



Cooperative Extension Service
Institute of Food and Agricultural Sciences

Fresh Juice Processing GMPs¹

R.H. Schmidt, R.M. Goodrich, C.A. Sims, and M.E. Parish²

Background

Fresh-squeezed (not-pasteurized) citrus juices have become increasingly popular products because of their fresh, natural quality. The feature which sets these juices apart from conventional citrus juices is the lack of heat pasteurization which, while increasing shelf-life due to enzyme and spoilage microorganism destruction, can result in flavor loss and other changes.

Recent outbreaks involving non-pasteurized apple cider contaminated with *Escherichia coli* 0157:H7 have received news media and regulatory attention. While this microorganism has not been associated (to date) with citrus juice, a *Salmonellosis* outbreak has occurred with non-pasteurized orange juice. The commonality with all fresh juice illness outbreaks has been manufacture under poor sanitation conditions.

Regulatory Responses

State regulatory agencies, including the Florida Dept. of Citrus (DOC), the Florida Dept. of Agriculture & Consumer Services (DACS), and agencies in other states have increased regulatory surveillance over the fresh juice industry. The U.S. Dept. of Health and Human Services/Food & Drug Admin. (FDA) has recently issued regulations (63 Fed. Reg. 37029) which requires a warning label or labeling for packaged fruit and vegetable juices which have not been pasteurized or otherwise treated to reduce the potential presence of

pathogenic microorganisms. FDA is also proposing mandatory Hazard Analysis Critical Control Point (HACCP) systems for all fruit and vegetable juices (63 Fed. Reg. 20450). This mandatory HACCP regulation follows the agency's seafood HACCP program (60 FR 65096) and the U.S. Dept. of Agriculture/Food Safety and Inspection Service (FSIS) mandatory HACCP regulation for meats and poultry (61 FR 38805).

The HACCP System

HACCP is a logical and thorough system designed to identify potential hazards and/or critical situations and to produce a structured plan to provide control for elimination, reduction, or prevention of these identified hazards. Overviews of HACCP applied to fresh citrus juice operations have been previously published (Florida Dept. Agric. Consumer Serv. 1997; Schmidt *et al.* 1997).

Many prerequisite programs provide the foundation of a HACCP system. Included in these prerequisite programs are three well-defined and documented sanitation and management programs

1. Good Manufacturing Practices (GMPs) are general statements regarding sanitation, facilities, equipment, processes and controls. Current Good Manufacturing Practices (cGMPs) are included in FDA regulations for the food industry (21 CFR 110) and have been stressed in the proposed mandatory HACCP rule for fruit and vegetable juice and juice products.

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2. R.H. Schmidt, Ph.D., professor, and C.A. Sims, Ph.D., associate professor, Food Science and Human Nutrition department, Cooperative Extension Service, Institute of Food and Agricultural Sciences, University of Florida, Gainesville, 32611. R.M. Goodrich, Ph.D., assistant professor, and M.E. Parish, Ph.D., associate professor, Citrus Research and Experiment Station, Lake Alfred, FL 33850.

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2. Standard Operating Procedures (SOPs) are more specifically written and detailed, and are tailored to individual operations. FSIS mandatory HACCP regulations for meats and poultry (61 FR 38805), require that facilities develop, implement, and maintain written SOPs for sanitation which are termed Sanitation Standard Operating Procedures (SSOPs).

3. Good Agricultural Practices (GAPs) are broad guidelines for minimizing microbial contamination of raw agricultural commodities through the control of water, manure, worker health and hygiene, field and facility sanitation, and transportation. A proposed guidance document (63 FR 18029) recently published by FDA includes GAPs for fresh fruits and vegetables.

General sanitation procedures (Schmidt 1997) and cleaning and sanitizing procedures (Schmidt 1997) have been previously published. In addition, sanitation procedures as applied to fresh citrus juice have been generally discussed (Carter 1989; Schmidt *et al.* 1997).

Model GMPs and SOPs

Model GMPs and SOPs for unpasteurized apple cider have also been developed as guidelines for manufacture of unpasteurized apple cider (See listing in References). The following are similar guidelines for fresh citrus juice operations which can be used in writing individualized GMPs and SOPs.

Flow Diagrams

The important first step in developing a set of practices for sanitation and/or management is to establish a complete understanding of the flow of the product through the entire processing and handling system. To do this, develop accurate flow diagrams for each product handled or processed. Flow diagrams are most useful not as complicated engineering drawings, but as a simple box diagram easily understood by all personnel involved. Walk-through inspections should be done to verify the accuracy of the flow diagram. An example of a flow diagram for fresh citrus juice is presented in Figure.

