than 10 ppm free chlorine. Fresh-cut lettuce was then fed into the system at the fastest rate and smallest cut size (i.e., 6,000 pounds/hour and 0.5 inches, respectively).
- During study, the PCQI expected variation in:
 - o free chlorine levels (due to depletion during production and adjustments by the automated monitoring system); and

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- o pH (due to automatic adjustments to add phosphoric acid based on input from the automated monitoring sensors).
- During the study, the readings from each free chlorine and pH sensor were recorded on a continuous basis. To verify that the operating conditions were as intended and that the greatest organic load was achieved during the study, chemical oxygen demand of the flume water was determined manually from samples collected from the end of the flume line every 30 minutes.
- For the study, the system was run with fresh-cut romaine lettuce for 3 hours (i.e., 1 hour past the point where the data from the organic load study demonstrated that the organic load would plateau).

From this experiment the PCQI identified the sensor location(s) where free chlorine concentrations were consistently at the lowest levels, and where the pH levels diverged the most from the desired pH (6.0), during the three individual trials. The PCQI confirmed that the end of the flume line was the best location to place the free chlorine and pH sensors for the automated monitoring system. The PCQI also confirmed that their automated system (which monitors continuously) was capable of maintaining the free chlorine and pH conditions set under the worst-case conditions.

c. Example 2: Use of PAA in wash water used for fresh-cut onions

The PCQI determined that process validation needed to address:

- the frequency of monitoring during normal production (because the procedure for monitoring during normal operating conditions would be a manual operation in which water samples are collected and then tested by titration for PAA); and
- the location to monitor during normal production.

The PCQI decided to document the operating conditions during the study:

- by measuring PAA concentration (by titration) and measuring organic load (by chemical oxygen demand); but without monitoring:
 - o pH (because the pH is decreased with the addition of PAA and because pH was consistently in the expected range during worst-case conditions).

The PCQI decided to determine the frequency of, and location for, monitoring by measuring the degradation rate of PAA during a three-hour study conducted under worst-case operating conditions for organic load (setting the speed of the conveyor feeding product into the dicer at the maximum speed (2,200 pounds/hour) and setting the dicer to the smallest product cut size (0.25 inches).

- First, the PCQI needed to determine where to collect samples during the study. To do so, the PCQI used personnel knowledge about the operation to identify specific sampling locations along the flume line that are likely to show the lowest PAA levels, including locations farthest from where the antimicrobial is dosed, areas of minimal water movement, and at the flume water return to the recirculation tank (i.e., at the end of the flume line).

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- Next, the PCQI needed to decide the concentration of PAA during the study. The PCQI decided to conduct the study at the operating range of 60 to 80 ppm with a target concentration of 70 ppm.
- During the first phase of the study, personnel took two flume water samples at each location every 15 minutes after the first hour of the processing run (one to measure PAA and the other to test organic load). The output of this first phase of the study was the determination of the location resulting in the lowest levels of PAA, which was at the flume water return to the recirculation tank (i.e., at the end of the line).
- During the second phase of the study:
 - o Personnel collected samples every 5-10 minutes, but only at the flume water return to the recirculation tank;
 - o The degradation rate was determined by discontinuing PAA dosing to determine the minimum time before the PAA level dropped below 50 ppm; and
 - o The degradation rate was used to determine the sampling interval necessary to ensure that a drop below the minimum PAA concentration would be detected.

Based on the findings of the study, the PCQI determined that:

- the location for monitoring during production is at the end of the flume line because this was the point that consistently demonstrated the lowest PAA levels in the study; and
- the minimum frequency of monitoring during production is every 30 minutes to ensure antimicrobial levels will not fall below the critical limit in the time period between sampling events.

9. Summary and conclusions of the validation studies

a. Example 1: Use of sodium hypochlorite in wash water for fresh-cut leafy greens

In summary, the PCQI for the fresh-cut leafy greens processor approached process validation for their wash water process control as follows:

- determined the commodity for validation based on information about the commodities that are processed;
- determined the target microorganism for their validation study from the pathogens identified in their hazard analysis as requiring a preventive control, and, to the extent practicable, which pathogen has the greatest resistance to sodium hypochlorite;
- used the scientific literature to determine critical limit for the concentration of free chlorine;
- used the scientific literature to determine the upper critical limit for the pH level;
- conducted studies to determine the timeframe for the greatest organic load to be reached under worst-case operating conditions;
- conducted studies to determine the location in the processing line to place sensors that automatically monitor free chlorine and pH during production; and

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- noted that the frequency of monitoring free chlorine and pH would be continuous and, with that automated system, determined that the critical limits for free chlorine and pH can be maintained during production.

The conclusions of the process validation are limited to the conditions under which the trials were performed. In this example, the outputs of the validation process are:

- fresh-cut romaine as the commodity for validation;
- *E. coli* O157:H7 as the target microorganism;
- a minimum free chlorine concentration of 10 ppm and a maximum pH of 7.5 as the critical limits (as determined from the literature);
- a timeframe of 2 hours for greatest organic load to be reached under the worst-case operating conditions (maximum speed of the conveyor feeding product into the shredder (6,000 pounds/hour) and the smallest product cut size (0.5 inches));
- the end of the flume as the location where the free chlorine concentration is consistently at the lowest level, and where the pH diverges the most from the desired pH (6.0) in the recirculating water system, during the worst-case conditions; and
- It was not necessary to determine the appropriate frequency of monitoring free chlorine concentration and pH level during the validation process because there is an automated system that monitors continuously.

b. Example 2: Use of PAA in wash water used for fresh-cut onions

The PCQI for the fresh-cut onions processor approached process validation for their wash water process control as follows:

- determined the commodity for validation based on information about the commodities that are processed;
- determined the target microorganism for their validation study from the pathogens identified in their hazard analysis as requiring a preventive control, and, to the extent practicable, which pathogen has the greatest resistance to PAA;
- conducted studies to determine critical limits for the concentration of PAA;
- conducted studies to determine the timeframe for the greatest organic load to be reached under worst-case operating conditions;
- conducted studies to determine the location in the processing line for monitoring PAA during production by manually collecting samples of wash water and measuring them for the concentration of PAA; and
- conducted studies to determine the frequency of monitoring the PAA concentration during production that will be used to ensure that a PAA concentration above the critical limit will be maintained.

