

GUIDANCE DOCUMENT

Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables

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See additional PRA statement in section XIII of this guidance.

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I. Introduction

The Federal Government provides advice on healthful eating, including consuming a diet rich in a variety of fruits and vegetables, through the *Dietary Guidelines for Americans* and the related MyPyramid food guidance system (Ref. 1, 2). In response, per capita consumption data show that Americans are eating more fresh produce (Ref. 3). With \$12 billion in annual sales in the past few years (Ref. 4), the fresh-cut sector of the produce industry is its fastest growing segment. As the fresh-cut produce market continues to grow, the processors of such produce are faced with the challenge of processing an increasing variety and volume of products in a manner that ensures the safety of this produce. From 1996 to 2006, seventy-two foodborne illness outbreaks were associated with the consumption of fresh produce. Of these produce related outbreaks, 25 percent (18 outbreaks) implicated fresh-cut produce (Ref. 5). Many factors may play a role in the incidence and reporting of foodborne illness outbreaks that implicate fresh produce, such as an aging population that is susceptible to foodborne illness, an increase in global trade, a more complex supply chain, improved surveillance and detection of foodborne illness, improvements in epidemiological investigation, and increasingly better methods to identify pathogens (Refs. 6 thru 12).

Processing fresh produce into fresh-cut products increases the risk of bacterial growth and contamination by breaking the natural exterior barrier of the produce (Ref. 6). The release of plant cellular fluids when produce is chopped or shredded provides a nutritive medium in which pathogens, if present, can survive or grow (Ref. 6). Thus, if pathogens are present when the surface integrity of the fruit or vegetable is broken, pathogen growth can occur and contamination may spread. The processing of fresh produce without proper sanitation procedures in the processing environment increases the potential for contamination by pathogens (see Appendix B, "Foodborne Pathogens Associated with Fresh Fruits and Vegetables."). In addition, the degree of handling and product mixing common to many fresh-cut processing operations can provide opportunities for contamination and for spreading contamination through a large volume of product. The potential for pathogens to survive or grow is increased by the high moisture and nutrient content of fresh-cut fruits and vegetables, the absence of a lethal process (e.g., heat) during production to eliminate pathogens, and the potential for temperature abuse during processing, storage, transport, and retail display (Ref. 6). Importantly, however, fresh-cut produce processing has the capability to reduce the risk of contamination by placing the preparation of fresh-cut produce in a controlled, sanitary facility.

This guidance is intended for all fresh-cut produce processing firms, both domestic firms and firms importing or offering fresh-cut product for import into the U.S., to enhance the safety of fresh-cut produce by minimizing the microbial food safety hazards. This guidance does not set binding requirements or identify all possible preventive measures to minimize microbial food safety hazards. We recommend that each fresh-cut produce processor assess the recommendations in this guidance and then tailor its food safety practices to the processor's particular operation. Alternative approaches that minimize microbial food safety hazards may be used so long as they are consistent with applicable laws and regulations.

This guidance primarily addresses microbiological hazards and appropriate control measures for such hazards. However, some chapters in the guidance discuss physical and chemical hazards.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Scope and Use

Fresh-cut Produce: This guidance covers fresh-cut fruits and vegetables that have been minimally processed (e.g., no lethal kill step), and altered in form, by peeling, slicing, chopping, shredding, coring, or trimming, with or without washing or other treatment, prior to being packaged for use by the consumer or a retail establishment. Examples of fresh-cut products are shredded lettuce, sliced tomatoes, salad mixes (raw vegetable salads), peeled baby carrots, broccoli florets, cauliflower florets, cut celery stalks, shredded cabbage, cut melon, sliced pineapple, and sectioned grapefruit.⁽²⁾ Fresh-cut produce does not require additional preparation, processing, or cooking before consumption, with the possible exception of washing⁽³⁾ or the addition of salad dressing, seasoning, or other accompaniments. As the fresh-cut produce market continues to evolve, the scope of this guidance may need to be modified to address new or novel types of products.

Fresh-cut Produce and Current Good Manufacturing Practice requirements for foods (CGMPs) (21 CFR Part 110) ⁽⁴⁾: FDA's regulations in 21 CFR Part 110 establish CGMPs in manufacturing, packing, or holding human food. However, raw agricultural commodities (RACs), as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act (the Act), are not subject to the CGMP requirements by virtue of the exclusion in 21 CFR 110.19. Section 201(r) defines a raw agricultural commodity as any food "in its raw or natural state...." Fresh-cut fruits and vegetables are not RACs because they are no longer "in [their] raw or natural state" and instead have become "processed food" as that term is defined in the Act. Section 201(gg) of the Act defines a "processed food" as "any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydrating, or milling." Under 21 CFR 110.3, the definitions in section 201 of the Act apply to Part 110. Thus, fresh-cut fruits and vegetables are appropriately considered "processed foods" and are subject to the CGMPs in Part 110. The conclusion that fresh-cut produce are not RACs is consistent with the preamble to the proposed revisions to the CGMP regulation (44 FR 33238 at 33239, June 8, 1979), which states, when discussing the exclusion for RACs, that such products may be excluded because "food from those commodities is... brought into compliance with the Act at the later stages of manufacturing, processing, packing, or holding." The CGMPs establish food safety practices applicable to processors who manufacture, process, pack, or hold processed food. FDA believes that the recommendations in this guidance complement the CGMPs by suggesting more specific food safety practices for processors of fresh-cut produce.

Fresh-cut Produce and HACCP Systems: A Hazard Analysis and Critical Control Point (HACCP) system is a prevention-based food safety system designed to prevent, reduce to acceptable levels, or eliminate the microbial, chemical, and physical hazards associated with food production (Ref. 6). One strength of HACCP is its proactive approach to prevent food contamination rather than trying to identify and control

contamination after it has occurred.

Although HACCP is not currently required for the processing of fresh-cut produce, the United Fresh Produce Association recommends use of HACCP principles, and according to the association, many segments of the fresh-cut produce industry have adopted HACCP principles.(5)

FDA encourages fresh-cut produce processors to take a proactive role in minimizing microbial food safety hazards potentially associated with fresh-cut produce. We recommend that fresh-cut processors consider a preventive control program to build safety into the processing operations for fresh-cut fruits and vegetables. Awareness of the common risk factors discussed in this guidance and implementation of preventive controls determined by a firm to be appropriate to its individual operations will enhance the safety of fresh-cut fruits and vegetables. FDA also recommends that processors encourage the adoption of safe practices (See Chapter IV) by their partners throughout the supply chain, including produce growers, packers, distributors, transporters, importers, exporters, retailers, food service operators, and consumers, to ensure that the processor's efforts will be enhanced.

This guidance begins with a discussion of primary production and harvesting of fresh produce in Chapter IV and continues with recommendations for fresh-cut processing in four areas-- (1) personnel health and hygiene, (2) training, (3) building and equipment, and (4) sanitation operations. Following this discussion, the guidance covers fresh-cut produce production and processing controls from product specification to storage and transport. The final chapters provide recommendations on recordkeeping and on recalls and tracebacks.

III. Definitions

The following definitions apply to this guidance.

Adequate quality water: The determination of adequate quality water is based on its use, where adequate quality water for one purpose is not necessarily adequate for another purpose. (1) Where the water does not become a component of the fresh-cut produce, adequate quality refers to water that is safe and sanitary, at suitable temperatures, and under pressure as needed for all uses; and (2) where the water is used in a manner such that it may become a component of the fresh-cut produce (e.g., when such water contacts components, fresh-cut produce, or any contact surface), adequate quality water refers to water that complies with applicable Federal, State, and local requirements.

Fresh fruits and vegetables: fresh produce that is likely to be sold to consumers in an unprocessed (i.e., raw) form. Fresh produce may be intact, such as whole strawberries, carrots, radishes, or tomatoes, or cut from roots or stems during harvesting, such as celery, broccoli, lettuce, or cauliflower.

Fresh-cut fruits and vegetables or fresh-cut produce: fresh fruits and vegetables for human consumption that have been minimally processed and altered in form by peeling, slicing, chopping, shredding, coring, or trimming, with or without washing, prior to being packaged for use by the consumer or a retail establishment (e.g., pre-cut, packaged, ready-to-eat salad mixes). Fresh-cut produce does not require additional preparation, processing, or cooking before consumption, with the possible exception of washing or the addition of salad dressing, seasoning or other accompaniments.

Food hazard: a biological, chemical, or physical agent that is reasonably likely to cause human illness or injury in the absence of its control.

Pathogen: a microorganism capable of causing human illness or injury.

Processing water: water that is used for post-harvest handling of produce, such as washing, cooling, waxing, or product transport.

Standard Operating Procedures (SOPs): Procedures established by an operator for the day-to-day activities involved in the production of safe and wholesome food.

Sanitation Standard Operating Procedures (SSOPs): Procedures established by an operator for the day-to-day sanitation activities involved in the production of safe and wholesome food.

IV. Primary Production and Harvesting of Fresh Fruits and Vegetables

In general, anything that comes into contact with fresh produce has the potential to contaminate it. Fresh produce may become contaminated at any point along the farm-to-table continuum. The major source of microbial contamination of fresh produce is indirect or direct contact with animal or human feces. Once fresh produce has been contaminated, removing or killing the microbial pathogens is very difficult. Prevention of microbial contamination at all steps in the farm-to-table continuum is preferable to treatment to eliminate contamination after it has occurred.

On the farm, potential contamination avenues include contact with untreated manure used as a soil amendment, contaminated water, infected workers, or conditions in the field or packing facility such as unclean containers and tools used in harvesting and packing, and the presence of animals. In transport, conditions such as unclean floors and walls of the transport vehicle and unclean containers can contribute to contamination with pathogens. Thus, it is important that fresh-cut produce processors be aware of the conditions under which their fresh produce is grown, harvested, packed, and transported. Furthermore, knowing your suppliers and what they are doing to minimize risk of contamination is prudent.

To reduce potential contamination, the 1998 "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" (GAPs Guide) (Ref. 15) provides recommendations for growers, packers, and shippers to use good agricultural and good manufacturing practices in those areas over which they have control to prevent or minimize microbial food safety hazards in fresh produce. Potential sources of contamination identified in the GAPs Guide are biosolids and manure, water, field workers, equipment, and containers.