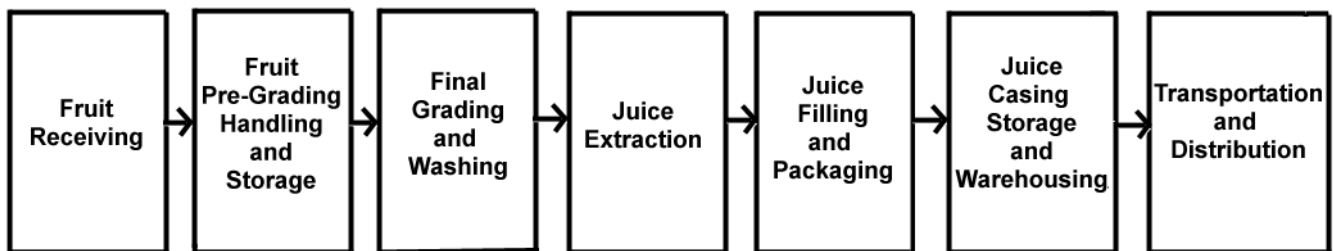


Figure. Flow Diagram for fresh citrus juice.

General Good Manufacturing Practices (GMPs) for Food Processing and Handling

The following tables are general guidelines to be use in developing individualized GMPs for: Employees, Personnel, and Management

- Table 1. Responsibilities, Knowledge, and Training
- Table 2. Personal Cleanliness and Practices
- Physical Facilities, Premises, and Surroundings
- Table 3. Exterior Environment
- Table 4. General Construction, Layout, and Design of Physical Facilities
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- Materials and Fabrication
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- Table 13. Equipment Design and Construction
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- Table 15. Maintenance and Repair
- Table 16. Cleaning and Sanitizing Raw Products, Ingredients, Additives, and Packing Materials
- Table 17. Source
- Table 18. Receiving and Storage
- Product Processing , Handling, and Packaging
- Table 19. Processing and Handling
- Table 20. Filling and Packaging
- Storage, Warehousing, Transportation, and Distribution
- Table 21. Storage and Warehousing
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- Chemicals, Pesticides, and Poisonous or Toxic Materials
- Table 23. Source, Labeling, and Identification
- Table 24. Storage and Use.
- Administration, Management, Maintenance, and Operations
- Table 25. Identification of Responsible Personnel
- Table 26. Documentation and Records
- Table 27. Product Recall Program

Table 1. Responsibilities, Knowledge, and Training

<p>Responsible employees must have the appropriate training and knowledge to carry out their assigned duties in a sanitary manner.</p>	<p><i>Evaluate and assess the knowledge and/or training needs of all employees.</i></p> <p>Are all responsible personnel appropriately trained in sanitation principles, hygienic practices, and food-borne disease prevention procedures?</p> <p>Are all responsible personnel appropriately trained in the importance of hand washing, prevention of cross contamination, maintaining the facility in good repair and sanitary condition, housekeeping and cleaning of non-product contact and environmental surfaces, and cleaning and sanitizing food-contact surfaces?</p> <p>Are all responsible personnel appropriately trained in the risks of handling food products when infected or diagnosed with a contagious disease condition?</p> <p>Are employees involved in sanitation functions, cleaning and sanitizing equipment, and similar activities regarded by line personnel and management as an essential part of the processing operation and accorded with equally important value to those involved in other activities?</p> <p>Is it required that employees report (to their immediate supervisor) any potential infection or diagnosis with a contagious disease?</p> <p>Is it required that employees infected or diagnosed with a cold, contagious disease, open wounds, exposed bandages, or other infective conditions not be involved in handling food products?</p>
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Table 2. Personal Cleanliness and Practices

<p>Poor hygienic and management practices by personnel and employees is a major source of contamination in a food handling and processing facility.</p> <p>A majority of reported food-borne illness outbreaks can be attributed to poor employee practices.</p>	<p><i>Evaluate the food handling and hygienic practices of all employees.</i></p> <p>Are all employees observed and/or inspected while engaged in food handling and processing operations at a regular, predetermined frequency?</p> <p>Are employee traffic patterns assessed and evaluated throughout the facility?</p> <p>Are employees involved with raw materials operations or who may be a source of contamination restricted from entering finished product areas?</p> <p>Are visitors restricted from critical food handling and processing areas?</p> <p>Is it required and assured that all employees remove all jewelry (except plain wedding bands) before engaging in food handling or processing?</p> <p>Is it required and assured that all employees wear clean outer clothing, uniforms, boots, and appropriate hair restraints (hats, caps, hair nets, beard nets, etc.) when engaging in food handling or processing operations?</p> <p>Is it required and assured that all employees keep their hands, arms, and exposed portions clean while engaging in food handling or processing operations?</p> <p>Is it required and assured that all employees follow proper hand washing procedures and that they wash their hands immediately before engaging in food handling or processing?</p> <p>Is it required and assured that all employees do not handle animals or pets before engaging in or during food handling or processing?</p> <p>Is it required and assured that all employees do not eat, drink, or use tobacco while engaged in food handling or processing?</p>
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Table 3. Exterior Environment

<p>Any food handling facility should be isolated from pests, vermin, dust and other exterior sources of contamination.</p> <p>Care should be taken to minimize harborage of pests and vermin in the exterior environment.</p>	<p><i>Evaluate and minimize contamination from exterior environment.</i></p> <p>Is the drainage adequate to prevent pooled or standing water near buildings?</p> <p>Are exterior grasses and vegetation kept appropriately trimmed?</p> <p>Is sufficient effort being made to control contamination from insects and vermin including: rats, mice, frogs, toads, and birds?</p> <p>Are harborage areas for insect and vermin which may create contamination problems eliminated?</p> <p>Is exterior screening and wall integrity (including sealing all piping, electrical conduit inlets, etc.) sufficient to keep out vermin, insects, birds, and animals?</p>
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Table 4. General Construction, Layout and Design of Physical Facilities