The conclusions of the process validation are limited to the conditions under which the trials were performed. In this example, the outputs of the validation process are:

- fresh-cut yellow onions as the commodity for validation;
- *Salmonella* as the target microorganism, and *Enterococcus faecium* NRRL B-2354 as a surrogate;

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- a critical limit of 50 ppm PAA;
- a timeframe of 1.5 hours for greatest organic load to be reached under worst-case operating conditions (dicer set at the maximum speed (2,200 pounds/hour) and the dicer set to the smallest product cut size (0.25 inches));
- the flume water return as the location where the PAA is consistently at the lowest level and thus where PAA monitoring during operation will occur; and
- a monitoring frequency of every 30 minutes during operation.

10. Records documenting validation

a. General

Validation is a verification activity that you must document in your records (see 21 CFR 117.155). The records you keep to document validation of a process control depend on your approach to validation of the process control. For example:

- If you rely in part on scientific literature as a basis for determining critical limits for a process parameter, you should retain that scientific literature as a record.
- If you conduct a study, you should establish and maintain a validation report that describes the process or system being validated, the objective of the study, the experimental design of the study, the data generated during the study, and the conclusion(s) of the study.

b. Example 1: Use of sodium hypochlorite in wash water for fresh-cut leafy greens

The processor maintains the following records applicable to its validation procedure:

- The scientific publications that identify 10 ppm as the minimum concentration of free chlorine to be effective as a process control when pH is controlled; and
- The validation report that includes the description of the system evaluated (including the product used for validation), objective, design, results, and conclusions of the validation studies to determine:
 - o the timeframe to reach greatest organic load; and
 - o the location to place sensors to measure free chlorine and pH.

c. Example 2: Use of PAA in wash water used for fresh-cut onions

The processor maintains the following records applicable to its validation procedure:

- The instructions for use provided by the vendor of PAA;
- The scientific publications that provide a basis for use of *E. faecium* NRRL-2354 as a surrogate microorganism for validation studies to determine critical limits for PAA; and
- The validation report that includes the description of the system evaluated (including the product used for validation), objective, design, results, and conclusions of the validation studies to determine:
 - o critical limits for PAA;
 - o the timeframe to reach greatest organic load;

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- o the frequency of monitoring; and
- o the location to collect samples of wash water to monitor for the concentration of PAA.

E. Establish and Implement Preventive Controls, Preventive Control Management Components, and Associated Records

1. General

Part 117 specifies PCHF requirements for preventive controls (including specific requirements applicable to process controls) (21 CFR 117.135), preventive control management components (i.e., monitoring, corrective actions, verification (including validation), and associated records) (21 CFR 117.140, 117.145, 117.150, 117.155, 117.160, and 117.165), and recordkeeping (part 117, subpart F). See Appendix 2 for a brief description of these requirements.

Sections XV.A through XV.C provide general recommendations applicable to a wash water process control and section XV.D provides recommendations for validation of a wash water process control, including recommendations to identify parameters associated with the control of biological hazards (as required by 21 CFR 117.135(c)(1)(i)) and the maximum or minimum value (i.e., critical limits), or combination of values, to which a parameter must be controlled to significantly minimize or prevent a biological hazard requiring a process control (as required by 21 CFR 117.135(c)(1)(ii)). The examples discussed in section XV.D emphasize:

- the role of establishing operating limits that result in the implementation of corrections to provide assurance that the critical limits for a wash water process control will be achieved and maintained during your operations; and
- the types of monitoring systems (i.e., continuous monitoring and manual monitoring) that enable you to make adjustments, when necessary, to avoid having a process parameter fall outside critical limits.

Examples of corrective action procedures to ensure that appropriate action is taken to identify and correct a problem that has occurred with implementation of a wash water process control and reduce the likelihood that the problem will recur include:

- Empty the processing line;
- Clean and sanitize all affected FCSs (e.g., wash, post-wash);
- Determine what caused the problem; and
- Determine what actions can be taken to prevent the problem from happening again (e.g., replace faulty sensors; increase the frequency of manual monitoring; decrease the product feed rate).

If you are unsure whether affected food is adulterated under section 402 of the FD&C Act, a corrective action procedure step would be to identify the affected food and prevent it from entering commerce. For example, you could segregate the product back to the last time the monitored parameters were within the critical limits and either destroy the segregated product or divert it to animal food (usually for animals other than pets), if it is safe or suitable (e.g., not

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adulterated) for the intended animal as long as you comply with requirements applicable to animal food.³²

Importantly, rewashing produce that has been exposed to wash water in which the antimicrobial substance deviated outside of the critical limits is not an appropriate corrective action. Such conditions could have resulted in the spread of pathogens to previously uncontaminated produce, and a rewash step would not ensure that pathogens are removed from the contaminated produce.

Examples of activities that you could conduct to verify implementation and effectiveness of a wash water process control include:

- calibrating process monitoring instruments (such as antimicrobial sensors) and verification instruments (or checking them for accuracy); and
- review of records.

2. Example 1: Use of sodium hypochlorite in wash water for fresh-cut leafy greens

The processor establishes the process control (see Appendix 5 for a summary of the process control and the associated PC management components) as follows:

- The processor uses liquid sodium hypochlorite and phosphoric acid as the wash water process control;
- The processor establishes a critical limit of 10 ppm, and an operating limit of 20 ppm, for free chlorine;
- The processor establishes a maximum critical limit of 7.5 for pH and a minimum operating limit of 4.0 and maximum operating limit of 7.2 for pH; and
- The processor begins production by feeding sodium hypochlorite until the concentration of free chlorine reaches a startup concentration of 25 ± 5 ppm, and feeding phosphoric acid until the pH is approximately 6.0.