We recommend the following practices to ensure that incoming fresh produce is safe and suitable for processing into fresh-cut product:

- Becoming aware of practices used by your suppliers (i.e., growers, packers, coolers, transporters, etc.)
- Evaluating the practices of your suppliers by a knowledgeable food safety expert
- Accepting produce from suppliers who use GAPs, GMPs or other appropriate practice from the farm to the processing facility
- Using a mechanism to verify the use of food safety practices by your suppliers (e.g., letter of certification or guarantee from a supplier)

V. Personnel

This section provides recommendations regarding personnel of an establishment that processes fresh-cut produce. The recommendations address two major areas: worker health and hygiene, and training.

A. Worker Health and Hygiene

Workers can carry microbial pathogens on their skin, in their hair, on their hands, and in their digestive systems or respiratory tracts. Unless workers understand and follow basic food protection principles, they may unintentionally contaminate fresh produce and fresh-cut produce, food contact surfaces, water supplies, or other workers, and thereby, create the opportunity to transmit foodborne illness. Basic food protection practices related to worker health and hygiene fall into two categories, disease control and cleanliness.

1. Disease Control

FDA recommends that employees with direct access (such as processing, storage, and transport workers) and indirect access (such as equipment operators, buyers, and pest control operators) to the production areas of fresh-cut fruits and vegetables follow good hygienic practices for maintaining personal health and hygiene in order to protect the product from contamination.

FDA recommends the following practices to prevent food, food contact surfaces, and food packaging materials from becoming contaminated with microbial pathogens from an employee with an infectious illness or wound:

- Establishing a company policy that requires employees to report any active case of illness to supervisors before beginning work
- Training supervisors to know the typical signs and symptoms of infectious disease

We recommend that firms train employees to report to their supervisor any information about personal health status or activities relating to diseases transmitted through food. Such information would include reporting an active case of illness. FDA recommends that supervisors be trained to recognize the symptoms of active infectious disease; these symptoms are vomiting, nausea, diarrhea, and abdominal cramps. We recommend that employees with these symptoms be excluded from any operations which may be expected to result in contamination of fresh or fresh-cut produce or food contact surfaces, including equipment and utensils, until the medical condition is resolved.

- Covering cuts and wounds with a suitable water proof dressing when workers with such injuries are permitted to continue working.

We recommend that firms maintain an adequate supply of bandages that provide protection from any wound. A wound containing pus (such as an open and draining boil or other infected wound) that is located on a part of the body that could contact fresh produce or fresh-cut produce, processing equipment, or tools, presents a risk of contaminating fresh-cut produce. When a worker in the processing area needs a bandage, we recommend that the firm consider using a bandage that is detectable by a metal detector if there is a metal detector in the processing line. Using detectable bandages will allow the facility to detect when a bandage has fallen into the processing line so that corrective action can be taken. We also recommend that a worker with a wound that cannot be covered to prevent contact with fresh produce or fresh-cut produce, processing equipment, or tools not work with any aspect of fresh produce or fresh-cut produce, processing equipment or tools until the wound has healed.

2. Cleanliness

FDA recommends that employees use the following food protection practices to prevent fresh or fresh-cut produce or food contact surfaces including equipment or utensils from becoming contaminated as a result of poor employee hygiene or inappropriate employee conduct:

- Maintaining adequate personal cleanliness
- Washing hands frequently and effectively and sanitizing hands if needed

FDA recommends that employees wash their hands before beginning work and after engaging in any activity that may contaminate their hands. FDA's recommendations regarding when employees should wash their hands are reflected in the following list

1. Before beginning work, especially if the employee has direct contact with fresh produce
2. Before putting on a new pair of disposable or non-disposable gloves and after removing the gloves
3. After touching human body parts or anything other than food or food contact surfaces
4. After using the toilet; after coughing, sneezing, using a handkerchief or tissue
5. After using tobacco, eating, or drinking
6. After engaging in any activity that may contaminate hands, such as handling garbage, cleaning chemicals, or incoming produce before it has been washed
7. After caring for or touching animals
8. Before returning to a workstation

- Washing and sanitizing non-disposable gloves before starting work, and as needed
- Changing disposable gloves whenever contamination is a possibility

Improperly used gloves may become a vehicle for spreading pathogens. The use of gloves does not lessen the need for, or importance of, hand-washing and other proper hygiene practices. We recommend that if gloves are used in a facility, the firm develop guidelines for their safe use, sanitation, and changing.

- Wearing appropriate attire on the job

FDA recommends that employees wear clean clothes and any additional outer items (e.g., hairnets and beard covers, lab coats, aprons, and appropriate footwear) that will help protect fresh and fresh-cut produce from inadvertent contamination during processing.

- Not engaging in certain activities where food may be exposed or utensils are washed

FDA recommends that employees in food processing areas not engage in activities that could contaminate food, such as eating, using tobacco, chewing gum, or spitting.

B. Training

Training every employee about the CGMPs and preventive controls will help to eliminate or minimize contamination of fresh-cut produce. We recommend that education and training programs be designed to help employees understand what is expected of them and why what is expected is important. We also recommend that company expectations for proper employee hygiene and food protection techniques be clearly communicated to new employees before starting employment and reaffirmed during periodic training programs. There are many materials available to firms to support employee training. We recommend that firms consider whether the language of the training and training materials is appropriate for the employees. Useful materials and information may be found at the [Fight BAC!](http://www.fightbac.org) (<http://www.fightbac.org>) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)® campaign of the Partnership for Food Safety Education, and Gateway to Government Food Safety Information (<http://www.FoodSafety.gov/>) (<http://www.foodsafety.gov/>).

Training employees before they begin work with fresh or fresh-cut produce, at regular intervals, and at a minimum annually provides employees with important information about food safety best practices and company policies. We recommend that firms consider teaching, in the same training session, only a small number of employees at or near their workstation, if the environment permits it, for short periods of time, such as 10-15 minutes per session. The sessions could cover only one topic at a time and could be targeted to specific food safety concerns of that workstation. For example, washing station employees could be trained about appropriate antimicrobial chemical usage, and packaging station employees could be trained about proper handling and cleanliness of boxes and totes. We recommend refresher or follow-up training to reinforce the initial training. Training a few employees at a time can be an effective way to provide refresher training with the least disruption to work.

A firm may wish to post signs and pictorial representations of good practices covered in training as an additional way to reinforce training. We recommend that signs be multilingual and posted in areas close to where the practice is performed. We also recommend that the training provided to employees be documented so there is a record of the training topics covered and which employees completed it.

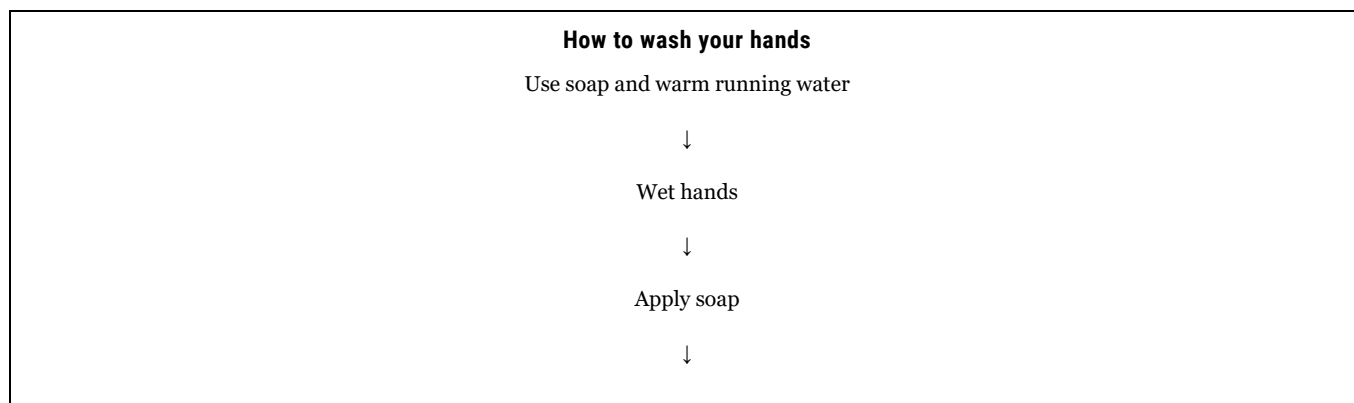
A well-designed training program provides information to help employees apply CGMPs while on the job. We recommend that a fresh-cut produce firm's training program for employees (including temporary, seasonal, and full time employees) include training on the CGMPs for production, maintenance, quality assurance, and quality control with an emphasis on worker health and hygiene; employee roles and responsibilities; and sanitation principles and sanitary practices.

1. Training for Worker Health and Hygiene

We recommend that employees be trained to follow good personal hygiene practices, including the use of proper hand washing techniques, wearing clean clothes and any additional outer coverings (e.g., hairnets and beard covers, disposable gloves, aprons), and appropriate conduct on the job. FDA also recommends that employees be trained on how, when, and to whom to report illness. Hand washing training is particularly important. We recommend that employees be trained about how, when, and why they must properly wash their hands and exposed portions of their arms. We also recommend that employees be taught to wash and sanitize their hands before entering areas where fresh or fresh-cut produce is present.

Figure 1 is an example of an aid that could be used to train employees on the proper technique to use in washing hands:

Figure 1. Example of a training aid on how to wash your hands



Vigorously rub hands up to elbows for 20 seconds



Rinse Hands



Turn off running water with a paper towel, not bare hands



Dry hands with a paper towel or air dry. Do not share towels

Soap combined with scrubbing helps dislodge and remove dirt and germs.

2. Training on Employee Roles and Responsibilities

We recommend that employees be trained consistent with the level of complexity of their jobs and that additional training be provided as needed to ensure current knowledge of equipment and process technology.

One goal of a training program is to help workers understand the importance of the tasks for which they are responsible, particularly those tasks that are important to minimizing microbial food safety hazards (such as monitoring the disinfectant level in wash water). We recommend that employees be trained about how to perform these tasks; to be aware of the microbial food safety hazards associated with them; to understand the procedures for monitoring conditions such as the disinfectant level, pH, and the temperature of the wash water, and any associated recordkeeping that the firm chooses to implement; to know the actions that are needed to minimize contamination of the product; and to consult with their supervisors if the established limits (such as the appropriate level of disinfectant in the wash water) are not met.

We recommend that personnel responsible for maintaining equipment that may have an impact on food safety be trained to understand the importance of their role in the production of safe food. Equipment maintenance jobs that may have an impact on food safety include changing water filters, maintaining refrigeration units, treating processing water, and calibrating equipment. We recommend that employees be trained to identify deficiencies that could affect product safety, to take the appropriate corrective actions (e.g., in-house repairs, contract repairs), and to be able to understand how indirect cross-contamination may occur when proper equipment controls are not maintained.