<p>Buildings, rooms, and facilities which are improperly constructed or in poor repair cannot be cleaned and maintained in a sanitary manner.</p>	<p><i>Evaluate the construction and design features of all buildings, rooms, and facilities and make appropriate repairs.</i></p> <p>Are buildings and facilities of adequate size for the food processing and handling operations?</p> <p>Are buildings and facilities of suitable construction such that they can be readily cleaned and maintained in a sanitary manner?</p>
<p>Improper design and flow-through features of buildings, rooms, and facilities could result in cross-contamination problems.</p>	<p>Are the floors, walls, and ceilings in good repair, sealed to prevent outside sources of contamination, and constructed of impervious, non-porous, readily cleanable materials?</p> <p>Are facilities designed such that a logical flow-through pattern from raw to finished product exists to prevent the risk of cross-contamination of finished product with raw materials?</p> <p>Are "clean rooms" identified for critical operations such as final container filling which are constructed separate from other areas?</p> <p>Is positive HEPA-filtered air provided for "clean rooms"?</p> <p>Are refrigeration facilities of sufficient number and adequate size for the food processing and handling operations?</p> <p>Are service sinks and facilities properly constructed and of sufficient size and adequate number?</p> <p>Are physical facilities properly cleaned as often as necessary and are cleaning functions performed during periods when the least amount of food is exposed?</p>

Table 5. Sanitary Facilities

<p>Facilities which are not of sanitary construction cannot be appropriately cleaned and maintained.</p>	<p><i>Evaluate the construction, accessibility, and adequacy of sanitary facilities including: lavatories, wash rooms, toilets, dressing areas and/or locker room facilities.</i></p> <p>Are there sufficient number of sanitary facilities for the number of employees?</p>
<p>If not accessible for employee use or adequate for the number of employees, such facilities will not be appropriately used.</p>	<p>Are sanitary facilities accessible to employees during all hours of operation?</p> <p>Are sanitary facilities appropriately separated from food processing and handling areas?</p> <p>Are the doors of the sanitary facilities tight-fitting and self-closing?</p> <p>Are sanitary facilities appropriately constructed to be readily cleaned and maintained in a sanitary manner?</p> <p>Are sanitary facilities clean and maintained in a sanitary manner?</p>

Table 6. Hand-Washing Facilities

<p>An improperly located, constructed and maintained hand washing sink will not be properly used by employees.</p>	<p><i>Evaluate the construction, accessibility, and adequacy of hand washing sinks or facilities.</i></p>
<p>Adequate hand washing cannot be accomplished without hot water, appropriate hand cleanser and clean, single service towel.</p>	<p>Are hand washing sinks or facilities, separate from food handling and service sinks, provided?</p> <p>Are hand washing sinks accessible to work areas such that they can be used just before food handling operations?</p> <p>Are hand washing facilities provided with an appropriate hand cleanser, both cold and <u>hot water</u> at a temperature of at least 110° F (43° C), individual disposable towels, and a clean, well-maintained waste receptacle?</p> <p>If water is too hot, the hand washing sink will not be used properly.</p>
<p>If water is too hot, the hand washing sink will not be used properly.</p>	<p>Are water heating systems such as steam mixing valves which provide excessively hot water <u>not</u> used for hand washing facilities?</p> <p>Are faucets foot or electric eye operated, or are other means provided to prevent contamination of the faucets with dirty hands?</p>

Table 7. Lighting

<p>Effective food processing and handling, maintenance, and cleaning functions are not possible without sufficient light.</p>	<p><i>Evaluate the adequacy of lighting in the facility.</i></p>
<p>Light fixtures can be a source of contamination if not properly installed.</p>	<p>Are all lights in food processing and handling areas appropriately sealed or provided with appropriate protection so that broken glass is not a problem?</p> <p>Is a light intensity of 110 lux (10 foot candles) or higher provided at a distance of 75 cm (30 in) above the floor in walk-in refrigeration units, and dry food storage areas?</p> <p>Is a light intensity of 220 lux (20 foot candles) or higher provided inside reach-in refrigeration units and a distance of 75 cm (30 in) above the floor in areas used for food handling operations, hand washing, cleaning and sanitizing equipment surfaces, and in toilet rooms?</p> <p>Is a light intensity of 540 lux (50 foot candles) provided at the surfaces of equipment or areas where employee safety is a factor?</p>

Table 8. Heating, Ventilation, and Air Conditioning

<p>A poorly ventilated plant will have condensation problems which increase the risk of overhead contamination.</p> <p>HVAC systems which are not properly installed or routinely cleaned can be a source of airborne contamination.</p>	<p><i>Evaluate the heating, ventilation, and air conditioning (HVAC) systems in the facility.</i></p> <p>Are HVAC systems of a cleanable design and cleaned at an appropriate frequency?</p> <p>Is the source of intake air properly filtered?</p> <p>Is the source of intake air so located to not be able to pick up dust, noxious odors, or exhaust air from the plant and on the roof or at least 6 ft above ground?</p> <p>Is positive air pressure maintained in packaging rooms and in finished product areas?</p>
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Table 9. Water and Ice

