FSHN05-05

Guidance for Processing FRESH-CUT PRODUCE *in Retail Operations*

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Credits

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Background

This guidance has been prepared in response to a notable increase in on-site retail processing (manufacturing) of foods traditionally processed in controlled plant environments. Such retail processing can involve, but is not limited to acidifying, smoking, drying, fermenting, curing, reduced oxygen packaging, and other operations that are traditionally done at a food manufacturing plant level. The key distinction for processing as related to this guidance is that the processing occurs on-site in the retail setting.

This guidance is intended for retailers and regulatory personnel to help understand the controls to implement in a retail operation in order to process and sell safe food products. It can be referenced in developing considerations for **variances** for any exception or special provision to state or local food safety or sanitary codes. It addresses those special variances required by the FDA Food Code which may require HACCP plans for those jurisdictions that have adopted those portions of the FDA Food Code. In addition, it also applies to regulatory oversight and/or approval for regulatory overlap that may occur between the states' processing requirements and the state or local retail food safety and sanitary codes. This guidance assumes retail compliance with applicable retail food codes, prerequisite standard sanitary operations procedures, and labeling requirements specified in 21 CFR 101. This guidance is not intended to replace or duplicate existing regulations, but it does offer a reference for more uniform practices.

Disclaimer

This guidance is not a binding set of requirements. The information provided in the guidance are recommendations based on current science, commercial experience and practical considerations as assembled by the assigned committees and reviewed by a variety of selected experts and the Project Steering Committee. Use of these recommendations would likely result in retail processing practices that are acceptable to the pertinent authorities for food safety. Retail compliance and enforcement will remain within the interpretations and decisions of the pertinent state and local regulatory authorities.

Product Description

The International Fresh-cut Produce Association (IFPA) defines fresh-cut produce as "any fresh-cut fruit or vegetable or any combination thereof that has been physically altered but remains in the fresh state. These products are items such as bagged salads, baby cut carrots and broccoli florets." This definition covers a wide range of products which require vastly different handling practices. This definition is broadened to include the repacking of fresh-cut herbs and their use on packaged fresh-cut products manufactured in the retail setting and/or held for sale. This guidance will give general recommendations for fresh-cut produce, but is not intended to be applicable for all instances.

Related terminology:

Approved food grade sanitizer - means a sanitizer approved for intended purposes of sanitizing food contact surfaces and disinfecting produce wash water. Additional information can be found at 21 CFR 178.1010 for sanitizers designated for food contact surfaces and 21 CFR 173.315 for wash water treatments for washing produce: (https://www.govinfo.gov/app/details/CFR-2012-title21-vol3/CFR-2012-title21-vol3-sec173-315).

Approved source - a source that has been determined to conform to principles, practices, and standards that protect public health.

Clean - means the complete removal of food soil using appropriate chemicals under recommended conditions.

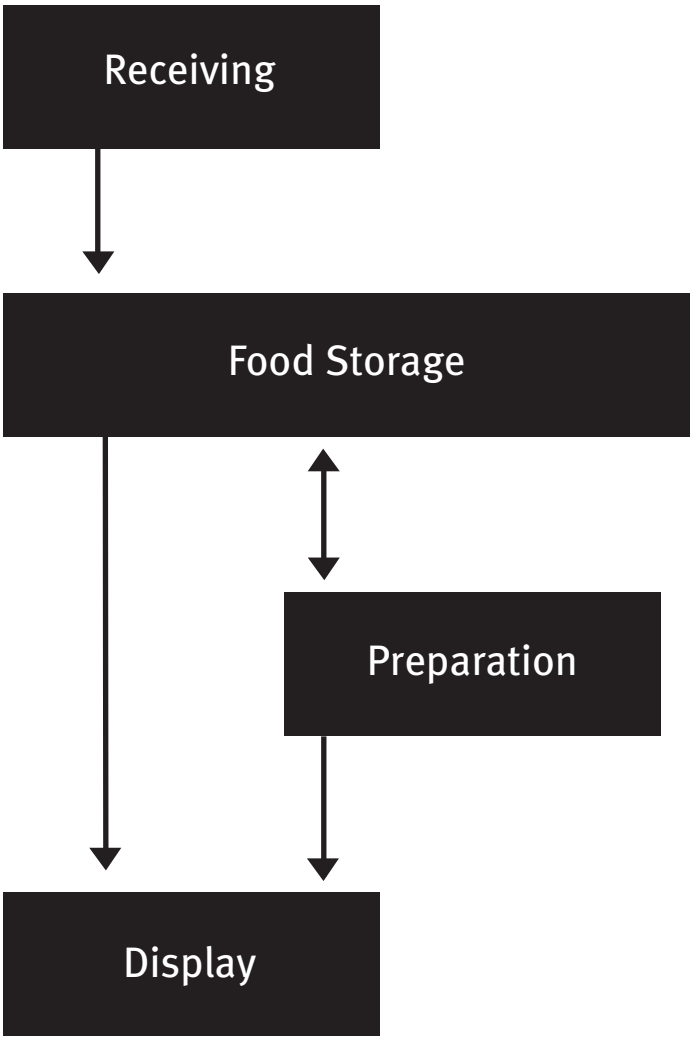
Food Hazard - Any biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