3. Training on Sanitation Principles and Sanitary Practices

We recommend that employees with cleaning and sanitation duties be trained to understand the principles and methods required for effective cleaning and sanitation, especially as those methods relate to food safety. We recommend that supervisors be trained to identify and promote good sanitary practices.

We also recommend that employees be trained in the proper use of sanitizing agents (sanitizers) and foot foam, foot baths, or spray systems, in proper cleaning and sanitizing steps of the equipment and facility, in proper use of equipment in the production environment, such as hoses and tools, and in the proper use, handling, and storage of chemicals used in sanitation.

Figure 2 is an example of an aid that could be used to train employees on the proper use of sanitizers:

Figure 2. Example of a training aid on proper use of sanitizers

Use sanitizers properly for food safety

Hand sanitizing stations

- After hand washing, sanitize your clean hands with a sanitizer solution
- Allow hands to air dry
- Wash hands and sanitize gloves (disposable or reusable) before wearing
- Re-sanitize your hands after touching non-food contact surfaces

Foot Sanitizer

- When entering any area where fresh produce or fresh-cut produce is present, walk through a foot sanitizer unit

Sanitizer maintenance

- Monitor and change hand and foot sanitizer solutions as needed to maintain effective sanitizer strength, per manufacturer's recommendation

Equipment (whether fixed or free standing), fixtures, floors, walls, and other structures in a processing facility can become a source of microbial contamination if not adequately maintained in sanitary condition. The high humidity and structural niches in a fresh-cut produce processing facility encourage microbial build-up. To prevent fresh-cut produce from becoming contaminated by equipment or other structures in the facility, we recommend that employees be trained on proper cleaning and sanitizing steps within the processing areas.

Figure 3 is an example of an aid that could be used to train employees on the cleaning and maintenance of processing equipment and facilities:

Figure 3. An example of a training aid on cleaning and sanitizing steps within processing areas

Cleaning and sanitizing steps*

1. Remove heavy debris from floors with brooms or shovels and dry clean processing equipment, if needed
2. Pre-rinse the equipment with adequate quality water
3. Clean remaining debris from floor
4. Rinse floor and drains with adequate quality water using a low pressure hose
5. Use dedicated brushes to scrub floor and drains with an effective cleaner, applying adequate quality water as needed
6. Foam and scrub the equipment with an effective cleaner and scrub using dedicated brushes
7. Thoroughly rinse the equipment, floors, and drains with adequate quality water using a low pressure hose
8. Remove excess water from floors
9. Sanitize (according to manufacturer directions) the equipment and floors*

* Work from top down for cleaning and sanitizing activities. Some equipment may need to be disassembled before cleaning and sanitizing followed by reassembly.

In addition to using sanitizers appropriately and cleaning and sanitizing the equipment and facility regularly, proper use of equipment, such as hoses, can also reduce the risk of contamination of fresh and fresh-cut produce. For example, keeping hose nozzles off the floor can help prevent nozzles and employee hands from becoming a source of contamination. We recommend that sections of hose that touch the floor or other unclean surface not make contact with fresh produce, food-contact surfaces, or packaging materials. A retractable hose suspended from the ceiling may help to prevent such contamination. In addition, allowing hose ends to sit in standing water or to be submerged in water tanks could allow back siphonage of water, thereby contaminating the water distribution system.

Further, we recommend that employees be trained to avoid use of high-pressure water hoses to clean floors, walls, and equipment in the processing and packaging areas during production or after production equipment has been cleaned. This practice will help prevent aerosols from contacting processing equipment and food-contact surfaces, product, or packaging materials. Therefore, we recommend that employees be trained on the proper use of cleaning equipment.

VI. Building and Equipment

FDA recommends that the processing facility and its structures (such as walls, ceilings, floors, windows, doors, vents, and drains) be designed to be easy to clean and maintain and to protect the product from microbial, physical, and chemical contamination. For example, designing food contact surfaces to be smooth, nonabsorbent, smoothly bonded, without niches, and sealed would make these surfaces easier to clean and thus, would prevent the harborage of microbial pathogens.

A. Building

Both direct contamination and cross-contamination of produce can be minimized by giving proper attention to physical design, emphasizing proper product flow, using appropriate construction materials, managing facility traffic, and ensuring proper airflow. We recommend that facilities and staging areas be designed to facilitate maintenance and good sanitation practices so that contamination may be controlled throughout receiving, cooling, processing, packing, and storage operations. We also recommend that buildings, fixtures, and equipment be maintained in a condition that will protect fresh-cut produce from potential microbial, chemical, and physical contamination.

1. External/Internal Structures

In general, we recommend limiting access to the facility and to its processing areas, providing adequate space for operations, ensuring adequate drainage of processing and wash water, installing food contact surfaces that are easy to clean and maintain, and designing areas and structures to protect the product and equipment from contamination.

In addition, we recommend the following practices:

- Adequately screening open windows, vents, fans, and similar features to prevent pest (insect, bird, rodent, reptile) entry
- Closing all exterior doors and entrances when not in use and ensuring an adequate seal when exterior doors and entrances are closed
- Properly constructing all walls, ceilings, windows, doors, floors, and overheads (e.g., pipes, air vents, and lights) and maintaining them in good condition (e.g., no cracks, rust, breakage, missing parts, or dips allowing puddles to form) so that they do not harbor pests or pathogens
- Designing properly sloping floors to drains ($\frac{1}{4}$ inch per foot), and sealing and keeping them in good repair so as to provide adequate drainage
- Designing floor drains to prevent the accumulation of water in or around the drains and making drains accessible for cleaning
- Fitting floor drains with seals and grates capable of preventing pest entry
- Using floor flumes with caution due to the potential for water aerosol contamination of the room air and nearby equipment surfaces

We recommend against the use of a floor flume transfer from the produce cooling and packing operation into or across an area housing fresh-cut produce operations.

- Constructing trench drains for automatic flushing
- Using under-floor drains in fresh-cut produce processing areas
- Designing collection areas for waste stream water to prevent product and equipment contamination
- Designing pipelines to avoid pipe and wall condensation from becoming a source of contamination

Where overhead condensate cannot be prevented, we recommend that catch pans be utilized, and be cleaned and sanitized on a regular basis.

- Avoiding wood construction materials wherever possible

If wooden equipment is used (including pallets), we recommend that the equipment be in good condition and well maintained so it is not a source of physical or microbial contamination. Non-wooden construction materials, such as plastic or stainless steel, are preferable for use in processing areas because they reduce the risk of microbial harborage and cross-contamination of final product.

- Using protective guards for light fixtures to prevent broken glass from falling into product

2. Facility Layout

We recommend that a fresh-cut fruit or vegetable processing facility be designed so that incoming raw products never cross paths with or are commingled with finished fresh-cut produce products. Similarly, we recommend maintaining separate raw incoming product, in process, and finished product areas so as to prevent the potential for microbial cross-contamination. Adequate food safety controls, operating practices, and facility design can reduce the potential for contamination by using location and/or flow of humans, product, equipment, and air.

We recommend the following practices that use *location* to reduce the potential for contamination:

- Having rest rooms that open into a location other than a processing area
- Locating the door to the outside in an area other than into a processing area
- Having a microbiology lab that opens into an area other than into a processing area
- Storing in-process and raw produce materials in different rooms
- Establishing dedicated cold rooms for raw product and processed product
- Locating hand washing and sanitizing facilities to facilitate regular and appropriate use by employees
- Locating a disinfectant foot foam, foot bath, or foot spray at all entrances and exits to all production and finished product storage areas.

We recommend the following practices that use *flow* of personnel, product, equipment, or air to reduce the potential for contamination:

- Having short direct routes for both product and personnel flow
- Designing the plant for one direction of personnel traffic, product, and air flow
- Designing product areas to have traffic patterns that separate raw and finished product using either linear product flow (raw to finished product) or by physical partition

(Figure 7 in Appendix E is an example of product and personnel flow patterns in a fresh-cut processing plant.)

- Using an air filtration system for central air distribution and airflow that is counter to product flow, so that filtered air moves with a positive pressure from the cleanest areas (e.g., from packaging and finished product storage) toward less clean areas (e.g., the receiving area)

We also recommend that air intake for the facility be located to minimize contamination of the intake air by:

- Keeping the number of entrances and exits to the processing areas to a minimum
- Restricting the movement of lift trucks, bins, totes, maintenance tools, cleaning implements, clothing, and people from receiving and storage zones to processing and packaging areas

Color coding bins, totes, clothing, cleaning implements, maintenance tools, and other items (e.g., blue aprons for receiving zones and red aprons for processing and packaging areas) may help achieve separation of traffic and thereby, minimize cross-contamination.

B. Equipment Design, Construction, and Maintenance

We recommend that the processing equipment be designed and constructed to be easy to clean and maintain and to avoid microbial contamination of the fresh-cut product.

1. Equipment Design and Construction

We recommend the following to facilitate cleaning and to help ensure that fresh-cut produce is not contaminated during the processing operation:

- Using smooth, non-absorbent, sealed, and easily cleanable food contact surfaces that are sloped to drain freely and made of durable, non-corrosive, nontoxic materials

Food contact surfaces include items such as knives, conveyors, belts, chutes, product totes, gloves, tools including shovels and racks, cutting boards, tables, dryers and spinner baskets, and packing scales. We recommend that all food contact surfaces be smoothly bonded (e.g., free of pits, folds, cracks, crevices, open seams, cotter pins, exposed threads, and piano hinges) to avoid harboring pathogens.

Where two food contact surfaces meet, we recommend use of a cover over the juncture to prevent food debris from collecting in the crevice and creating an area that is difficult to clean.

- Locating catwalks with open grating so they do *not* pass over areas of exposed fresh or fresh-cut produce or food-contact surfaces
- Designing equipment in the processing area to prevent water collection

We suggest cautious use of hollow structures, such as catwalk framework, table legs, conveyor rollers, and racks, because they may collect water and debris, and thus, harbor pathogens.