The processor establishes and implements the associated preventive control management components as follows:

- Monitoring Procedures:
 - o The processor establishes and implements a continuous monitoring system for free chlorine and pH using an automated system that has sensors at the end of the flume line to measure free chlorine concentration and pH.
- Corrective Action Procedures:
 - o If, despite the adjustments (corrections) by the system to correct deviations from the operating limits, the free chlorine concentration drops below the critical limit of 10 ppm, or if the pH level exceeds the upper critical limit of 7.5, the conveyor feeding

³² See the discussion in section XI of CGMP requirements for holding and distribution of human food by-products for use as animal food (21 CFR 117.95). If your corrective action plan will include diversion to animal food, you should periodically check our website for the most current policy applicable to such diversion and consult with the entity that will receive the diverted produce regarding the suitability of your diverted food for the animal species that will consume it.

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- the fresh-cut leafy greens into the flume line stops automatically.³³ The processor then takes corrective actions by removing product from the system, cleaning and sanitizing the system, and restarting the system. The processor segregates the product back to the last time the monitored parameters were within the critical limits. Because the segregation is a precaution associated with falling outside a critical limit (rather than a known or suspected instance of product contamination), the processor diverts the product to a pre-determined safe and suitable animal food use in accordance with their plan; and
- o The processor drains and replaces the flume water every 8 hours of operation or daily, whichever occurs first.
 - Verification Procedures:
 - o On a weekly basis, a QA Technician checks the accuracy of sensors used for monitoring free chlorine concentration by comparing in-plant sensor readings with those of a calibrated benchtop spectrophotometer and, if not accurate, has them recalibrated (or replaced if they cannot be recalibrated) and records the results;
 - o On a weekly basis, a QA Technician checks the accuracy of sensors used for monitoring the pH level by comparing in-plant sensor readings with those of a calibrated pH meter and, if not accurate, has them recalibrated (or replaced if they cannot be recalibrated) and records the results;
 - o Twice per shift, the QA Technician verifies the free chlorine concentration reading displayed by the continuous monitoring device using a titration test kit and records the results in the process log;
 - o Twice per shift, the QA Technician verifies the pH level reading displayed by the continuous monitoring device using a calibrated pH meter and records the results in the process log;
 - o Within a week of the creation of calibration and accuracy check records, the PCQI reviews the records and initials and dates them;
 - o Within a week of the creation of process logs, the PCQI reviews the results of the verification titration tests for free chlorine and pH tests, and initials and dates them; and
 - o Within a week of a problem requiring a corrective action, the PCQI reviews the corrective action records and initials and dates them.
 - The processor establishes and maintains the following implementation records that are initialed and dated by the PCQI to document review of the records:
 - o records of accuracy checks and calibration records for monitoring/measuring devices;
 - o continuous monitoring records documenting free chlorine concentration and pH level that are automatically generated from the readings on the automated sensors;
 - o free chlorine titration and pH level verification test records; and
 - o corrective action records.

³³ If the free chlorine concentration falls to the operating limit of 20 ppm, or the pH exceeds the operating limit of 7.2, the system makes corrections by automatically adding liquid sodium hypochlorite or phosphoric acid as applicable.

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- Records included in the food safety plan:
 - o the written process control as required by § 117.135(b);
 - o the written procedures for monitoring (e.g., the procedures for automatic monitoring of free chlorine and pH) as required by § 117.145(a);
 - o the written corrective action procedures as required by § 117.150(a)(1); and
 - o the written verification procedures (e.g., calibration procedures, records review) as required by § 117.165(b).

3. Example 2: Use of PAA in wash water used for fresh-cut onions

The processor establishes the process control (see Appendix 6) as follows:

- The processor uses PAA as wash water process control;
- The processor establishes a critical limit of 50 ppm, and an operating range of 60 to 80 ppm, for the concentration of PAA; and
- The processor manually adds PAA at the beginning of production to achieve a startup concentration of approximately 70 ppm.

The processor establishes and implements the associated preventive control management components as follows:

- Monitoring Procedures:
 - o The processor establishes and implements a manual monitoring system in which personnel take water samples every 30 minutes at the end of the flume line and test the samples for PAA using a titration method.
- Corrective Action Procedures:
 - o If, despite the manual adjustments (corrections) to the system to correct deviations from the operating limit, the PAA drops below the critical limit of 50 ppm, the processor stops the processing line manually and takes corrective actions by removing product from the system, cleaning and sanitizing the system, and restarting the system.³⁴ The processor segregates the product back to the last time the monitored parameters were within the critical limits and diverts the product to a pre-determined safe and suitable animal food use in accordance with their plan; and
 - o The processor drains and replaces the flume water every 8 hours of operation or daily, whichever occurs first.
- Verification Procedures:
 - o Within a week of the creation of process logs documenting the titration tests for PAA, the PCQI reviews, initials, and dates them; and
 - o Within a week of a problem requiring a corrective action, the PCQI reviews the corrective action records and initials and dates them.

³⁴ When the results for PAA demonstrate that the PAA level has dropped below 60 ppm, the processor makes a correction by manually adding additional PAA to bring the concentration back to 60 to 80 ppm (the operating range).

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- The processor establishes and maintains the following implementation records that are initialed and dated by the PCQI to document review of the records:
 - o monitoring records documenting PAA concentration generated by testing manually collected samples using a titration method; and
 - o corrective action records.
- Records included in the food safety plan:
 - o the written preventive control as required by § 117.135(b);
 - o the written procedures for monitoring (e.g., the procedures for sampling and testing the PAA concentration in the wash water) as required by § 117.145(a);
 - o the written corrective action procedures as required by § 117.150(a)(1); and
 - o the written verification procedures (e.g., records review) as required by § 117.165(b).