<p>Contaminated or poor quality water and ice can be a significant source of contamination.</p> <p>Water hardness can hinder cleaning and sanitizing effectiveness.</p> <p>Water supply can be contaminated by improperly installed or maintained plumbing.</p> <p>Ice manufactured under unsanitary conditions or from an un-approved source can be a source of contamination.</p> <p>Ice machines must be cleaned and maintained.</p>	<p><i>Evaluate the chemical, physical and microbiological quality of all water and ice used for all food handling and processing operations and cleaning and sanitizing equipment.</i></p> <p>Is the facility provided with sanitary, potable water from an approved source which is of high microbiological purity which is low in hardness and suspended solids?</p> <p>Is the plumbing designed and constructed according to existing plumbing codes and maintained in good repair?</p> <p>If well water is used, is it located at least 50 feet from potential sources of contamination, and is it designed, constructed, and installed to meet existing codes?</p> <p>Are appropriate backflow prevention devices and/or air gaps installed on faucets and hoses, and are submerged inlets avoided to prevent back-siphonage from contamination sources into the water supply?</p> <p>Is the water supply evaluated by appropriate microbiological and chemical testing at a regular, predetermined frequency?</p> <p>Is all ice used in food handling and processing of sanitary, potable quality and manufactured under sanitary conditions or from an approved source?</p> <p>Are ice machines designed, constructed and installed to be cleanable, and properly plumbed to prevent waste or sewage backup into the ice?</p> <p>Are ice machines cleaned and maintained at a regular, predetermined frequency?</p>
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Table 10. Waste Disposal, Handling and Facilities

<p>Improperly designed and maintained waste facilities attract pests, vermin, and other sources of contamination.</p> <p>The plant environment can be contaminated by improper waste disposal practices and improperly constructed, installed, and maintained floor drains.</p>	<p><i>Evaluate waste facilities and waste handling practices.</i></p> <p>Are waste facilities, trash disposal receptacles, and operations separated from processing/handling areas?</p> <p>Are waste facilities cleaned and maintained on a regular basis?</p> <p>Are garbage and trash containers or bags covered and sealed or otherwise handled so as not to attract vermin or pests?</p> <p>Are sewer lines and floor drains constructed, designed and installed according to existing sanitation codes?</p> <p>Are trapped floor drains cleaned on a regular, predetermined frequency, maintained in a sanitary condition, and kept in good repair?</p>
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Table 11. Food-Contact Surfaces

<p>Improper materials used for food-contact surfaces may allow migration of deleterious substances, impart off-flavors or colors, or may absorb food materials and become a source of contamination.</p> <p>Food-contact surfaces which are not smooth and durable and food equipment which is not designed to be cleaned cannot be cleaned and sanitized properly. Most wood surfaces have a high porosity and are not cleanable.</p> <p>Many plastic and rubber materials are not acceptable for food-contact surfaces.</p>	<p><i>Thoroughly evaluate the materials and fabrication characteristics and design of all food-contact surfaces in the food processing and handling operation.</i></p> <p>Is all food equipment used in the facility of sanitary design and construction and does it meet all applicable standards for food grade equipment?</p> <p>Are food-contact surfaces constructed from materials which are safe, durable, corrosion-resistant, non-absorbent, and resistant to pitting, chipping, scratching, scoring, distortion or decomposition?</p> <p>Are all food-contact surfaces manufactured and fabricated using impervious materials which are free of crevices and cleanable?</p> <p>Is 300 series stainless steel (or a metal which is at least as corrosion resistant) with a surface finish which is at least as smooth as a No. 4 ground finish used for food-contact surfaces wherever feasible?</p> <p>Is the use of wood for food-contact surfaces limited to cutting boards and similar applications (hard maple or equivalent), and wood shipping containers for raw produce, and, if treated, does the preservative meet FDA requirements?</p> <p>Is the use of cast iron, galvanized metal, and lead-containing materials for food-contact surfaces prohibited?</p> <p>Is the use of sponges in contact with cleaned and sanitized or in-use food-contact surfaces prohibited?</p> <p>Is copper prohibited for use in contact with food that has a pH of 6.0 or below?</p>
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Plastic or rubber which has a lot of wear are not considered cleanable in design.

Aluminum can easily become corroded, cracked, and pitted with long term exposure to chemicals or corrosive food materials. Corroded aluminum is not cleanable.

Is the use of plastic for food-contact surfaces limited to specific applications (i.e. rotors, liners, gaskets, O-rings, seals and related parts) or in minimal use for other applications, and, if used, is it suitably impervious, nonabsorbent, nontoxic, and in good repair?

Is the use of aluminum for food-contact surfaces minimized, and, if used, is it impervious, cleanable, and in good repair?