- Elevating food-contact surfaces sufficiently above the floor (with accessibility for cleaning) to prevent contamination from floor splashes
- Installing stationary equipment away from floor drains to allow accessibility to drains for cleaning and to prevent contamination of the equipment

2. Equipment Maintenance

Establishing a preventive maintenance program helps to ensure that all equipment functions as intended. Equipment failure requiring maintenance activities during production may increase the risk of microbial contamination, particularly from *L. monocytogenes* (Ref. 16). Preventive maintenance includes periodic examination and maintenance of equipment such as valves, gaskets, o-rings, pumps, screens, filters, and heat exchanger plates. We recommend that a firm develop appropriate plans of action in case important equipment, such as refrigeration equipment, disinfectant delivery systems, power systems, or alarm systems, malfunctions. We also recommend the following practices:

- Performing maintenance and calibration of equipment by appropriately trained personnel
We recommend that maintenance personnel who work in the processing or packaging areas comply with the hygiene requirements for production employees.
- Installing, calibrating, and maintaining temperature measuring or recording devices as necessary to ensure accuracy
- Frequently sharpening knives, if used, including retractable knives, and disinfecting before use
We recommend that knives be replaced if damaged or if they cannot otherwise be maintained in a sanitary condition.
- Frequently inspecting cutting blades and belts during processing operations for damage, product residue build up, or cleaning needs
We recommend that blades be removed and cleaned separately, and remaining equipment parts disassembled (if possible) and cleaned on a regular basis.
- Operating metal detectors in accordance with the manufacturer's instructions and checking for proper functioning at least daily to ensure effective detection of metal and removal of affected product
We recommend that procedures be in place, such as the use of metal detectors during packaging operations, to minimize the possibility that metal ends up in finished product packages.
- Calibrating safety control devices that are essential for maintaining the proper level and activity of wash water disinfectant, at a frequency recommended by the manufacturer and documenting this activity on the instrument calibration forms/logs
- Examining air filters for both intake air and compressed air and changing at least as often as the manufacturer specifies, or more frequently if a problem is indicated, such as evidence of filter fouling or perforation

VII. Sanitation Operations

Pathogenic microorganisms may be found on floors, in drains, and on the surfaces of sorting, grading, processing, and packaging equipment. Without appropriate sanitation practices, these surfaces may be a source of microbial contamination.

A. Sanitation Program

We recommend the use of a comprehensive sanitation program developed by a trained employee such as a certified sanitarian to avoid microbial contamination of the product in a fresh-cut processing facility.

We recommend that fresh-cut processors consider using the following practices for their sanitation program:

- Establishing sanitation standard operating procedures (SSOPs), including a cleaning and sanitizing procedure with a regular schedule for all equipment, storage areas, fresh and fresh-cut produce production areas, air systems, and water storage areas

An example of such a schedule is included in Figure 4. When visual inspection or environmental monitoring results for equipment or the facility reveal dirt, food residues, or other debris, we recommend a more frequent cleaning and sanitizing schedule relative to what is shown in Figure 4.

Figure 4. An Example of a Processing Plant Environmental Sanitation Master Schedule(6),(7)

Area	Cleaning/ Sanitation Method	Tools	Cleaning Materials	Frequency
Walls	Foam, brush, rinse	Soft nylon brush and High Pressure Hose (when appropriate)	Chlorine-Quaternary ammonium ("quat")-based cleaner	Once/Month Walls adjacent to processing equipment should be cleaned daily
Ceiling	Foam, brush, rinse	Nylon brush, high pressure machine	Chlorine-quat-based cleaner	Once/Month

Area	Cleaning/ Sanitation Method	Tools	Cleaning Materials	Frequency
Floors	Wash, rinse	Hard bristle broom (not straw), floor scrubbers, low pressure hose	Chlorine-quat or iodine based cleaner	Daily
Doors	Foam, scrub, rinse	Scouring pad, cloth	Chlorine-quat-based cleaner	Once/Week
Plastic curtains	Foam, rinse	Foam and Rinse	Chlorine-quat-based cleaner	Once/Week
Overhead pipes, electrical conduits, structural beams	Foam, brush	Brush, bucket, high water pressure machine	Chlorine-quat-based cleaner	Once/Month
Hoist, overhead light fixtures	Wipe, clean	Cleaning pad	Water, light detergent	Once/Quarter
Refrigeration coils	Rinse, sanitize	High pressure hose	Water, sanitize with quat	Once/Quarter
Chillers	Scouring	Scouring pad	Acid cleaner	As Needed/Audit
Air distribution filters	Soak	Plastic bins	Chlorine-alkaline detergent	Once/Quarter
Drains, trench	Clean, flood, rinse	Soft Nylon brush, 50 gallon container	Chlorine-alkaline detergent, quat or iodine based sanitizer	Daily
Grids	Brush, rinse	Nylon brush, high water pressure machine	Chlorine-alkaline detergent	Daily
Waste, dumpster areas	Foam, brush, rinse	Nylon brush, high water pressure machine	Heavy duty chlorine-based cleaner	Daily
Employee break rooms/bathrooms	Wash, rinse	Nylon brush, sanitary brushes	Chlorine-based soap or quat	Frequently throughout the day
Maintenance areas	Scrub, rinse	Nylon brush	Degreasing agent	Once/Month

- Including as part of the sanitation schedule the name of the employee (and alternate when primary employee is absent) responsible for the activity, the equipment to be cleaned and how to disassemble it, the frequency of cleaning, procedures for cleaning (including type and concentration of cleaning compound and sanitizer), time and temperature requirements, cleaning solution flow rate (pressure) if applicable, and the name of an employee responsible for verifying the program effectiveness by inspection
- Cleaning the condenser unit, drip pans, and hoses of refrigerators
- Keeping cold storage as dry as possible
- After cleaning and sanitizing, visually inspecting the area cleaned for product residue and conducting routine microbiological tests (conventional or rapid microbiological methods, such as total count or bioluminescence) to verify effectiveness of the cleaning and sanitizing program
- When reassembling sanitized equipment, placing the equipment parts on a sanitary mat and not on the floor
- Cleaning and sanitizing all processing equipment, facility utilities (e.g., air system, water system), and food-contact surfaces after maintenance work and prior to use in production
- Cleaning and sanitizing processing equipment and food-contact surfaces between the processing of different commodities, if appropriate based on risk
- Avoiding cleaning and sanitizing equipment during processing operations to prevent contamination
- Minimizing splashing during the cleaning of floor drains by using an appropriate brush, such as a ¼ inch smaller brush than the diameter of the drain opening, or a splash guard
For cleaning drains, we recommend using dedicated utensils (color coded and used for cleaning drains only) to minimize the potential for contamination. We also recommend that floor drains not be cleaned during processing operations and that the person who cleaned drains not clean fresh-cut produce food contact surfaces without changing outer garments, and washing and sanitizing his or her hands.
- Regularly inspecting tools for cutting, slicing, and shredding for damage that could impair cleaning and sanitizing them
We recommend replacing a tool if it cannot be fixed so that it can be adequately cleaned.

1. Cleaning and Sanitizing Chemicals

Cleaning and sanitizing chemicals may be toxic, and should be stored in dry, secure, and ventilated areas away from facility traffic and processing operations. They should be handled by employees trained in the use of such chemicals.

We recommend the following practices in using cleaning and sanitizing chemicals:

- Using adequate quality water for cleaning and sanitizing at temperatures appropriate for the chemicals used
- Using toxic chemicals for cleaning operations in accordance with the manufacturer's instructions and in accordance with relevant Federal, State, and local government regulations
- Clearly labeling toxic chemicals
- Storing toxic chemicals and pesticides in a manner that protects against contamination of food, food-contact surfaces, and food-packaging materials and in accordance with relevant Federal, State, and local government regulations
- Monitoring the effectiveness of cleaning and sanitizing chemicals by visual inspection and environmental testing (especially grooves and niches) for microbial growth

2. Pest Control

We recommend a pest control program be implemented throughout the entire processing facility to eliminate pests (such as rodents, birds, reptiles, and insects) that may harbor or be a vector for a variety of pathogens. As part of the plant's pest control program, consider frequent monitoring of affected and treated areas to assess accurately the effectiveness of the program. Some helpful physical and chemical controls are

recommended below:

- Using window screens, screen doors, and weather stripping for all doors, and air fans at all doorways
 - Keeping all exterior doors closed when not in use
 - Removing waste products to, and storing waste products in, a location outside the facility
 - Removing old, unused equipment from the facility
 - Maintaining the exterior grounds surrounding the facility in a manner that will control pest harborage
 - Properly storing ingredients, finished product, and food packaging
 - Cleaning up spills and produce debris in a timely manner
 - Using pesticides, traps, bait, and chemicals that are acceptable for use in a food processing facility and that will not contaminate foods, food ingredients, or food packaging
- Chemical controls should be applied by a licensed pest control operator or according to local regulations.
- Maintaining a map to identify by numbered locations all rodent traps and bait boxes used both inside and outside the processing facility

B. Sanitary Facilities and Controls

1. Employee Changing Facilities and Toilets

We recommend that changing facilities and restrooms be adequate and located in proximity to processing areas, but not so close that they could be a source of contamination. We recommend that restrooms not open directly into processing areas and doors be equipped with self-closing mechanisms or have a maze-type entrance/exit.

2. Hand Washing Facilities

FDA recommends the following practices for employee hand washing facilities:

- Providing a sink, hot and cold running water of adequate quality, effective hand cleaning preparations (e.g., liquid soap), sanitary hand drying devices (such as disposable paper towels), and a waste container
- Installing water control devices (such as knee, foot, or elbow faucet controls) that will protect against contamination of clean hands
- Posting signs that show proper hand washing procedures

We recommend that these signs be posted near the facility entrance, in restrooms, near all hand washing stations, and wherever employees may handle produce, food packaging materials, or food-contact surfaces. We further recommend that these signs be multilingual where some of the workers in the facility are not native English speakers or pictorial where literacy is a concern.

3. Air Quality

Air inside a processing plant can be a vehicle for contamination of food by mold, yeast, dust, or pathogens if not properly controlled. Where fresh and fresh-cut fruits and vegetables are exposed to open air, we recommend that air quality be monitored to ensure that it is of suitable quality.