XVI. Examples of a Supply-Chain Program

A. Requirements of Subpart G – Supply-Chain Program

Subpart G of part 117 generally requires that a receiving facility 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). For the purposes of subpart G, food distributors, brokers, aggregators, labelers/relabelers and packers/repackers would not meet the definition of “supplier” unless they otherwise perform a manufacturing/processing activity on the food that is more than de minimis in nature.

If you are a manufacturer/processor of fresh-cut produce and are subject to subparts C and G of part 117, you are a receiving facility as defined in 21 CFR 117.3. Your suppliers generally 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 Rule (PSR) (21 CFR part 112).

An exception to coverage under the PSR that is relevant to this guidance is for RACs that you receive that are designated as “rarely consumed raw” in 21 CFR 112.2(a). In general, you do not have to establish a supply-chain program for fresh-cut produce that is included in the list but you should establish a supply-chain program for control of pathogens in fresh-cut produce that is not listed as rarely consumed raw in 21 CFR 112.2(a)(1). However, there may be circumstances in which you have knowledge that your fresh-cut produce is not consumed without a kill-step that is sufficient to significantly minimize microorganisms of public health significance (i.e., it is not ready-to-eat), even though it is not listed as a rarely consumed raw commodity in the PSR. In these circumstances, it would not be necessary to implement a supply-chain program for control of pathogens in that product. In rare instances, you may have knowledge that your fresh-cut

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produce that is included in the rarely consumed raw list is, in fact, consumed without a kill-step that is sufficient to significantly minimize microorganisms of public health significance. In these circumstances, it would generally be necessary to implement a supply-chain program for control of pathogens in that product. In any case, you should make your own determination about whether your fresh-cut produce requires a supply-chain-applied control for hazards other than pathogens (e.g., chemical or physical hazards).

In other cases, your supplier may not be subject to the PSR or may not be subject to the relevant portions of that rule (i.e., your supplier is not a covered farm because it is subject to an exemption or qualified exemption related to its size and/or pattern of distribution, in accordance with §112.4(a) or §112.4(b) and §112.5). The requirements for your supply-chain program differ depending upon which of these circumstances apply to your suppliers. We provide examples below in the next section.

Subpart G of part 117 specifies:

- The requirement to establish and implement a supply-chain program;
- Responsibilities of the receiving facility;
- Requirements for:
 - Using approved suppliers;
 - Determining appropriate supplier verification activities (including determining the frequency of conducting the activity);
 - Conducting supplier verification activities for raw materials and other ingredients;
 - Using an onsite audit; and
 - Maintaining a records program.

You should refer to subpart G for the complete requirements. Chapter 15 of the PCHF draft guidance (Ref. 16) contains discussion to help receiving facilities generally comply with the requirements of subpart G for establishing and implementing a supply-chain program for their suppliers.

B. Four Examples of Fresh-Cut Processing Facilities' Produce Sourcing

The purpose of these four examples is to illustrate how you could establish and implement a supply-chain program for the production of fresh-cut produce. In these examples, the fresh-cut processing facilities produce sliced apples, diced onions, cubed melon, and cut lettuce, respectively, and receive produce RACs as follows:

- Example 1: Apples from a local primary production farm that is not a covered farm under the PSR (Table 2);
- Example 2: Onions from two domestic primary production farms that are subject to the PSR (Table 3);
- Example 3: Melons from a U.S. distribution center that imports the melons from three foreign primary production farms that are subject to the PSR (Table 4); and

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- Example 4: Lettuce from a domestic primary production farm that is subject to the PSR, where the harvesting operations are conducted by a business entity separate from the grower (Table 5).

C. The Supply-Chain Program Requirements for Four Examples of Fresh-Cut Processing Facilities

1. Use Approved Suppliers

In each of these examples, the receiving facility approves its produce suppliers and establishes and follows written procedures for receiving the produce (21 CFR 117.420). The written procedures include completing a checklist at each receipt to document that the incoming produce is received only from the farms that have been approved as suppliers.

The farms are the “suppliers” of produce to the fresh-cut (receiving) facility, as that term is defined by the PCHF regulation (i.e., because the farms manufacture/process the food, raise the animal, or grow the food that is provided to the 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 (see 21 CFR 117.3)).

2. Conducting Supplier Verification Activities

As specified in 21 CFR 117.410(b), appropriate supplier verification activities include:

- Onsite audits;
- Sampling and testing of the raw material or other ingredient;
- Review of the supplier’s relevant food safety records; and
- Other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient.

In each of these examples, in approving suppliers and determining the appropriate supplier verification activities (as required by 21 CFR 117.410(d)), the PCQI considers:

- the results of the PCQI’s own hazard analysis, including the nature of the hazard the supplier is controlling;
- the supplier’s procedures, processes, and practices related to the safety of the produce;
- applicable FDA food safety regulations and information relevant to the supplier’s conformance with those regulations; and
- the supplier’s food safety history relevant to the produce that the receiving facility receives from the supplier (including available information about results from testing the produce for hazards, audit results relating to the safety of the food, and responsiveness of the supplier in correcting problems).

In each of these examples, the PCQI conducted a hazard analysis and determined that pathogenic bacteria (such as pathogenic *E. coli*, *Salmonella* spp., and *L. monocytogenes*) on incoming produce RACs are a hazard requiring a supply-chain-applied control. The PCQI determined that

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the fresh-cut produce items are ready to eat and that their in-house preventive controls (e.g., antimicrobial treatment of wash water, sanitation, environmental monitoring) are insufficient to ensure product safety without on-farm control of pathogens, necessitating supply-chain programs for the products.