Is the use of rubber and rubber-like materials limited to special applications (i.e. rotors, liners, gaskets, O-rings, seals and related parts) and, if used, is it suitably impervious, nonabsorbent, nontoxic, and in good repair?

Are welded areas of food-contact surfaces fabricated and finished to be at least as smooth as a No. 4 ground finish on stainless steel and free of pits, folds, and crevices?

Is solder, if used, of the silver bearing type which is free of lead, cadmium, and antimony, nonabsorbent, and nontoxic?

Is the use of glass for food-contact surfaces limited to special applications where necessary, and, if used, is it protected by encasing with a shatterproof coating (i.e. glass sensors or stems of temperature measuring devices)?

Are food-contact surfaces constructed and finished to be smooth and cleanable?

Table 12. Non-food Contact Surfaces

Improperly constructed or maintained nonfood-contact surfaces can harbor environmental pathogens and other contaminants.

Evaluate the materials, fabrication, and condition of all nonfood-contact surfaces.

Are nonfood-contact surfaces of suitable durability for adequate cleaning and free of corrosion.

Are nonfood-contact surfaces which are exposed to splash, spillage, or soiling and which require frequent cleaning, constructed of an appropriately corrosion-resistant, nonabsorbant, and smooth material?

Table 13. Equipment Design and Construction

Equipment should be covered or provided with drip shields or similar devices which protect it from overhead contamination.

Evaluate the sanitary design and construction of all equipment.

Is food equipment constructed and designed to be free of sharp internal angles, corners, or crevices, readily accessible for cleaning and inspection, and properly sloped to allow drainage?

Are openings fitted with a cover or lid which overlaps the opening and is sloped to drain?

<p>Equipment should be designed such that the food product is not exposed or is protected from environmental contamination due to splash.</p>	<p>Are all tank and similar reservoirs constructed such that product inlets and outlets are substantially flush (with nipple of no more than one pipe diameter in length) such that no dead-end exists which allows accumulation of product or cleaning solution?</p> <p>Are drip shields, condensate trays, and similar devices provided as needed, and are they constructed to be cleanable and sloped to drain away from food products to prevent overhead contamination?</p> <p>Is equipment which contains exposed bearings and gears that require lubricants designed, constructed, and installed so that the lubricant cannot leak, drip, or be drawn into food or onto food-contact surfaces?</p> <p>Are all temperature measuring devices properly installed and located, and are they checked for accuracy?</p> <p>Is equipment designed to be free of unnecessary ledges, projections, and crevices to allow easy cleaning and to facilitate maintenance, and are they maintained in good repair?</p> <p>Are legs, casters, wheels, pedestals, or similar supports provided for equipment of sufficient length to provide a minimum clearance of 4 in (100 mm) or more between the lowest part of the base and the floor or counter?</p>
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Table 14 . Installation and Operation

<p>Food equipment not located or installed to allow for cleaning cannot be properly cleaned and sanitized.</p>	<p><i>Evaluate the location, installation, and operation of all food processing and handling equipment.</i></p> <p>Is the equipment located and installed to minimize the risk of contamination from the outdoor environment, from floor drains, and from other environmental sources?</p> <p>Is the equipment located and installed to minimize the risk of overhead, splash contamination, or contamination from raw product sources?</p> <p>Is there sufficient room around equipment to allow for adequate cleaning and sanitizing operations?</p> <p>Is non-movable equipment which does not provide a minimum clearance of 4 in (100 mm) or more between the base and the floor or counter, adequately sealed to the floor or counter to prevent soil buildup under the equipment?</p> <p>Is all equipment operated in a safe and sanitary manner?</p>
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Table 15. Maintenance and Repair

<p>Food equipment which is not in good repair and which has deteriorated food-contact surfaces cannot be properly cleaned and sanitized.</p>	<p><i>Evaluate the maintenance program for all food equipment.</i></p> <p>Is equipment checked for wear at a predetermined schedule?</p> <p>Is equipment repaired as needed?</p>
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Is equipment discarded which has become badly pitted, chipped, scratched, scored, or otherwise rendered uncleanable?

Table 16. Cleaning and Sanitizing

Equipment which has not been properly cleaned and sanitized will contaminate all food products with which it comes in contact.

Thoroughly evaluate the cleaning and sanitizing protocols for all equipment.

Has a reputable chemical supply and sanitation company been consulted for assistance in setting up and validating an effective cleaning and sanitizing program?

Are chemical sanitizers in use appropriately registered as an antimicrobial agent with the Environmental Protection Agency (EPA), and of a formulation and usage concentration which does not exceed FDA regulations for no-rinse food contact sanitizers (21 CFR 178.1010)?

Are recommended temperatures, chemical concentrations and contact times used for all cleaning and sanitizing procedures?

Is all equipment cleaned and sanitized prior to use?

Are written procedures and protocols developed for all equipment?

Are procedures in place for cleaning and sanitizing wet conveyors and rollers?

Are mechanical cleaning (clean-in-place) procedures only used on equipment designed for mechanical cleaning and are recommended procedures used?

Is equipment dismantled and hand cleaned and sanitized when necessary?

Is cleaned, sanitized equipment stored on a drain table or properly disassembled to allow drainage, and is it protected from contamination?