Identifiable source - can include the name and address of the immediate supplier and the actual source or location of the supplies.

Sanitize - means the application of cumulative heat or chemicals on cleaned food contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, which is equal to a 99.999% reduction, of representative disease causing microorganisms of public health importance.

Potentially hazardous food - means a food that is natural or synthetic and that requires temperature control because it is in a form capable of supporting the rapid and progressive growth of infectious or toxigenic microorganisms or the growth and toxin production of *Clostridium botulinum* (e.g., as in the case of mushrooms packaged in a non-oxygen permeable film). Potentially hazardous food includes an animal food that is raw or heat-treated, shell eggs, or a food of plant origin that is heat-treated or consists of raw seed spouts, cut melons, mushrooms, and garlic-in-oil mixtures that are not modified in a way that results in mixtures that do not support growth as specified in this definition.

Flow Diagram of Operations



Receiving

All produce, including fruits, vegetables and other fresh-cut produce components, i.e., health food supplements, herbs, wheat germ, etc., are obtained from an identifiable, approved source. All supplies and ingredients must be from identifiable suppliers, operating in accordance with applicable food safety requirements. Identifiers can include the name and address of the immediate supplier and the actual source or location of the supplies. Evidence for suppliers may include a letter from the supplier that indicates they follow Good Agriculture Practices (GAPs). The GAPs information and prior agreements with the retail fresh-cut produce operation are intended to reduce the risk of potential biological, chemical or physical food safety hazards (Appendix 1 - Hazards).

Traceability of the food sources is important in the investigation of foodborne outbreaks and should be an aspect of a food safety program.

All package materials used in the production of fresh-cut produce comes from an identifiable, approved source. All fresh-cut packaging materials are appropriate for their intended purpose.

All produce is to be delivered at recommended, commodity-specific, temperatures. If refrigeration is absent or questionable, a calibrated thermometer should be available to monitor the internal temperature of the incoming foods before acceptance (Appendix 2 - Calibrations).

Retail establishment actively manages a program for routine inspection of incoming products for approved sources, product condition and temperature as necessary, integrity of packaging and proper label information, and documents product acceptance or rejection with dates, times and the person in decision, plus any necessary comments.

Food Storage

Storage can include temperature control units used to hold raw and fresh-cut produce. These types of foods can be stored in separate units or segregated with protection in the same unit. Display counters are not considered storage units and should not be used to store raw ingredients.

The storage unit maintains the fresh-cut produce products at appropriate temperature. Potentially hazardous fresh-cut produce must be maintained and stored at or below 41°F (5°C).

Routine monitoring for proper refrigerated storage unit temperatures involves use of a continuous time-temperature recording device or by periodic checks with a calibrated thermometer. All recorders and thermometers are calibrated periodically or as needed (Appendix 2 - Calibrations). When storage conditions above 41°F (5°C) are detected, an evaluation is conducted of all products stored in the unit. The evaluations will record considerations for the actual temperature of the products and duration of exposure. All unacceptable temperature abused, off-color, off-odor, off-condition, out-of-date or otherwise suspect product is discarded.

The storage unit(s) is clean and orderly.

Products are appropriately contained.

Fresh-cut produce is marked for identity and date of preparation.

Ready-to-eat items and items ready-for-display are physically separated from products that require further handling or processing.

Products should be stored so as to reduce the potential for cross contamination by leakage between products.

Condensers and catch pans underneath should be clean and sanitary.

Condensation from cooler drip pans and other sources should not be allowed to contact products or packaging materials.

Products are stored at least 6 inches above the floor and away from walls and the ceiling. Storage should not involve use of unsanitary containers, shelves, supports, pallets, etc.

The schedule for product rotation should use a 'First-in First-out' rule (FIFO).

Preparation

The work area, facilities and utensils should be designated and, where possible, dedicated to the fresh-cut produce operations. If it is necessary to share work space and facilities, there must be a schedule of operations, including personnel traffic, product traffic, and cleaning and sanitizing of food contact surfaces to reduce the potential for cross contamination of the ready-to-eat fresh-cut produce products.