In all examples except for the first example (in which the supplier of apples is not a covered farm for the purpose of the PSR), the PCQI determined that an onsite audit of the supplier was an appropriate annual verification activity because consumption of produce contaminated with hazards such as pathogenic *E. coli*, *Salmonella* spp., *L. monocytogenes*, and *Cyclospora cayetanensis* can result in serious adverse health consequences or death to humans (SAHCODH). For such SAHCODH hazards, generally the appropriate supplier verification activity is an onsite audit of the supplier, and the audit generally must be conducted by a qualified auditor (as defined in 21 CFR 117.3), before using the raw material or other ingredients from the supplier and at least annually thereafter (21 CFR 117.430(b)(1)).³⁵

In these examples, the receiving facilities annually review FDA Warning Letters (Ref. 91), Import Alerts (Ref. 92), recalls, state inspection reports and enforcement actions, and other reliable industry specific information (e.g., from the USDA, CanadaGAP, or other government agencies' audit standards) 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.

In these examples, for each supplier the receiving facilities annually review the results of past audits and sample analyses, where relevant, and consider the responsiveness of the supplier in correcting any past problems.

Tables 2 through 5 summarize the supplier approval and verification activities and the records of the fresh-cut (receiving) facility for the indicated commodities.

³⁵ See 21 CFR 117.430(b)(2) and (d) and 117.435(c) for an alternative to an audit that may be suitable under certain circumstances.

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Table 2. Example of Supplier Approval and Verification Activities and Records for apples from local farms not covered by the PSR

Supplier Approval Activities	Supplier Verification Activities	Records
Before first receiving apples from the supplier, the PCQI obtains written assurance that the apples are not subject to the PSR in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5, and that the farm acknowledges that its apples are subject to section 402 of the FD&C Act (21 CFR 117.410(d)(2)(ii)).	Annually (by December 31) receives written assurance that the apples are not subject to the PSR. (21 CFR 117.430(d)(1)). Every two years, receives from the farm an acknowledgment that its apples are subject to section 402 of the FD&C Act (21 CFR 117.430(d)(2)).³⁶	Written supply chain program (21 CFR 117.475(c)(1)) Documentation of the approval of each supplier (21 CFR 117.475(c)(3)) Procedures for receiving apples (21 CFR 117.420(b)(2) and 117.475(c)(4)) Receiving checklists documenting that the apples were received from an approved supplier (21 CFR 117.475(c)(5)) Copies of the assurances and acknowledgements provided by the supplier (21 CFR 117.475(c)(13)) Documentation of actions taken with respect to supplier non-conformance (21 CFR 117.475(c)(16))

If the supplier is a farm that grows produce and is not a covered farm under the PSR, the receiving facility is not required to perform annual audits of that supplier to meet the supplier verification requirements of 21 CFR 117.430 (see 21 CFR 117.430(d)). Such is the case for the apples received by the receiving facility in this example, which receives them from a primary production farm that (in the previous three years) has \$25k or less in annual produce sales,³⁷ and is thus exempt from the requirements of the PSR. In this case, the receiving facility instead must obtain written assurance that the raw material or other ingredient provided by the supplier is not subject to the PSR before first approving the supplier and, on an annual basis thereafter, by

³⁶ If the PCQI concludes that this provides insufficient assurance of the safety of the incoming produce, the processor should take additional steps to provide added assurance (e.g., a discussion with the owner of the farm about their approach to producing safe product).

³⁷ See <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs> for information on FDA Food Safety Modernization Act (FSMA) inflation-adjusted cut-offs.

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December 31 of each calendar year. If the receiving facility chooses this option, it must also obtain written assurance, at least every two years, that the farm acknowledges that its food is subject to section 402 of the FD&C Act (or, when applicable, that its food is subject to relevant laws and regulation of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

Table 3. Example of Supplier Approval and Verification Activities and Records for onions from two domestic primary production farms that are subject to the PSR

Supplier Approval Activities	Supplier Verification Activities	Records
Before first purchasing and receiving onions from the suppliers, the receiving facility's auditing team performs an initial audit of the two onion supplier farms (21 CFR 117.410(b)(1)). ³⁸	On an annual basis, the receiving facility's auditing team performs an audit of the supplying farms and confirms that the audits continue to show compliance with the PSR (21 CFR 117.430(b)(1)(i)).	Written supply chain program (21 CFR 117.475(c)(1)) Documentation of the approval of each supplier (21 CFR 117.475(c)(3)) Procedures for receiving onions (21 CFR 117.420(b)(2) and 117.475(c)(4)) Receiving checklists documenting that the onions were received from approved suppliers (21 CFR 117.475(c)(5)) Copies of the audits and the PCQI's review and assessment of audit reports (21 CFR 117.475(c)(7) and 117.475(c)(9)) Documentation of actions taken with respect to supplier non-conformance (21 CFR 117.475(c)(16))

In this example, both onion suppliers are domestic farms subject to the PSR. Because the receiving facility has determined that pathogenic bacteria on incoming onions represent a SAHCODH hazard requiring a supply-chain-applied control, annual onsite audits conducted by qualified auditors are the appropriate supplier verification activity. The receiving facility's

³⁸ Generally, the audits must consider the PSR and should include an assessment of the farm's procedures, processes, and practices during its growing, harvesting, and packing operations related to compliance with that regulation.

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auditing team conducts these audits to verify that the farms' procedures, processes, and practices during growing, harvesting, and packing operations comply with the PSR requirements.