Are reusable towels not used for wiping and drying cleaned, sanitized equipment?

Is the effectiveness of the cleaning and sanitizing program documented at regular intervals through inspection and/or the use of microbial swabbing or other techniques (i.e. bioluminescence methodology)?

Is a cleaning and sanitizing program in place for nonfood product contact and environmental surfaces in the facility?

Table 17. Source

Contaminated or sub-standard raw materials are a major source of contamination.

Evaluate the source and quality of all raw products, food ingredients, food additives, and packaging materials used in food handling/processing.

Are detailed written specifications in place for all raw products, ingredients, additives and packaging materials?

<p>Food ingredients and additives must be from an approved source and meet established specifications.</p> <p>Raw product must be properly stored in such a manner to prevent contamination or growth of microorganisms.</p> <p>Raw materials destined for return or disposition must be appropriately handled to avoid contamination of the facility.</p>	<p>Do written specifications include product description, transportation and storage requirements, microbiological and chemical quality, and appropriate analytical tests or documentation?</p> <p>Have raw products been grown, harvested, and transported under Good Agricultural Practices (GAPs) which prevent contamination from microbiological, chemical or physical hazards?</p> <p>Is a monitoring program in place to evaluate compliance with specifications?</p> <p>Are procedures in place for the sanitary disposition of raw materials which do not meet specifications?</p>
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Table 18. Receiving and Storage

<p>Receiving rooms and storage areas for raw materials, ingredients, additives and packaging materials must be maintained in a sanitary manner and at appropriate temperature and humidity to prevent or reduce contamination.</p>	<p><i>Evaluate the receiving practices for all raw products, ingredients, additives, and packaging materials.</i></p> <p>Are trucks, vehicles, trailers, bins, pallets and other product conveyances used for raw materials maintained in a clean and sanitary manner?</p> <p>Are procedures in place for cleaning and sanitizing trucks, vehicles, trailers, bins, pallets, and other product conveyances used for raw materials?</p> <p>Is the receiving room for raw materials separate from the food handling and processing areas and are they of adequate size?</p> <p>Is the receiving room for raw materials of proper sanitary design and construction and is it maintained in a sanitary condition?</p> <p>Are bins, pallets and other conveyances which are in poor repair or no longer cleanable discarded?</p> <p>Are materials received in a sanitary manner and checked upon arrival?</p> <p>Are raw materials stored indoors, protected from overhead contamination or contamination from the exterior environment and at the appropriate temperature and relative humidity?</p> <p>Are ingredients, additives, and packaging materials kept in their original sealed container, outer wrap, or otherwise packaged, and stored to prevent contamination?</p>
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Table 19. Processing and Handling

Food products must be processed and handled in such a manner to prevent, reduce, or eliminate food safety hazards.

Evaluate the practices used for food product handling and processing throughout the entire processing and handling.

Is sufficient care taken to wash and sanitize or otherwise decontaminate raw produce?

Is raw produce subjected to a kill step process aimed at destruction of pathogenic microorganisms [the National Advisory Committee on Microbiological Criteria for Food (NACMCF) recommends a five-log reduction of pertinent pathogens.]?

Is a microbial testing plan in place for evaluation of the effectiveness of the processing system?

Are all food products sufficiently protected from contamination from food safety hazards throughout the processing system?

Table 20. Filling and Packaging Operations

As packaging is done after processing, extra care must be exercised to prevent contamination from food safety hazards.

Evaluate all filling and packaging operations.

Are filling operations done in a clean room so designed to minimize exposure to air-borne contaminants?

Is the clean room so designed and filler equipment so located to minimize the potential for product contamination during filling (i.e. floor drains, overhead receptacles, splash, and other sources)?

Are sufficient precautions in use to prevent contamination during the filling operations?

Are packages and packaging materials stored and handled in a sanitary manner?

Is each package labeled according to existing regulations, and is it coded at the time of filling in a manner to ensure traceability?

Table 21. Storage and Warehousing

Finished product must be stored and handled in such a manner to prevent contamination with food safety hazards.

Evaluate product storage and warehousing practices.

Is an adequate cleaning and sanitation program in place for finished product handling such as crates and conveyors?

Are crating, overwrapping, conveying, transporting and related activities done in a sanitary manner?

Are products requiring refrigeration to prevent growth of pathogenic microorganisms cooled rapidly to below 41° F?

Are warehouse and refrigerated storage facilities of adequate size for the operation?

Is an appropriate inventory management system in use?

Table 22. Transportation and Distribution

Care must be taken in the transportation and distribution of food products to prevent contamination.

Evaluate all transportation and distribution practices.

Are trucks, delivery vehicles, trailers, bins, pallets and other product conveyances used for finished product maintained in a clean and sanitary manner?

Are procedures in place for cleaning and sanitizing delivery vehicles, trailers, bins, pallets, and other product conveyances?

Are bins, pallets and other conveyances which are in poor repair or no longer cleanable discarded?

Are food products transported and delivered in a sanitary manner and at appropriate temperature?

Are delivery drivers and related personnel appropriately trained in sanitation and food handling practices?