Standard Operating Procedures for basic sanitation and food safety are used and documented daily (Appendix 4 - Daily SOP Check List).

The preparation schedule ensures that the product handling time at room temperature is minimized for those products considered potentially hazardous.

The preparation area should provide for the protection of trays, films, overstock, lids, etc. from physical, chemical or biological contaminants.

Preparation – Handling of Fresh-cut Produce

Special care should be taken in preparation of any fresh-cut produce to reduce the potential for bacterial contamination and/or growth of human pathogens. These include, but are not limited to, proper handwashing and glove use, cleaning and sanitizing food contact surfaces, the reduction of potential cross contamination and appropriate finished product holding temperatures.

The product type and time of manufacture are recorded for each batch of fresh-cut produce (Appendix 4 - Daily SOP Check List).

The washing of fruits and vegetables is performed as defined by the FDA Food Code:

(A) Raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants, or washed as specified in paragraph (B) of this section, before being cut, combined with other ingredients, served, or offered for human consumption in ready-to-eat form except as specified in (B) of this section.

(B) Fruits and vegetables may be washed by using chemicals as specified under §7-204.12 of the FDA Food Code.

(C) Potable running water is referred to sinks or tanks of standing water to allow run-off of contamination. Water temperature used to wash should be warmer than the temperature of the produce being washed to prevent infiltration of wash water.

Employees handling fruit and vegetables should maintain proper personal hygiene.

No bare hand contact with the finished product. Single use gloves should be use to prevent cross-contamination. Proper hand washing practices are required.

Packaging material must be food grade and maintained in clean condition.

Use packaging material appropriate for specific product (e.g., the use of oxygen permeable films for the packaging of mushrooms to prevent the formation of an anaerobic environment and subsequent growth of Clostridium botulinum.

Display

Display involves holding the finished products in temperature control units for a specified duration and condition for public sale. Retail preparation and display introduces more prolonged storage that must be controlled and monitored to assure product safety before consumption.

The display unit maintains the fresh-cut produce products at the appropriate temperature. Potentially hazardous fresh-cut produce must be maintained and displayed at or below 41°F (5°C).

The display unit, including liner and shelving, are cleaned and maintained to provide a sanitary environment for product.

Packaged product information should conform to federal, state and local labeling requirements and includes instructions for proper storage and shelf-life. (Appendix 3 - Product Labels).

Appendices

1. Food Safety Hazards
2. Calibrations
3. Product Labels
4. Daily SOP Check List

Appendix 1 Food Safety Hazards

Fruits and vegetables, like all other foods, may occasionally become contaminated with human pathogens or chemical contaminants which may cause illnesses. For several years the Centers for Disease Control and Prevention has identified a significant increase in the number of foodborne disease outbreaks associated with fresh produce. Contamination may occur in the field, during postharvest handling, during transportation, during preparation in food service establishments, in stores or in consumer's homes. Produce associated outbreaks may be caused by microbial hazards including viruses, bacteria and protozoa. Foodborne illnesses have been associated mostly with microbes that are associated with and spread via fecal contamination or by exposure to contaminated water. While outbreaks associated with fresh produce are rare, there have been isolated incidents involving specific commodities. The primary implicated product(s) of concern (PIPC) for each hazard have been listed below. This is not intended to be a complete list of products nor a statement regarding risk, but rather a historical reference of some of the outbreaks that have occurred.

Organisms of note include hepatitis A and noroviruses, *Shigella* and the protozoan parasite *Cyclospora cayetanensis*. Other feces associated microbes that have caused foodborne illness outbreaks include *Salmonella*, enterohaemorrhagic *Escherichia coli* (including O157:H7), and the protozoa *Cryptosporidium and Cyclospora*. Other micro-organisms of note which occur naturally in soil and decaying plant matter include *Bacillus cereus, Listeria monocytogenes, and Clostridium botulinum*. These organisms may contaminate the produce in the field, during and after harvesting, during storage or transport and finally in the retail establishment. Listed below are the organisms most commonly associated with produce; in many cases these have been associated with foodborne illness outbreaks. It should be noted that the control steps, which in most cases involves washing the produce, will not completely eliminate human pathogens on produce. Prevention of contamination is the key food safety issue. Washing produce will, however, reduce the risk. For those products where washing is not an option due to the frailty of the commodity, added importance should be given to obtaining the produce from an approved and/or identifiable source where Good Agricultural Practices (GAPs) are followed.