Table 4. Example of Supplier Approval and Verification Activities and Records for cantaloupes from a U.S. distribution center that imports the melons

Supplier Approval Activities	Supplier Verification Activities	Records
Before first receiving cantaloupes from the distributor, the PCQI receives from the distributor and reviews (and documents the review) the distributor's program for approving and verifying their suppliers. This review includes the conclusions of a third-party audit that the distributor (an importer) obtained in approving and verifying its foreign suppliers under its FSVP (21 CFR 1.506).³⁹	On an annual basis, the PCQI receives from the distributor and reviews (and documents the review) the conclusions of a third-party audit of the supplying farms conducted under the distributor's FSVP (21 CFR 1.506(d)(3) and 21 CFR 117.430(b)(1)(i)).	Documentation obtained from the distributor of its written foreign supplier verification program (21 CFR 1.506(a)(1)) Documentation of the approval of each grower (21 CFR 117.475(c)(3)) Procedures for receiving cantaloupes (21 CFR 117.420(b)(2) and 117.475(c)(4)) Receiving checklists documenting that the cantaloupes were received from approved suppliers (21 CFR 117.475(c)(5)) Documentation obtained from the distributor showing copies of the third-party audits conducted under 21 CFR 1.506(d)(3) (21 CFR 117.475(c)(7)) Documentation of the PCQI's review and assessment of audit reports supplied by the distributor (21 CFR 117.475(c)(9)) Documentation of actions taken with respect to supplier non-conformance (21 CFR 117.475(c)(16))

³⁹ Generally, the audits must consider the PSR and should include an assessment of the farm's procedures, processes, and practices during its growing, harvesting, and packing operations related to compliance with that regulation.

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In this example, the foreign farms that grow the melons are the suppliers to the fresh-cut facility. The receiving facility does not directly import cantaloupe, instead purchasing from a U.S. distributor of imported melon. The melon distributor is not subject to the PSR (i.e., because it is not a farm), but is subject to the PCHF Regulation (i.e., because it holds food for consumption in the U.S. and is not covered by any of the exemptions or partial exemptions established by that regulation). However, the melon distributor is not a “receiving facility” and thus is not required by the PCHF regulation to establish and implement a supply-chain program (i.e., because it does not manufacture/process a raw material or other ingredient that it receives from a supplier (see 21 CFR 117.3)). The melon distributor is also not the “supplier” of the melon, as defined by the PCHF regulation.

In this example, the U.S. distributor is the importer of the melon and would be subject to provisions or modified provisions of the Foreign Supplier Verification Program in 21 CFR Part 1, subpart L. Guidance on that program is provided in FDA’s Guidance for Industry: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals.

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Table 5. Example of Supplier Approval and Verification Activities and Records for lettuce from a farm that uses a contract harvester

Supplier Approval Activities	Supplier Verification Activities ⁴⁰	Records
Before first receiving lettuce from the supplier, the receiving facility's auditing team performs an initial audit of the lettuce supplier farm (21 CFR 117.410(b)(1)).⁴¹ To verify controls applied by the harvester, the PCQI reviews the harvester's applicable food safety records, sufficient to have adequate assurance that the hazards have been controlled during the covered activities performed by the contract harvester. Examples of such records are: records of required training (e.g., on the hazard posed by <i>Cyclospora</i> for workers who hand harvest the RTE lettuce, certificates of compliance of the quality of water used during harvesting from a public water system; and records of cleaning and sanitizing of harvesting equipment) (21 CFR 117.405(c), and 117.475).	On an annual basis, the receiving facility's auditing team performs an audit of the supplying farm and confirms that the audit shows compliance with the PSR (21 CFR 117.430(b)(1)(i)).	Written supply-chain program (21 CFR 117.475(c)(1)) Procedures for receiving lettuce (21 CFR 117.420(b)(2) and 117.475 (c)(4)) Receiving checklists documenting that the lettuce was received from an approved supplier (21 CFR 117.475(c)(5)) Copies of the audit and the PCQI's review and assessment of audit report (21 CFR 117.475(c)(7) and 117.475(c)(9)) Copies of the PCQI's review of the harvester's records (21 CFR 117.475(c)(9)) Documentation of actions taken with respect to supplier non-conformance (21 CFR 117.475(c)(16))

In this case some of the covered activities of the farm (i.e., harvesting) are performed by an entity other than the farm (i.e., the contract harvester). As such, the contract harvester plays an important role in assuring the safety of the lettuce during the harvest activities. When a supply-

⁴⁰ We do not expect the receiving facility to follow all the requirements of subpart G applicable to "suppliers" when verifying control by another entity in the supply chain (e.g., a harvesting operation). Instead, we expect the receiving facility will take steps such as a review of that entity's applicable food safety records to have adequate assurance that the hazards have been controlled.

⁴¹ Generally, the audits must consider the PSR and should include an assessment of the farm's procedures, processes, and practices during its growing, harvesting, and packing operations related to compliance with that regulation.

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chain-applied control is applied by an entity other than the receiving facility's supplier (e.g., when a contract harvester applies controls to produce covered by part 112, because growing, harvesting, and packing activities are under different management), the receiving facility must 1) verify the supply-chain-applied control; or 2) obtain documentation of an appropriate verification activity from another entity, review and assess the entity's applicable documentation, and document that review and assessment (see 21 CFR 117.405(c)). In this example, the "other entity" could be the supplier farm or a third party.

XVII. Time/Temperature Controls

Time/temperature controls have been used extensively throughout production and storage of fresh-cut produce to prevent microbial growth and extend shelf life. Exposing fresh-cut produce to elevated temperatures for significant periods of time can lead to microbial growth, including growth of bacterial pathogens that could be present. In addition to the exposure times and temperatures, the extent of bacterial growth in fresh-cut produce is influenced by its intrinsic characteristics (such as pH and water activity). Bacterial pathogen growth on fresh-cut produce is of particular concern, in comparison to such growth on intact raw agricultural commodities, because cellular fluids and nutrients released from the produce after its cutting support pathogen growth (Ref. 9). Fresh-cut produce facilities frequently conduct processing operations under refrigeration temperatures throughout the production cycle.

Your hazard analysis should be the basis for determining whether you would establish time/temperature controls as a CGMP measure or as a preventive control. Time/temperature controls can be used to address pathogen growth/toxin production that may occur during production of fresh-cut produce, including during such steps as:

- keeping food at refrigeration temperatures during production, including finished product holding; and
- cooling food down to refrigeration temperatures.