Table 23. Source, Labeling, and Identification

Only accepted food grade chemicals such as cleaners, sanitizers, and pesticides should be used in a food processing and handling facility.

Identify and evaluate the presence, source and labeling of all non-food chemicals (i.e. cleaners, sanitizers, pesticides, and/or other toxic materials) in use in the food processing and handling facility.

Are non-food chemicals which are not approved for food use by an appropriate regulatory authority prohibited from use in the food processing or handling facility?

Are non-food chemicals which are not required for the operation and maintenance prohibited?

Does the label of all non-food chemicals in their original container bear the name and address of the manufacture and contain safety information and instructions for handling and use?

Are working containers of chemicals taken from bulk supplies clearly identified with the common name of the material?

Table 24. Storage and Use

Chemicals used for cleaning and sanitizing and pesticides can be a significant source of chemical contamination if not used or stored properly.

Evaluate the procedures used for storage and use of non-food chemicals.

Are detailed written procedures and protocols in place for the handling, storage and use of all non-food chemicals?

	<p>Are non-food chemicals stored separately from food ingredients or food products so as to prevent chemical contamination?</p> <p>Are first aid supplies and medicines only stored in clearly marked first aid cabinets?</p> <p>Are personal care items only stored in lockers or in locker room areas?</p> <p>Is use according to manufacturers or suppliers instructions?</p> <p>Are pesticide applied by a certified pesticide applicator or a person under direct supervision of a certified applicator?</p> <p>Are chemicals applied or used in such a manner to prevent a hazard to employees?</p> <p>Are chemicals applied or used in such a manner to prevent food product contamination due to dripping, draining, fogging, splashing, spraying on food, or food equipment?</p> <p>Are food equipment or food products removed or covered prior to the use of pesticides?</p> <p>Are rodent bait stations contained in covered, tamper-resistant bait station?</p> <p>Is the pest control program monitored and documented for effectiveness by a designated, reliable employee?</p>
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Table 25. Identification of Responsible Personnel

<p>Quality and sanitation are the responsibility of all employees, however, specific people should be identified to administer the overall program.</p>	<p><i>Evaluate and identify the responsible personnel for all functions related to sanitary handling of product(s) and evaluate their assigned responsibilities.</i></p> <p>Are responsible personnel identified for all critical functions in the operation including receiving operations, processing/handling operations, packing operations, and sanitation?</p> <p>Are responsibilities clearly identified and defined for quality control managers, team leaders and supervisors?</p> <p>Are assigned responsibilities of each employee recorded in written form?</p>
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Table 26. Documentation and Records

<p>A logical, simple yet comprehensive system of documentation is an integral part of a GMP program.</p>	<p><i>Evaluate the record and documentation system for all operations related to food safety.</i></p> <p>Are all forms of a design to be simple and easy to use by all employees?</p> <p>Are written standard operating procedures in place and appropriate records and documents kept for personnel safety, product receiving and supplier verification, product processing, handling and packaging, sanitation programs, cleaning and sanitizing of equipment, pest control, water quality, product recalls?</p> <p>Where applicable, are recordings made onto forms at an appropriate predetermined time intervals for each operation being recorded?</p>
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	<p>Is a cross-check system in place which requires supervisor signature or initials on employee recordings of data?</p> <p>Are records for monitoring critical control points as part of a HACCP plan kept together in a separate file?</p> <p>Are records legible and maintained for an appropriate time period which exceeds the expected shelf-life of the food product?</p>
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Table 27. Product Recall Program

<p>Pre-planning and practice tests for a potential recall ensure effective execution should one ever become necessary.</p>	<p><i>Evaluate the ability to recall product from the marketplace.</i></p> <p>Is product recall information including name and address of manufacturer, date of manufacture, lot number or other coding included in package labeling?</p> <p>Are systematic, written product recall procedures in place?</p> <p>Are test runs or checks on product recall procedures conducted on a regular, predetermined frequency?</p>
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Specific Good Manufacturing Practices (GMPs) for Fresh Squeezed Citrus Juice

The following guideline GMPs checklist specifically addresses selected unit operations in the manufacture of fresh squeezed citrus juice.

Table 28. Fruit Receiving, Pre-Grading, Handling, and Storage

- Table 29. Final Grading and Washing
- Table 30. Juice Extraction
- Table 31. Juice Filling and Packaging
- Table 32. Juice Casing, Storage, and Warehousing
- Table 33. Transportation and Distribution