We also recommend that fresh-cut processors consider the following to maintain appropriate air quality:

- Using positive, negative, and ambient air pressure differentials to direct potential airborne contaminants away from microbially sensitive areas. For example, negative air pressures in raw product areas, microbiology laboratories, and rest rooms may help to keep air from those areas from flowing into the processing areas. Similarly, positive air pressure can be maintained in areas such as the processing and packaging area.
- If air filtering equipment is used in a fresh-cut processing facility, filters should be performing at manufacturer specified levels of performance
- Filtering compressed air (such as oxygen (O₂), nitrogen (N₂), and carbon dioxide (CO₂) used in modified atmospheric packaging) when such air contacts fresh produce using a 0.3 micron filter (with an efficiency of approximately 75%)

4. Water Supply

Water can be a carrier of microorganisms including pathogens. Adequate quality water is critical in a fresh-cut processing facility because of the absence of a step lethal to pathogens (kill step) in processing the product as well as the presence of factors such as the high degree of product handling, the damage to product during cutting, shredding, etc., and the potential for temperature abuse in processing and storage. We recommend that the water supply in a food processing plant be sufficient for the operations intended and be derived from an adequate source. We recommend that water for operations in the processing facility, such as cleaning and sanitizing the facility and equipment as well as preparing the product for processing, processing the product, and manufacturing ice, be of adequate quality. Where water does not become a component of the fresh-cut produce, we recommend that water be safe and sanitary, at suitable temperatures, and under pressure as needed for all uses. For water that is used in a manner such that the water may become a component of the fresh-cut produce (such as when such water contacts components, fresh-cut produce, or any contact surface), we recommend that water comply with applicable Federal, State, and local requirements.

See Section VIII.C., which provides our recommendations for maintaining water quality used from preparation for processing through processing operations.

We recommend the following practices regarding the water used in a processing facility:

- Complying with applicable Federal, State, and local requirements for water that contacts fresh-cut produce or food-contact surfaces, including water used to make ice

We recommend that processors protect sources of water and ice from contamination and that ice be manufactured, transported, and stored under sanitary conditions.

- Testing well water, if used, at the site of the well and at the point in the plant most distant from the well on a regular basis to ensure compliance with Federal, State, and local requirements
- Maintaining and inspecting on a routine basis any water charcoal filtering system to prevent it from becoming a source of microbial or physical contamination of water
- Reviewing on a periodic basis water systems to ensure that no cross-connections exist between systems carrying water that is of adequate quality and systems carrying water that is not
- Ensuring that the volume, temperature, and pressure of water is adequate for all operational and clean up demands

5. Environmental Monitoring

FDA recommends an environmental monitoring program designed to detect areas of pathogen harborage and to verify the effectiveness of cleaning and sanitizing programs in preventing cross-contamination. We recommend the following practices:

- Performing environmental sampling on both food contact and non-food contact surfaces (e.g., drains)
- Determining the appropriate target pathogen, test locations, and frequency of sampling

We recommend that the appropriate target pathogen be the most resistant microorganism of public health significance that is likely to occur in fresh-cut produce.

- Focusing environmental monitoring on an indicator organism, such as *Listeria* spp., which indicates microbial contamination but is nonpathogenic and more easily detectable than a target pathogen, such as *L. monocytogenes*
- Establishing a plan for action in the event that a microbiological test indicates the presence of a target pathogen or indicator organism
- Documenting corrective actions and follow-up for all positive microbial test results

VIII. Production and Process Controls

To minimize the potential for the growth of microorganisms and for the contamination of fresh-cut produce, FDA recommends that control measures be in place to prepare, process, package, and store the product.

A. Product Specifications

We recommend that food processors consider developing specifications and controls for all ingredients and components (including raw fruits and vegetables, packaging materials, and gases) that are necessary for production of safe finished product. Specifications provide standards by which a food processor can assess the acceptability of ingredients and components and thus, minimize microbial, chemical, and physical hazards. We recommend, for example, that the fresh-cut processor know as much as possible about the production practices and conditions for the firm's incoming product. The "Guide to Minimize Microbial Food Safety Hazards in Fresh Fruits and Vegetables" (Ref .15) provides useful guidance when reviewing primary production practices.

B. Receipt and Inspection of Ingredients

Opportunities for contamination of fresh produce occur from the field to the processing facility. Loading, transporting, and unloading produce may introduce contaminants. Damaged produce, soil, debris, and pests may all arrive with the produce when it is delivered to the facility. To help ensure the quality of incoming fresh produce, we recommend that the processor carefully inspect the produce upon receipt at the processing facility. We also recommend the following practices:

- Transporting the produce from the field to the processing, packing, or cooling facility as soon as practical after harvest
- Inspecting delivery vehicles carrying fresh produce and other components of the finished product, e.g., cartons, packaging materials, for cleanliness
- Visually inspecting incoming fresh produce for damage, filth, and infestation according to a predetermined sampling plan and rejecting products that do not meet established specifications
- Removing all damaged, moldy, or decomposed product and extraneous matter (such as metal or other foreign material) from in-coming raw ingredients to a designated area
- Retaining information about all incoming ingredients, such as the identity of the grower or supplier, date of harvest, the field, and linking the information on the incoming product with the operation's production records (e.g., when processed, date, shift) for finished product

This information will be useful in the event a traceback is conducted. See section X in this guide for more information on tracebacks.

C. Specific Processing Steps

1. Preparation for Processing

Appropriate preprocessing of incoming produce can help minimize microbial, chemical, and physical hazards. We recommend that fresh-cut produce processors consider the following activities to help minimize microbial, chemical, and physical hazards in in-coming produce:

- Inspecting fresh produce throughout the processing stream for field contaminants that may not have been noticed during the incoming produce inspection
- Removing from the processing stream damaged or decomposed produce, extraneous matter, and produce that appears to be contaminated by animal feces, fuel, machine grease, or oil
- Removing as much dirt as possible from incoming produce

We recommend, when appropriate, washing incoming RACs prior to further processing (such as cutting or chopping) to reduce the overall potential for microbial contamination from the surface of intact fruits and vegetables.

2. Processing Water

Water is used extensively in almost all aspects of processing fresh-cut fruits and vegetables, including during cooling, washing, and conveying of produce. Although water may be a useful tool for reducing potential contamination, it may also introduce or spread contaminants. When used for washing, cooling, rinsing, or conveying food, we recommend that water comply with applicable Federal, State, and local requirements.

In a fresh-cut processing operation, water quality changes as the water is used and, thus, maintaining the quality of processing water should be considered. Reusing processing water may present a risk of new or increased number of microbial populations, including human pathogens.

We recommend the following practices:

- Where water is reused in a series of processes, arranging water flow to be counter to the movement of produce through different operations, with the result that as produce is further processed, it is exposed to the cleanest water
- Monitoring and treating processing water for level of disinfectant chemical to ensure the water is maintained in a condition suitable for the application (e.g., washing, cooling, or transporting) and does not become a source of microbial contamination
- Routinely inspecting and maintaining equipment designed to assist in maintaining water quality, such as chlorine injectors, filtration systems, and backflow devices, to ensure efficient operation

We recommend that ice used on fresh or fresh-cut produce be included in routine water quality testing.

a. Maintaining Water Quality

When used appropriately with adequate quality water, antimicrobial chemicals help minimize the potential for microbial contamination of processing water and subsequent cross contamination of the product. The effectiveness of an antimicrobial agent, as well as the amount that should be used, depends on the treatment conditions, such as water temperature, acidity [pH], water hardness, contact time, amount and rate of product throughput, type of product, water to product ratio, amount of organic material, and the resistance of pathogens to the particular antimicrobial agent. For example, the antimicrobial activity of a chlorine-based disinfectant depends on the amount of hypochlorous acid (also called "free chlorine") present in the water. The amount of hypochlorous acid in the water depends upon the pH of the water, the amount of organic material in the water, and, to some extent, the temperature of the water. If the amount of hypochlorous acid is not maintained when the amount of organic material increases, the antimicrobial agent may lose effectiveness in maintaining water quality. If a fresh-cut processor uses a chlorine containing compound as a disinfectant, we recommend that the processor monitor the processing water for free chlorine or hypochlorous acid concentrations. As another example, the measurement of Oxidation-Reduction Potential (ORP) is used as an indicator of the activity of any antimicrobial agent that is an oxidizer and as a measure of the agent's effectiveness during processing. Variables that affect antimicrobial activity during processing directly affect the ORP value and may also be used to determine the effectiveness of these oxidizers such as hypochlorous acid, hypobromous acid, chlorine dioxide, ozone, and peroxides.

We recommend that fresh-cut processors consider options for maintaining the quality of water most appropriate for their individual operations. Producers may wish to contact a local agricultural extension agent, their chemical supplier, or a food safety consultant for help in deciding what water treatment chemicals to use. In addition, processors may refer to 21 CFR 173.315, "Chemicals used in washing or to assist in the peeling of fruits and vegetables," for additional information about chemicals approved for use in wash water.

We recommend that fresh-cut processors also consider the following regarding water quality maintenance:

- Following the manufacturer's directions for correct mixing of antimicrobial agents to obtain effective concentrations and to minimize safety hazards

Manufacturers' suggested or allowable levels of antimicrobial chemicals in wash water should not be exceeded.

- Monitoring disinfectant levels frequently in water used for various processing operations to ensure appropriate concentrations are maintained

Test strips or test kits may be useful for monitoring some disinfectant levels.

- Minimizing the build up of organic material in wash water

For some operations, filtering recirculating water or using a net to scoop plant material or other debris from tanks may help reduce the build up of organic material.

- Following contact between produce and processing water containing antimicrobial chemicals with a clean water rinse of adequate quality to remove any treatment residues where appropriate and consistent with the manufacturer's directions

b. Washing Fresh Produce

Prior to arriving at the processing facility, RACs may be washed in the field or in a place such as a cooling facility. RACs may also go directly from the field to the processing facility to be washed after receipt. Regardless of where the initial washing of the produce takes place, washing produce can reduce the overall potential for microbial food safety hazards because most microbial contamination is on the surface of the produce. If pathogens are not removed, inactivated, or otherwise controlled at this initial stage, they can potentially spread the contamination to additional produce during processing. Washing RACs before any processing of the produce occurs may reduce potential surface contamination. However, washing, even with disinfectants, can only reduce, not eliminate, pathogens, if present. Washing has little or no effect on pathogens that have been internalized in the produce.

A number of post harvest processes, such as hydrocooling, use of dump tanks, and flume transport utilize a high degree of water-to-produce contact. We recommend that fresh-cut processors use practices to maximize the cleaning potential during these processes and to minimize the potential for cross-contamination.

We recommend the following practices:

- Using a series of washes, if appropriate

For some operations, a series of washes may be more effective than a single wash. An initial wash treatment may be used to remove the bulk of field soil from produce followed by an additional wash or washes containing an antimicrobial chemical.

- Using appropriate wash methods

Vigorous washing of produce not easily bruised or injured increases the likelihood of pathogen removal. Different methods may be used to wash different types of produce, including submersion, spray, or both. Regardless of the method used, maintaining the quality of the wash water (see section 2.a. above) is important in order to minimize the potential for contamination.