See section IX.C of this guidance for CGMP recommendations to minimize exposure of in-process products, rework, and finished product to unrefrigerated conditions during manufacturing, processing, packing, and holding if specific fresh-cut items can support the rapid growth of undesirable microorganisms.

Additionally, if you determine that a preventive control is necessary to significantly minimize or prevent pathogen growth during refrigerated storage of your fresh-cut produce, we recommend that you refer to 21 CFR 117.206 for activities to ensure the effectiveness of temperature controls, including appropriate preventive control management components. This provision contains modified requirements that apply to a facility solely engaged in the storage of unexposed packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens. However, with respect to management of time/temperature exposure during refrigerated storage at a fresh-cut produce manufacturing facility, the activities in 21 CFR 117.206 can be a reference for effective preventive control management components.

XVIII. Training and Qualifications

A. Training Requirements Specified in Part 117, Subpart A

Part 117 specifies qualifications applicable to all personnel engaged in manufacturing, processing, packing, or holding food (including training in the principles of food hygiene and food safety) and additional qualifications applicable to supervisory personnel (21 CFR 117.4). Part 117 also requires records of training (21 CFR 117.9).

B. Examples of 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 workstation, 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 certain health conditions who handles fresh-cut produce or contacts FCSs or food-packaging materials; and the potential for cross-contamination (e.g., for contaminants on unclean equipment or raw ingredients to be transferred to finished food or FCSs that have already been cleaned or already are in use for production, or cross-contamination via wash water));
- Indications that raw or processed produce is contaminated (e.g., produce that is damaged, rotten, or moldy; produce with animal excreta; produce that has touched/fallen on the floor);
- Preventive measures (i.e., taking measures to prevent or minimize contamination at those points where potential routes of contamination exist); and
- The importance of taking appropriate actions when a problem occurs with a preventive measure.

C. Examples of Training Topics Appropriate to Assigned Duties

A qualified individual under part 117 means personnel qualified by education, training, experience, or a combination thereof. 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. We recommend that you assess personnel knowledge and understanding of

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applicable requirements, and design training to address existing knowledge gaps. For example, CGMP requirements related to handling human food by-products were not traditionally part of GMPs, and therefore employees may benefit from training on this topic. See Table 6 for examples of training topics that could be appropriate for an individual's assigned duties.

Table 6. Examples of Training Topics Appropriate to an Individual's Assigned Duties

Personnel Function	Training Topics
Receiving	Procedures for receipt, handling, and storage of raw produce to ensure that raw produce is appropriately stored before use in production; Procedures for verifying that raw produce and other ingredients are received only from approved suppliers.
Production operations	The control measures employed during production, including the CGMP measures, preventive controls, 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, including procedures applicable to "Clean in Place" and "Clean Out of Place."
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;

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- 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.fspca.net>.

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Appendix 1. Abbreviations Used in This Document

Abbreviation	What It Means
CFR	Code of Federal Regulations
CGMP	Current good manufacturing practice
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
Part 117	Our regulation, established in 21 CFR 117, titled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food”
PCHF	Preventive Controls for Human Food
PC management components	Monitoring, corrective actions and corrections, and verification (with associated records) (see 21 CFR 117.140)
PCQI	Preventive Controls Qualified Individual
PSR	Produce Safety Rule
QA	Quality Assurance
RAC	Raw agricultural commodity
RTE	Ready-to-eat

Appendix 2. Regulatory Framework of Part 117

A. Terms Applicable to Part 117

See [§ 117.3](#) for terms defined in part 117.

See the PCHF draft guidance (Ref. 16) for terms that are applicable to part 117, but not defined in [§ 117.3](#).

B. CGMP requirements of Part 117

This guidance provides recommendations for measures to comply with the following part 117 CGMP requirements applicable to:

- personnel ([§ 117.10](#));
- plant and grounds ([§ 117.20](#))
- requirements for sanitary operations ([§ 117.35](#)) and sanitary facilities ([§ 117.37](#));
- requirements for equipment and utensils ([§ 117.40](#));
- requirements for processes and controls ([§ 117.80](#)), including requirements for:
 - o general processes and controls ([§ 117.80\(a\)](#));
 - o raw materials and other ingredients ([§ 117.80\(b\)](#)); and
 - o manufacturing operations ([§ 117.80\(c\)](#)).

C. PCHF Requirements of Part 117

This guidance provides recommendations that address the following PCHF requirements:

- requirements for conducting a hazard analysis to determine whether there are any hazards (including environmental pathogens) requiring a preventive control ([§ 117.130](#)), which include:
 - o requirements for hazard analysis ([§ 117.130\(a\)](#));
 - o requirements for hazard identification ([§ 117.130\(b\)](#)); and
 - o requirements for hazard evaluation ([§ 117.130\(c\)](#)). The requirements for hazard evaluation include:
 - a requirement 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 ([§ 117.130\(c\)\(1\)\(i\)](#)); and
 - a requirement that is specific to RTE foods – i.e., the hazard evaluation 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 ([§ 117.130\(c\)\(2\)\(ii\)](#)).
- requirements to 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 ([§ 117.135](#)); and
- requirements for preventive control management components ([§ 117.140](#)) for:
 - o monitoring preventive controls ([§ 117.145](#));
 - o verifying implementation and effectiveness of preventive controls ([§ 117.165](#)), specifically through:

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- calibration of process monitoring instruments and verification instruments (or checking them for accuracy) ([§ 117.165\(a\)\(1\)](#))
- product testing ([§ 117.165\(a\)\(2\)](#) and [\(b\)\(2\)](#)); and
- environmental monitoring ([§ 117.165\(a\)\(3\)](#) and [\(b\)\(3\)](#)); and
- review of the following records within specified timeframes: monitoring, corrective action ([§ 117.165\(a\)\(4\)\(i\)](#)), calibration, testing, supplier and supply chain-verification activities and other verification activities ([§ 117.165\(a\)\(4\)\(ii\)](#)); and
- o establishing and implementing corrective actions if preventive controls are not properly implemented ([§ 117.150](#)).
- requirements for a supply-chain program ([subpart G](#)), which include
 - o requirements for approving suppliers; and
 - o requirements for conducting and documenting supplier verification activities.