Biological

Hazard: Clostridium botulinum

Problem: *Clostridium botulinum* can grow under conditions in which oxygen is eliminated or reduced and form toxins that affect the human consumer. *C. botulinum* toxins are extremely lethal if consumed.

PIPC: Mushrooms

Controls: Ensure packaging has sufficient oxygen permeability to prevent an anaerobic environment from forming.

Hazard: *E. coli* **O157:H7**

Problem: May be found on incoming produce. Every effort should be made to reduce the potential for contamination prior to the preparation step or its growth should be prevented through proper holding temperatures.

PIPC: Sprouts; lettuce

Controls: Use produce from identifiable sources; wash with potable water and/or sanitizer approved for the intended purpose.

Hazard: *Listeria monocytogenes*

Problem: Has been linked to foodborne illness related to ready-to-eat foods that support growth. Listeriosis may affect the elderly, immune-compromised individuals as well as pregnant women causing death or stillbirth.

PIPC: Undetermined

Controls: Use produce from identifiable sources; wash with potable water and/or sanitizer approved for the intended purpose.

Hazard: *Salmonella spp.*

Problem: May be found on incoming produce. Every effort should be made to reduce the potential for contamination prior to the preparation step or its growth should be prevented through proper holding temperatures.

PIPC: Tomatoes; Cantaloupe; Sprouts

Controls: Use produce from identifiable sources; wash with potable water and/or sanitizer approved for the intended purpose.

Hazard: *Shigella spp.*

Problem: May be found on incoming produce. Every effort should be made to reduce the potential for contamination prior to the preparation step or its growth should be prevented through proper holding temperatures

PIPC: Cilantro; parsley; lettuce

Controls: Use produce from identifiable sources; wash with potable water and/or sanitizer approved for the intended purpose.

Hazard: *Cyclospora cayetanensis*

Problem: May be found on incoming produce and if not eliminated prior to the preparation step its presences could cause illness.

PIPC: Raspberries, blackberries, mesclun lettuce, basil

Controls: Use produce from identifiable sources; wash with potable water and/or sanitizer approved for the intended purpose. Ensure proper personal hygiene and handling of produce.

Hazard: *Cryptosporidium parvum*

Problem: May be found on incoming produce and if not eliminated prior to the preparation step its presences could cause illness.

PIPC: Green onions

Controls: Use produce from identifiable sources; wash with potable water and/or sanitizer approved for the intended purpose. Ensure proper personal hygiene and handling of produce.

Hazard: Hepatitis A

Problem: May be present on incoming produce or may be transmitted from worker hand to the finished product and cause illness.

PIPC: Strawberries

Controls: Use produce from identifiable sources; wash with potable water and/or approved food grade sanitizer. Ensure proper personal hygiene and handling of produce.

Hazard: Noroviruses

Problem: May be present on incoming produce or may be transmitted from worker hand to the finished product and cause illness.

PIPC: Raspberries; Strawberries

Controls: Use produce from identifiable sources; wash with potable water and/or approved food grade sanitizer. Ensure proper personal hygiene and handling of produce.

Chemical

Hazard: Allergens

Problem: May be associated with mixed salads and other items where allergenic foods are not typically found. Can result in mild to severe allergic reactions.

PIPC: Tree nuts; peanuts; croutons, etc.

Controls: Can be controlled or reduced through the prevention of cross-contamination and proper labeling.

Temperature Monitoring Devices – Thermometers

Many types of thermometers and temperature recording devices are readily available for use in food handling operations. We recommend thermistors, thermocouples and infrared thermometers with either a digital or analog readout. All of these instruments are acceptable for use in the food processing operations as long as the operator understands how they are used and if they are calibrated for proper readings.

The method and frequency of calibration for thermometers will depend on the use and temperature range where the equipment is used. In the absence of manufacture's recommendations, thermometers should be calibrated at least once a month with more frequent calibrations when the instrument is physically abused or if the readings are questionable.

Temperature Monitoring Devices (TMD) - Calibration Procedures (options):

a. TMD's can be calibrated against a thermometer certified by the National Institute of Standards and Technology (NIST) by simply comparing both units at two preset temperatures (hot and cold).

b. TMD's can be calibrated using an ice-water slush. Insert the temperature probe into a mixture of ice and water slush and stir (2-3 min) until the thermometer stabilizes. The probe should be at the center of the container. The thermometer should read 32±1°F (0±1°C). Adjust accordingly or discard and replace the faulty thermometer.

c. Hot point calibration is used when monitoring temperatures higher than room temperature (e.g., cooking temperatures). Heating blocks or boiling water can be used for this calibration. When using the boiling water procedure, the probe is placed inside a container with boiling water until the thermometer stabilizes (2-3 min). The probe should be at the center of the container. The thermometer should read 212±1°F (100±1°C) or appropriate temperature according to elevation (Table 1 - Altitude to Boiling Point of Pure Water Relationship). Adjust accordingly or discard and replace the faulty thermometer.

d. A combination of the procedures b and c is recommended for a more accurate calibration of thermometers used to moniter a wide range of temperatures.