- Maintaining the efficacy of wash treatments

- Using wash water of an appropriate temperature

Produce is susceptible to infiltration of wash water if warm produce is placed in water that is cooler than the produce. Such infiltration occurs when the temperature difference creates a pressure differential causing air spaces inside the fruit or vegetable to contract, thereby allowing water to be pulled into the fruit or vegetable. If pathogens are present in the cooling/wash water, they may infiltrate the produce, and subsequent washing will not reduce levels of these pathogens (Refs. 6, 14). Therefore, water used for washing or cooling produce should contain sufficient levels of disinfectant to reduce the potential for pathogens to persist in such water. When it is not practical to reduce the temperature differential between the wash/cooling water and the produce, it is especially important that processors follow practices to minimize pathogens in the water or on the surface of produce. Such practices may include using antimicrobial chemicals in the wash water or using spray type wash treatments instead of submerging produce. Alternatively, produce may be cooled by means other than hydrocooling and then washed with water that is warmer than the produce.

3. Precooling and Cold Storage

Sanitary cold storage of RACs and fresh-cut produce is important to reduce the risk of microbial contamination and potential for subsequent growth. However, most current temperature recommendations for both whole and fresh produce are based on temperatures that maintain quality attributes.⁽⁸⁾ Although we recognize that more research needs to be done to identify the types of whole and fresh-cut produce that will support the growth of human pathogens and the temperatures at which this pathogen growth will occur, certain practices can reduce the potential for pathogen growth and contamination during precooling and cold storage. We recommend the following practices to reduce this risk:

- Holding RACs and fresh-cut produce at appropriate cold storage temperatures to reduce the potential for microbial growth
- Preventing condensate and defrost water from evaporator-type cooling systems (e.g., vacuum cooling, cold storage) from dripping onto fresh and fresh-cut produce
- Designing and maintaining forced air cooling to avoid contaminating fresh produce
 - In most instances, vacuum cooling or use of fans poses the lowest risk of microbial contamination
- Holding cut melons and any other fresh-cut product determined to need temperature control for safety at $\leq 41^{\circ}\text{F}$ ($\leq 5^{\circ}\text{C}$)
- Locating temperature monitoring devices in the warm area of the refrigerator unit (e.g., near the door) and calibrating them on a regular basis
- Inspecting all refrigeration units on a regular basis and keeping them in good operating condition
- Storing similar commodities together (unprocessed product next to unprocessed product and finished product next to finished product) to avoid cross-contamination
- Using an appropriate inventory system to ensure first in first out (FIFO) use and FIFO shipment of raw materials and finished products

4. Washing Fresh-cut Produce: Post-processing Controls

Final washing of fresh produce after cutting, slicing, shredding, and similar fresh-cut processes helps remove some of the cellular fluids that could serve as nutrients for microbial growth. Monitoring the quality of water used in such operations and replacing it at an appropriate frequency as indicated by such monitoring may help prevent the build up of organic material in the water and reduce or prevent cross-contamination of processed produce. We have the following additional recommendations for use after the final wash of processed produce:

- Where appropriate for the product, removing as much excess water as possible from processed produce through draining methods such as spin drying
- Keeping containers used to hold produce (e.g., spin baskets) from direct contact with the floor and away from containers that have had direct contact with the floor (e.g., in cold storage)

D. Packaging

Anything that touches fresh-cut produce has the potential to contaminate it, including the materials used in packaging the finished product.

We recommend the following practices:

- Maintaining an effective system to prevent the use of contaminated, damaged, or defective cartons and totes in order to prevent microbial contamination of the fresh-cut produce during packing operations
- Overseeing incoming materials and gases used in packaging to confirm that they are not damaged or defective and are in appropriate working order
- Rejecting packaging materials that are damaged or contaminated
- Determining the appropriate gas mixtures for products
- Using containers and cartons for their intended purpose only. For example, we recommend against using a carton designated for holding fresh-cut produce to hold tools.
- Storing packaging containers and other packaging materials in a manner so as to protect them from contamination, such as away from pests, dirt, cleaning chemicals, and water condensation from overhead equipment and structures
- Maintaining a program to identify and correct situations where damage to containers may potentially occur
- Labeling all finished fresh-cut produce products with recommended storage instructions (e.g., "Keep Refrigerated") or storage temperature to inform all persons handling the product of the recommended storage conditions

1. Modified Atmosphere Packaging (MAP)

Some packaging controls used for fresh-cut produce affect the environment within the package by reducing the levels of oxygen. Low oxygen levels help maintain the quality of fresh produce and extend shelf-life by slowing respiration and senescence in plant tissues. Oxygen can be reduced passively by using gas permeable films in packaging that result in the natural development of the desired atmosphere; the desired atmosphere is a consequence of the products' respiration as gas diffuses through the film (Ref. 6). Oxygen can also be reduced actively by displacing the mixture of gases in a package with a gas mixture that has a low concentration of oxygen (1-5%). Microorganisms respond differently to the surrounding gases depending on their tolerance. While reduced oxygen and elevated carbon dioxide retard the growth of spoilage microorganisms such as *Pseudomonas spp.*, the same gas conditions may provide growth opportunities for pathogenic microorganisms. At extremely low oxygen levels (< 1%), anaerobic respiration can occur, resulting in tissue destruction that affects product quality and creating the potential for growth of foodborne pathogens such as *Clostridium botulinum* (Ref. 6). It is generally believed, however, that fresh-cut produce will spoil before the toxin becomes a concern (Ref. 6). Non-pathogenic aerobic and facultative microorganisms are present at the time of packaging and persist after packaging.

MAP is only effective in extending shelf-life if used in conjunction with good refrigeration. Elevated temperatures can promote the growth of spoilage organisms and pathogens that may be present. Thus, we recommend that food processors using MAP adhere to strict temperature controls and appropriate shelf-life parameters. Because refrigeration temperatures may not be maintained during distribution of the products or while they are held by retailers or consumers, we also recommend that controls be in place to either prevent increases in temperature, as feasible, or to alert the processor, retailer, or consumer that the product may not be safe to consume. Processors may wish to consider providing product handling guidelines on temperature control and washing to the distributor, retailer, and consumer. Another potential source of contamination of fresh cut produce packed in MAP occurs when the gases, equipment, or packaging materials are not properly maintained. As with any type of packaging, we recommend that controls be put in place to ensure that the process of packaging the product and the packaging materials themselves do not cause the product to become contaminated.

2. Shelf-life

Fresh-cut fruits and vegetables can cause illness due to contamination with a variety of microorganisms because these products do not undergo any processing to ensure the total elimination of microorganisms that might be present. Some packaging and storage techniques for fresh-cut produce (e.g., MAP, refrigerated storage) may slow the rate of physical deterioration by slowing respiration of the produce. However, if packaging and storage are not properly controlled, pathogens may grow to levels that could render the product unsafe for human consumption. The rate of respiration of fresh produce is inversely related to product shelf-life, which means that a higher respiration rate decreases shelf-life (Ref. 6). Fresh fruits and vegetables that have been cut or otherwise physically altered will have increased respiration, and thus, a shorter shelf-life. To address the risks of increased respiration, we recommend the following practices:

- Communicating (through product labeling) that the consumer should refrigerate the product to prevent product spoilage and the potential for growth of pathogens

- Ensuring that any "use by" date on the product package is validated by studies of the product with respect to microbiological safety

We recommend that records of these data and studies be maintained to document the reliability of the "use by" labeling.

E. Transportation and Storage

We recommend that finished fresh-cut product be stored and transported under conditions that will protect the food against physical, chemical, and microbiological contamination. We recommend, if feasible, that raw whole produce not be stored with finished product and finished product be transported in clean, sanitary vehicles. We also recommend the following practices:

- Keeping finished products refrigerated at temperatures appropriate for the product during storage, transportation, and display for sale to minimize the potential for growth of microbial pathogens
- Equipping refrigerated transportation vehicles and storage rooms with accurate temperature measuring devices, preferably including a temperature recording function

If a recording temperature device is not used, we recommend that a min/max thermometer, i.e., a thermometer that shows the range of temperatures attained over a set time period, be used.

- Shipping fresh-cut produce products on a FIFO basis to minimize storage time
- Ensuring that the equipment in refrigeration vehicles is designed to circulate cold air uniformly throughout the vehicle while taking the load layout into consideration
- Placing fresh-cut produce products in storage facilities and transportation vehicles in a manner that allows for proper air circulation
- Transporting and storing fresh-cut produce products in vehicles and containers that are dedicated to carrying food products and have been treated by a process that is effective in destroying vegetative cells of microorganisms of public health significance
- Inspecting transportation vehicles and containers for debris, soil, and off-odors prior to loading to increase their suitability for transporting fresh-cut produce
- Loading and unloading fresh-cut produce in a manner that minimizes the potential for damage and for microbial contamination

IX. Documentation and Records

We recommend as a general practice that food processors maintain records sufficient to reflect important product information and practices. Such documentation can be helpful to the processor in several ways. First, such records help ensure consistency of processing operations and end-product quality and safety. They are more reliable than human memory, and they are a useful tool to identify operational areas where inconsistencies occur and further employee training may be needed. Second, maintaining adequate documentation and records of processing operations is important if a traceback investigation of product is ever needed. We recommend that records be retained at the processing plant for at least six months after the date that the products were prepared unless a longer retention time is required under a relevant law or regulation. Records are most useful when they begin by including the date and time, name of person(s) who completed the record, and the activity or production station being recorded.

Records that may be kept for most food processing operations include the following:

- Water quality and supply records
- Water treatment and monitoring records
- Employee training records
- Temperature control records
- Equipment monitoring and maintenance records
- Calibration records
- Sanitation records
- Product processing batch records
- Corrective action records
- Pest control records
- Distribution records
- Inspection records (e.g., incoming product, facility, production area)
- Microbiological contamination records (e.g., food contact surfaces, equipment)

X. Traceback and Recall

Traceback is the process of tracking food items, such as fresh-cut produce, back to their source (growers, packers, processor, field and when harvested). The ability to identify the source of a product can serve as an important complement to food safety programs intended to prevent the occurrence of microbial contamination. Information gained from a traceback investigation may also be useful in limiting the impact of an outbreak of foodborne illness and in identifying and eliminating conditions that may have resulted in the produce becoming contaminated. We recommend that fresh-cut processors establish and maintain written traceback procedures to respond to food safety hazard problems when they arise.