[Subpart F](#) specifies general requirements applying to all required records. Required records include the food safety plan ([§ 117.126](#)) and implementation records ([§ 117.190](#)). The food safety plan includes records for hazard analysis, preventive controls, and written procedures for preventive control management components. It also includes records of reanalysis of the food safety plan as required by [§ 117.170](#). This guidance provides recommendations for implementation records for corrective actions ([§ 117.150\(d\)](#)).

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.⁴²

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 and arms 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.

⁴² 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 handwashing 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

Picture/Image [Insert one or more pictures/images 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]
 - o Hose
 - o Brush (including color when applicable for color-coded brushes)
 - o Other
- Safety Requirements (as applicable)
 - o Goggles/safety glasses
 - o Gloves
 - o Sanitation Rain Suit
 - o Other

Cleaning chemicals and sanitizers

Procedural Step	Explanation of the Actions to Be Performed
Step 1	Explanation of how to scrape/wipe down this equipment
Step 2	Explanation of how to pre-rinse this equipment
Step 3	Explanation of how to foam 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

Appendix 5. 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 Greens

FORM 2-C 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) 12/11/26 **SUPERSEDES:** (mm/dd/yy) 12/13/25

PROCESS CONTROL STEP: Leafy green washing

HAZARD(S): E. coli O157:H7

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records ⁴³
Minimum concentration of free chlorine is 10 ppm	Concentration of free chlorine in the wash water	Automated sensor	Continuous (automated sensor)	The automated sensor	- Empty the processing line and segregate the product back to the last time the monitored parameters were within the critical limits - Clean and sanitize all affected (e.g., wash, post-wash) FCSs - The PCQI takes steps to determine what caused the pH level to rise above 7.5 so that actions can be taken to prevent such occurrences from happening in the future - Replace non-functioning sensor(s), when applicable	- Weekly accuracy check of sensors used for monitoring free chlorine, with recalibration if needed - Twice-per-shift verification of free chlorine concentration displayed by the continuous monitoring device by using a titration test kit - Records review by PCQI within 7 days of record creation (continuous monitoring records, calibration of sensors, corrective action records)	- Continuous monitoring records documenting the free chlorine concentration - Accuracy checks and calibration records - Free chlorine titration test records comparing the free chlorine concentration displayed by the continuous monitoring device - Corrective action records

⁴³ Records include the date and initials of the PCQI (or designee) as verification.

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Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records⁴⁴
pH greater than 7.5	pH level in the wash water	Automated sensor	Continuous (automated sensor)	The automated sensor	- Empty the processing line and segregate the product back to the last time the monitored parameters were within the critical limits - Clean and sanitize all affected (e.g., wash, post-wash) FCSs - The PCQI takes steps to determine what caused the pH level to rise above 7.5 so that actions can be taken to prevent such occurrences from happening in the future - Replace non-functioning sensor(s), when applicable	- Weekly accuracy check of sensors used for monitoring pH, with recalibration if needed - Twice-per-shift verification of pH level displayed by the continuous monitoring device by using a calibrated pH meter - Records review by PCQI within 7 days of record creation (continuous monitoring records, calibration of sensors, corrective action records)	- Continuous monitoring records documenting the pH level - Accuracy checks and calibration records - pH reading test records comparing the pH displayed by the continuous monitoring device. - Corrective action records

⁴⁴ Records include the date and initials of the PCQI (or designee) as verification.

Appendix 6. Summary Process Control Chart for Adding Peracetic Acid to Wash Water as an Example of a Process Preventive Control in the Production of Fresh-cut Onions

FORM 2-C PROCESS CONTROLS

PAGE _____

PRODUCTS: Fresh-cut Onions

PLANT NAME: Fresh-cut Operation B **ADDRESS:** 123 Main Street, Anytown, State, Zip

ISSUE DATE: (mm/dd/yy) 12/10/26 **SUPERSEDES:** (mm/dd/yy) 12/13/25

PROCESS CONTROL STEP: Onion washing

HAZARD(S): Salmonella enterica

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records ⁴⁵
Minimum concentration of peracetic acid is 50 ppm	Concentration of PAA in the wash water	Manual titration using a test kit	Thirty minutes	QA Technician	- Empty the processing line and segregate the product back to the last time the monitored parameters were within the critical limits - Clean and sanitize all affected (e.g., wash, post-wash) FCSs - The PCQI takes steps to determine what caused the PAA concentration to drop below the critical limit so that actions can be taken to prevent such occurrences from happening in the future	Records review by PCQI within 7 days of record creation (process logs documenting the titration tests for PAA, correction action records)	- Process logs with PAA titration test records - Corrective action records

⁴⁵ Records include the date and initials of the PCQI (or designee) as verification.

Appendix 7. Antimicrobial Substances Authorized for Use in Wash Water for Fresh-Cut Produce

Although the examples in this guidance use sodium hypochlorite or peroxyacetic acid as the antimicrobial substances, there are other antimicrobial substances that have been authorized for use in wash water for fresh-cut produce that you could use. 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 produce;
- 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 Food Contact Substance Notifications (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>); 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.

Regardless of which substance you use, you should check the applicable 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 our web page titled “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 (as opposed to regulated by FDA as a food additive), see our guidance titled “Guidance for Industry: Antimicrobial Food Additives” (Ref. 42). A decision tree form of that guidance, titled “Determining Regulatory Authority for Antimicrobial Substances,” is available at

<https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/RegulatoryAuthorityAntimicrobialSubstances/default.htm>.