Altitude to Boiling Point of Pure Water Relationship

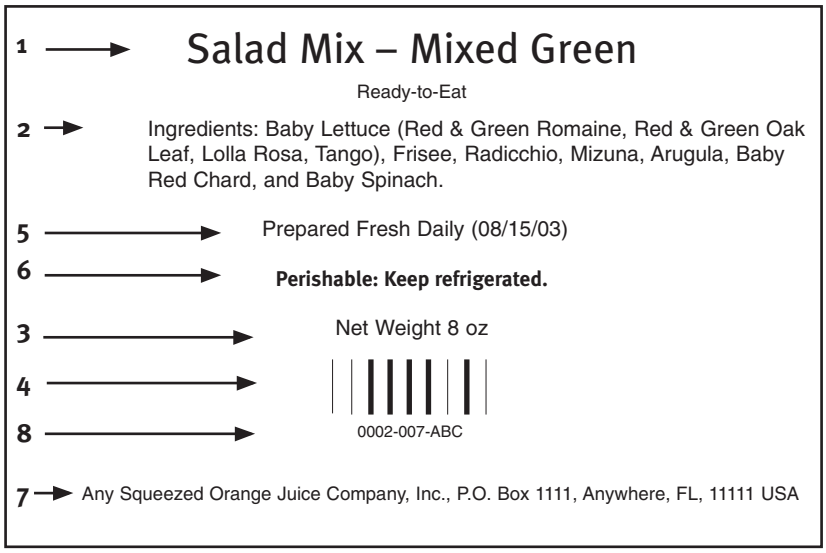
Feet Above Sea Level	Boiling Point (°F)
0	212
500	211
1,000	210
1,500	209
2,000	208
2,500	207
3,000	206
3,500	205
4,000	204
4,500	203
5,000	203
6,000	201
7,000	199
8,000	197
10,000	194
12,000	190
14,000	187

Source: Thermometer Calibration, food safety webpage, University of Nebraska Cooperative Extension (https://food.unl.edu/thermometer-calibration-information-and-measuring-ph-meat)

Label Information

All packaged fresh-cut produce sold through display in a retail setting must be in compliance with applicable state food code requirements and contain label information pursuant to the requirements of 21 CFR 101.

1. Product type used to describe the product. The description should be in common terms associated with the product and recognized by the consumer.
2. Product ingredients listed in order of the predominance in the food.
3. Net weight and pricing information.
4. Product inventory and identity code.
5. Lot and/or date code of the product.
6. Recommended handling statement to instruct consumer handling and storage.
7. Company name and address, including zip code.
8. Production code to facilitate tracking and recall.



Disclaimer: This label is simply provided as a guide. Retailers should consult with their local authorities to assure compliance with more immediate requirements in their region.

Appendix 4 Daily SOP Check list

Store Name/Number: _____ **DATE:** _____

Storage	**Time/Temp**	**Time/Temp**	**Time/Temp**	**Time/Temp**
Refrigerators (°F / Time)	°F	°F	°F	°F
Freezers (°F / Time)	°F	°F	°F	°F
Display	**Time/Temp**	**Time/Temp**	**Time/Temp**	**Time/Temp**
Display temperature (°F / Time)	°F	°F	°F	°F
Clean and Orderly. Food in good condition and properly labeled.				
	SOP CHECK LIST			
Work Area	**Comments**			
Orderly; Clean and Sanitized tables, countertops and sinks. Orderly, all work surfaces cleared. Clean floor and drains				
Proper storage and labeling of chemicals and cleaning items				
Wet and dry trash separate and removed from work area.				
All utensils, pots, pans, bowls, cutting boards, cooking or heating equipment properly cleaned and sanitized.				
Thermometer and recorder available and calibrated				
Personnel				
Personnel Health, hand-washing practices, glove use, clean and well maintained outer garments, proper hair covering and no jewelry.				
Food Storage				
All food protected, dated and labeled properly				
Refrigerators and freezers clean, orderly and operating correctly.				
	Pre-Op	**Time**	**Post-Op**	**Time**
Employee Initials				
Manager Review				

This particular form is not mandated but it does indicate information that should be recorded to demonstrate an appropriate process for food safety. Different and additional forms can be used to record the same information.

Notes:

Notes:

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