We also recommend that fresh-cut processors establish and maintain a current written contingency plan for use in initiating and carrying out a recall. Having procedures in place will enable the recall of any lot of product that may have been implicated in an outbreak or that tested positive for a pathogen and help provide detailed information to assist the investigation of any foodborne illness associated with the product. Recall procedures usually include the name of the contact persons responsible at all times; the roles and responsibilities for the coordination of a recall; the methods to identify (e.g., use of lot codes), locate, and control recalled products; requirements to investigate other possibly affected products which could subsequently be included in the recall; and procedures for monitoring the effectiveness of the recall.

Because a recall may extend to more than one lot of product, we recommend that processors develop a coding system to help identify incoming product sources, individual production lots and to whom each lot is distributed. Use of package and date codes can help link product packages with production times, equipment, and raw ingredient sources and may facilitate recovery of products during a recall.

In the event of a firm-initiated recall, if a firm believes its product is adulterated or otherwise violates the Act, we request that the firm immediately notify the appropriate FDA district office in the state where the processing facility is located. District office locations are provided in 21 CFR 5.115. (See Appendix A for information to include in the notification.)

Produce growers and packers, fresh-cut produce processors, and shippers are encouraged to work with their partners in growing, transporting, distributing, packing, and processing, and with retail sectors to develop technologies that allow identification of fresh-cut produce from the grower to your operation, to the retailer, and to the consumer.

XI. Additional Information

The following are additional resources for information on how to handle food products safely.

On the web:

1. [FDA/Center for Food Safety and Applied Nutrition \(/food\)](#)
2. [Fight BAC!](http://www.fightbac.org) (<http://www.fightbac.org>). [Ⓔ](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)[®]
3. [Gateway to Government Food Safety Information \(http://www.foodsafety.gov\)](http://www.foodsafety.gov)
4. [Centers for Disease Control and Prevention \(http://www.cdc.gov/\)](http://www.cdc.gov/) (CDC)
5. [USDA/Food Safety and Inspection Service \(http://www.fsis.usda.gov\)](http://www.fsis.usda.gov) (FSIS)
6. [NACMCF HACCP guidelines \(/food/hazard-analysis-critical-control-point-haccp/haccp-principles-application-guidelines\)](#)

Other resources:

7. Ednet: a monthly electronic newsletter for food safety educators. To subscribe, send an email message to Listserv@foodsafety.gov (<mailto:Listserv@foodsafety.gov>). Send the message: Subscribe EDNET-L first name last name.
8. [FDA's Outreach and Information Center \(/contact-cfsan\)](#): 1.888.SAFEFOOD
9. Code of Hygienic Practices for Fresh Fruits and Vegetables (CAC/RCP 53-2003)
10. General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003)

XII. References

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2. U.S. Department of Agriculture and Centers for Disease Control and Prevention, "MyPyramid (<http://www.mypyramid.gov/>)," April 2005. (accessed 2/27/07).
3. U.S. Department of Agriculture, Economic Research Service, *U.S. per Capita Food Consumption of Fruits and Vegetables, 2005*. (<http://www.ers.usda.gov/Data/FoodConsumption/>). Click on "Food Availability," then "Custom Queries," and then choose "fruits and vegetables" as the commodity group to begin the query. (accessed 2/27/07)
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15. FDA, U.S. Department of Agriculture, and the Centers for Disease Control and Prevention, [Guide to Minimize Microbial Food Safety Hazards in Fresh Fruits and Vegetables](http://www.fda.gov/food/guidance-documents-regulatory-information/topic/guidance-industry-guide-minimize-microbial-food-safety-hazards-fresh-fruits-and-vegetables) ([/food/guidance-documents-regulatory-information/topic/guidance-industry-guide-minimize-microbial-food-safety-hazards-fresh-fruits-and-vegetables](http://www.fda.gov/food/guidance-documents-regulatory-information/topic/guidance-industry-guide-minimize-microbial-food-safety-hazards-fresh-fruits-and-vegetables))," October 1998. (accessed 2/28/07).
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17. FDA, Center for Food Safety and Applied Nutrition, "[Foodborne Pathogenic Microorganisms and Natural Toxins Handbook \(Bad Bug Book\)](http://www.fda.gov/oc/ohrt/badbugbook/)" ([/bad-bug-book](http://www.fda.gov/oc/ohrt/badbugbook/))," January 2001. (accessed 2/28/07).
18. FDA and the Centers for Disease Control and Prevention, "[Reducing the Risk of *Listeria monocytogenes*, FDA/CDC 2003 Update of the *Listeria* Action Plan](http://www.fda.gov/oc/ohrt/listeria/)" ([http://wayback.archive-it.org/7993/20161022011257/http://www.fda.gov/Food/FoodborneIllnessContaminants/FoodborneIllnessesNeedToKnow/ucm332272.htm](http://www.fda.gov/oc/ohrt/listeria/)) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)," November 2003. (accessed 2/28/07).

XIII. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average 0.067 hour per record for SOP & SSOP maintenance, 40 hours per record for traceback maintenance, 0.067 hour per record for system implementation of a preventive control program comparable to a HACCP system, and 4 hours per record for implementation review of that preventive control program, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to: Office of Food Safety, Division of Plant and Dairy Food Safety (HFS-317), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0609 (expires 10/31/2010).

Appendices

1. Notifying FDA of a Recall
2. Foodborne Pathogens Associated with Fresh Fruits and Vegetables
3. Pathogens Often Transmitted by Food That Has Been Contaminated by Infected Employees
4. Sources of Microbial Contamination
 1. Potential Sources of Microbial Contamination
 2. Examples of Scenarios That May Cause Microbial Contamination of the Product
5. An Example of Product/Personnel Flow Patterns in a Fresh-cut Processing Plant

Appendix A - Notifying FDA of a Recall

In the event of a firm-initiated recall, if a firm believes its product is adulterated or otherwise violates the Act, we request that the firm immediately notify the appropriate FDA district office and that the notification include:

- the identity of the product involved (i.e., an adequate description of the type of food to include brand name and specific variety, date of releasing the food, the lot or code number or other identifier of the implicated product, the quantity and how the food is packaged);
- the reason for the recall and the date and circumstances under which the product deficiency or possible deficiency was discovered;
- an evaluation of the risk associated with the product;

- the total amount of implicated product units processed and the time span of processing;
- the total amount of product in inventory and the total amount of product distributed; the distribution information including the number of direct accounts and, where necessary, the identity of the direct accounts;
- a copy of the firm's recall communication, if any has issued, or the proposed communication if none has issued; the proposed strategy for conducting the recall; and
- the name and telephone number of the firm official who should be contacted concerning the recall

For further FDA guidance on recalls, see 21 CFR sections 7.40-7.59.

Appendix B - Foodborne Pathogens Associated with Fresh Fruits and Vegetables

The U.S. Public Health Service has identified a number of microorganisms associated with foodborne illness that are notable either because of the severity or because of the prevalence of the illness they cause. Foodborne microbial pathogens associated with the consumption of fresh fruits and vegetables include *Cyclospora cayetanensis*, *Escherichia coli* O157:H7, hepatitis A virus, *Listeria monocytogenes*, Norovirus, *Salmonella* spp., and *Shigella* spp.(9).

- **Cyclospora** infections (cyclosporiasis) are caused by the protozoan *Cyclospora cayetanensis*. The infections are spread by ingestion of food or water contaminated with infected stool. Direct person-to-person transmission is unlikely because excreted oocysts require days to weeks under favorable environmental conditions to become infectious (i.e., sporulate). The natural host for this parasite has not been identified; however, contaminated water used for irrigation and pesticide application and poor worker hygiene have been suggested as the most likely routes of contamination. The infection (cyclosporiasis) is commonly characterized by watery diarrhea, loss of appetite, weight loss, abdominal bloating and cramping, low-grade fever, nausea, vomiting, and fatigue. Relapses and asymptomatic infections can occur. Outbreaks of cyclosporiasis have been linked to fresh raspberries, mesclun lettuce, and basil or basil-containing products. (For more information: *Bad Bug Book*, *Cyclospora cayetanensis* (<http://wayback.archive-it.org/7993/20170110195835/http://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/ucm122216.htm>). [Ⓞ](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>))
- **E. coli O157:H7** is a bacterium and one of the enterovirulent strains of *Escherichia coli*. Most *E. coli* strains are nonpathogenic, found in the intestines of all animals, including humans, and function by suppressing harmful bacterial growth. However, there are a minority of strains such as serotype O157:H7 that may cause human illness. *E. coli* O157:H7 is a life-threatening bacterium that produces large quantities of potent toxins that can cause severe damage to the lining of the intestines. Human illness associated with *E. coli* O157:H7 infection may include nonbloody diarrhea, hemorrhagic colitis, hemolytic uremic syndrome (HUS), or thrombotic thrombocytopenic purpura (TTP). Hemorrhagic colitis progresses from abdominal cramps to nonbloody diarrhea to bloody diarrhea. HUS largely affects young children and is the leading cause of acute renal failure in children. TTP is a rare syndrome of *E. coli* O157:H7 infection, which largely affects adults and resembles HUS histology. *E. coli* O157:H7 outbreaks have been associated with meat (especially undercooked or raw hamburger), fresh produce, raw milk, unpasteurized apple juice, coleslaw, and contaminated water (For more information: *Bad Bug Book*, *Escherichia coli* (<http://wayback.archive-it.org/7993/20170110195835/http://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/ucm071284.htm>). [Ⓞ](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)).
- **Hepatitis A virus** may cause a serious, and sometimes fatal, disease. Hepatitis attributed to hepatitis A virus is characterized by sudden onset of fever, malaise, nausea, anorexia, and abdominal discomfort, followed in several days by jaundice. Hepatitis A virus is excreted in fecal material and is transmitted by the fecal-oral route, which include consumption of contaminated food. The most common food sources of Hepatitis A are shellfish and salads, but it may also be transmitted through drinking water. (For more information: *Bad Bug Book*, *Hepatitis A Virus* (<http://wayback.archive-it.org/7993/20161022011302/http://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/ucm071294.htm>). [Ⓞ](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>))
- **Listeria monocytogenes**(10) is a bacterium that causes listeriosis, a serious disease in pregnant women, the elderly, and those with weakened immune systems. *L. monocytogenes* is widespread in the environment (i.e., in soil, water, and decaying vegetation) and has been isolated from domestic animals, humans, raw produce, food processing environments (particularly cool damp areas), and home refrigerators. Outbreaks of listeriosis in the United States have been associated with the consumption of hot dogs, deli or luncheon meats, pate, salami, Mexican-style soft cheeses and butter made with raw milk, and raw vegetables (Ref. 16). (For more information: "Quantitative Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods")
- **Noroviruses** are a group of related, single-stranded RNA, nonenveloped viruses that cause acute gastroenteritis in humans. Norovirus was recently approved as the official genus name for the group of viruses provisionally described as "Norwalk-like viruses." Norovirus is transmitted by the fecal-oral route most commonly via contaminated water or contaminated foods. Shellfish and salad ingredients are the foods most often implicated in norovirus outbreaks. (For more information: *Bad Bug Book*, *The Norwalk virus family* (<http://wayback.archive-it.org/7993/20161022011304/http://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/ucm071344.htm>). [Ⓞ](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) and CDC, *Noroviruses* (<https://www.cdc.gov/norovirus/index.html>))
- **Salmonella** is the second most common cause of foodborne illness (salmonellosis) in the United States and is responsible for millions of cases of illness each year. Typical symptoms of salmonellosis are nausea, vomiting, abdominal cramps, fever, mild diarrhea, and headache; these symptoms usually last 6-48 hours. Salmonella outbreaks have been associated with the consumption of raw and

undercooked eggs, undercooked poultry and meat, dairy products made with unpasteurized milk, shrimp, fresh produce, and unpasteurized fruit juice. (For more information: *Bad Bug Book*, *Salmonella* spp.)

- **Shigella spp.** Humans are a natural reservoir for *Shigella* spp. The primary means of transmission of the shigella organism is by the fecal-oral route. Most cases of infection by shigella (shigellosis) are attributed to the ingestion of food or water contaminated with fecal matter. Contamination has often been associated with poor personal hygiene of food workers. Typical symptoms include abdominal pain, cramps, diarrhea, fever, vomiting, and blood, pus, or mucus in stools. Shigellosis outbreaks have been associated with shredded lettuce, potato salad, green onions, parsley, cheese, seafood, and poultry (Ref. 19). (For more information: *Bad Bug Book*, *Shigella* spp.)

Appendix C - Pathogens Often Transmitted by Food that Has Been Contaminated by Infected Employees*

A wide range of communicable diseases may be transmitted by infected employees to consumers through contaminated food or food utensils. We recommend that fresh-cut produce firms establish an ongoing program to identify employees who present a risk of transmitting foodborne pathogens to fresh produce or to other employees. Below is a list of the most common pathogens that may be transmitted through food and their associated symptoms.

Pathogen	Symptoms
1. Hepatitis A virus	fever, jaundice
2. <i>Salmonella typhi</i>	fever
3. <i>Shigella</i> species	diarrhea, fever, vomiting
4. Norwalk and Norwalk-like viruses	diarrhea, fever, vomiting
5. <i>Staphylococcus aureus</i>	diarrhea, vomiting

Diarrhea, fever, and vomiting are also symptoms of several other pathogens that could be transmitted by food contaminated by infected employees.

Please refer to the [CDC web site \(http://www.cdc.gov/foodsafety/disease.htm\)](http://www.cdc.gov/foodsafety/disease.htm) for further information on foodborne diseases, pathogens, and toxins: *.

Appendix D

Figure 5. Potential sources of microbial contamination

- **Ingredients**
 - Raw produce
 - Fresh-cut produce
- **Packaging materials**
 - Containers, films, lids, trays
- **Processing aids**
 - Compressed air
 - Untreated or inadequately treated wash water
 - Ice
 - Reused processing water
- **Facility environment**
 - Ceilings, overhead structures, catwalks
 - Rubber seals around doors (especially coolers)
 - Drains
 - Walls
 - Standing water
 - Wet insulation in walls or around pipes and cooling units
 - Condensate
 - Vacuum cleaner contents
 - Hand washing areas (sinks) and restrooms
- **Food contact surfaces**
 - Fibrous or porous type conveyor belts
 - Filling or packaging equipment
 - Equipment cleaning tools
 - Slicers, dicers, shredders, blenders,
 - Belts, peelers, collators

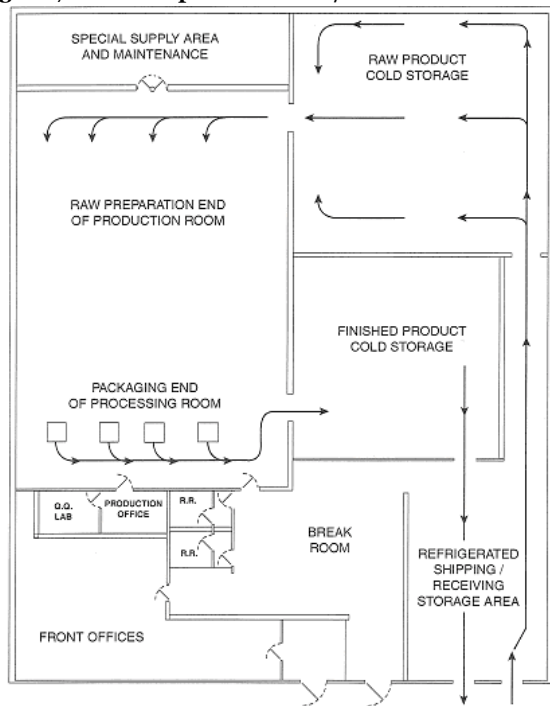
- Containers, bins, tubs, or baskets
- Hands, gloves, and outerwear
- Ice makers
- Utensils
- **Nonfood-contact surfaces**
 - In-floor weighing equipment
 - Hollow rollers for conveyors
 - Trash cans and other such ancillary items
 - Visible bearings within equipment
 - Condensate drip pans
 - Maintenance tools (wrenches, screw drivers, etc.)
 - On/off switches
 - Cracked hoses
 - Equipment framework
 - Wet rusting or hollow framework
 - Poorly maintained compressed air filters
 - Motor housing
 - Forklifts, hand trucks, trolleys, racks
 - Vacuum cleaners and floor scrubbers

Figure 6. Examples of Scenarios That May Cause Microbial Contamination of the Product

1. A processing line is moved or modified significantly.
2. Used equipment is brought in from storage or another plant and installed into the process flow.
3. An equipment breakdown occurs.
4. Construction or major modifications are made to a fresh-cut produce processing area (e.g., replacing refrigeration units or floors, replacing or building walls, modifications to sewer lines).
5. An employee unfamiliar with the operation and microbial controls has been hired or assigned to work or clean equipment in the processing areas.
6. Personnel who handle fresh produce and fresh-cut produce touch surfaces or equipment that are likely to be contaminated (e.g., floor, trash cans) and do not change gloves or follow other recommended procedures before handling product.
7. Periods of heavy production make it difficult to change processing water or clean food contact surfaces at the facility as scheduled.
8. A drain backs up.
9. Product is caught or hung up on equipment for an extended period and is not removed during equipment clean-up. Microorganisms may grow in stagnant product and can be a major source of contamination during production. FDA recommends that equipment be modified to eliminate areas where product stops moving along or through a processing line and cannot be readily removed during cleaning.
10. There are frequent product changes on a packaging line which necessitate changing packaging film, labels, forming pockets or molds, line speeds, etc.
11. Personnel are used interchangeably for handling unprocessed produce and finished fresh-cut product.
12. There is increased production requiring wet cleaning of down lines in the same room as lines running product.
13. Equipment parts, tubs, screens, etc. are cleaned on the floor.
14. Waste bins in the processing areas are not properly maintained, cleaned, and sanitized. Personnel handling product may come into contact with these items and then contaminate product and/or product contact surfaces.

Appendix E

Figure 7. An Example of Product/Personnel Flow Patterns in a Fresh-cut Processing Plant (11)



Notes

(1) This guidance has been prepared by the Division of Plant and Dairy Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

(2) Fresh sprouts are raw agricultural commodities and thus, their production is not governed by 21 CFR Part 110. FDA does, however, recommend that sprouting firms employ current good manufacturing practices. Also, FDA has published specific guidance for the production of sprouts. We recommend that producers of sprouts refer to this guidance, "[Reducing Microbial Food Safety Hazards for Sprouted Seeds](http://wayback.archive-it.org/7993/20170110195835/http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm120244.htm)" (<http://wayback.archive-it.org/7993/20170110195835/http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm120244.htm>). (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)" (Ref. 13) and "Guidance for Industry: Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production" (Ref. 14).

(3) For information regarding re-washing of fresh-cut produce, California Department of Health Services Food and Drug Branch "Recommendations from Fresh-cut Produce Re-wash Panel, April 4, 2006." (available in [PDF](http://www.dhs.ca.gov/fdb/local/PDF/Fresh%20cut%20Wash%20Panel%20Background%20web.pdf) (<http://www.dhs.ca.gov/fdb/local/PDF/Fresh%20cut%20Wash%20Panel%20Background%20web.pdf>)).

(4) A copy of the [CGMPs in 21 CFR Part 110](#) ([/current-good-manufacturing-practices-cgmps](#)) may be accessed on the internet.

(5) United Fresh Produce Association: <http://www.unitedfresh.org/> (<http://www.unitedfresh.org/>). (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>).

(6) Used with permission from the United Fresh Produce Association (UFPA), *Food Safety Guidelines for the Fresh-cut Produce Industry*, 4th Edition, 2001.

(7) Also, as noted previously in section V.B.3., we recommend that employees be trained to avoid use of high-pressure water hoses to clean floors, walls, and equipment in the processing and packaging areas during production or after production equipment has been cleaned. This practice will help prevent aerosols from contacting processing equipment and food-contact surfaces, product, or packaging materials.

(8) An exception is Chapter 1 of the [FDA Food Code \(2005\)](#) ([/food/food-code/food-code-2005](#)), which defines potentially hazardous food (PHF) and identifies specific fresh produce (among other foods) that is considered PHF and therefore requires refrigeration at 41°F. Cut melons are considered a PHF.

(9) More information about these and other microbiological pathogens can be found in [FDA's Bad Bug Book](#) ([/bad-bug-book](#)). See Ref. 17.

(10) For additional information, FDA, the Centers for Disease Control and Prevention, and the U.S. Department of Agriculture (USDA) have developed a *Listeria* Action Plan (Ref. 18) and a *Listeria* risk assessment (Ref. 16).

(11) Used with permission from UFPA, *Food Safety Guidelines for the Fresh-cut Produce Industry*, 4th Edition, 2001.

The above guidance supercedes the previous version issued March 2007.

Related Information

- [Produce & Plant Products Guidance Documents & Regulatory Information \(/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/produce-plant-products-guidance-documents-regulatory-information\)](https://www.regulations.gov/docket/FDA-2008-D-0108/document).
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