Table 28. Fruit Receiving, Pre-Grading, Handling, and Storage

<p>To produce juice of consistent quality and safety, it is necessary to establish and maintain a dependable supply of good quality fruit.</p>	<p><i>Evaluate fruit receiving, handling, and storage practices.</i></p> <p>Are raw fruit specifications defined and documented?</p> <p>Is all fruit grown and harvested using Good Agricultural Practices (GAPs)?</p> <p>Are groves fenced and are efforts in place to minimize entrance and habitation of domestic and wild animals?</p> <p>Is growth of underbrush minimized and are groves mowed on a regular, predetermined frequency?</p> <p>Is it required and assured that no cattle grazing is allowed in the groves?</p> <p>Is it required and assured that improperly composted manure is not used for fertilizer?</p>
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	<p>Is it required and assured that the fruit has not been in contact with contaminated water or animal wastes?</p> <p>Is the use of packinghouse eliminations, reject fruit, or dropped fruit prohibited?</p> <p>Is extra care employed when using late-season fruit (May, June) which may have low acidity and present an environment for higher pathogen survival?</p> <p>Are conveyors, drops, and line transfers designed and constructed so as to minimize damage to fruit as it is unloaded and pre-graded?</p> <p>Are dumping and pre-grading operations conducted in an enclosed facility which is separated from other fruit and juice handling and processing operations?</p> <p>Are fruit storage facilities indoors and maintained in a sanitary manner?</p> <p>If fruit is cooled and refrigerated during storage, is the refrigeration system adequate?</p> <p>Is an inventory and material rotation system used for fruit storage?</p> <p>Are pre-grading and receiving facilities inspected for sanitation at a regular, predetermined frequency and appropriate corrective actions taken as needed?</p>
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Table 29. Final Grading and Washing

<p>The fruit should be thoroughly graded before washing and extraction.</p> <p>All fruit needs to be graded and washed even if it was previously done at the packing house. Grading is your final assurance that the fruit going to the extractor is of acceptable quality.</p> <p>Fruit must be protected from contamination during grading, washing and conveyance.</p>	<p><i>Evaluate all grading and washing practices.</i></p> <p>Is fruit graded to effectively eliminate all rots or defective fruit with cuts, splits, punctures, black heart, or other defects that may allow microbial contamination prior to entering the processing facility?</p> <p>Is grading and washing of fruit done in an enclosed facility which is sealed and protected from exterior sources of contamination from insects or vermin including: rats, mice, frogs, toads, and birds?</p> <p>Is rejected fruit disposed of in a sanitary manner?</p> <p>Are the fruit graders in sufficient number and adequately trained?</p> <p>Are fruit grading operations verified by supervisors on a regular, predetermined frequency?</p> <p>Is fruit which is not extracted within a reasonable time period regraded?</p> <p>Are fruit conveyors provided with appropriate coverings or drip shields to prevent overhead contamination?</p> <p>Is fruit conveyed in a clean, sanitary manner?</p> <p>Are provisions made for effective cleaning and sanitizing of wet conveyors and rollers, and of boxes, lugs, and other containers used to transport fruit so to prevent contamination of the fruit?</p> <p>Are conveyers and rollers which are in poor repair or no longer cleanable replaced?</p> <p>Is fruit destined for extraction acid washed using roller brushes or equivalent cleaning procedure as recommended by a reputable detergent supplier?</p>
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<p>Is fruit destined for extraction sanitized using a hot water dip at a temperature and time period recommended by scientific authority, or a chemical sanitizing procedure using an approved no-rinse sanitizer at usage concentration, temperature and time as recommended by a reputable detergent supplier or scientific authority?</p> <p>Is a final water rinse (optional) used to remove sanitizer residues from fruit surfaces, and, if done, is special care used to ensure that the water used is of potable (or higher) quality and that the rinse is done in a sanitary manner?</p> <p>Is the effectiveness of the fruit cleaning and sanitizing procedures validated by microbial testing or scientific evaluation?</p> <p>Are chemical sanitizer levels and contact time checked and adjusted, if needed, at a regular, predetermined frequency?</p> <p>Is washed fruit visually inspected prior to extraction, and is fruit re-washed as deemed necessary?</p> <p>Is fruit re-washed and re-sanitized if not extracted within a reasonable time period?</p> <p>Are fruit grading, washing, and conveyance operations inspected for sanitation at a regular, predetermined frequency and appropriate corrective actions taken as needed?</p>

Table 30. Juice Extraction

<p>Care must be taken in juice extraction operations to avoid contamination of the juice from unclean equipment and/or airborne sources.</p> <p>Food-contact surfaces of extraction equipment must be impervious and cleanable, in good repair, and cleaned and sanitized at a regular frequency.</p> <p>As many of the working parts are of intricate design and are fabricated from aluminum which can become pitted or corroded, careful routine inspection of the condition of these surfaces is recommended.</p>	<p><i>Evaluate the operations involved in juice extraction.</i></p> <p>Are juice extraction operations done in a separate facility from raw fruit operations?</p> <p>Is the transfer of washed fruit to the extractor done in a sanitary manner using clean, sanitized conveyors or containers?</p> <p>Is fruit which is recycled from the extractor, re-washed and re-sanitized prior to extraction?</p> <p>Is juice extraction equipment operated and maintained according to the manufacturer's recommendation?</p> <p>Are food-contact surfaces (especially if not fabricated from stainless steel) of extraction equipment inspected on a regular, predetermined frequency to evaluate pitting, corrosion, or loss of cleanability due to wear, and are parts which are no longer cleanable replaced?</p> <p>Is extraction equipment disassembled, cleaned and sanitized prior to each use following written procedures and according to manufacturers recommendations?</p> <p>Are heat exchangers, if used to cool juice, of cleanable design, fabrication and construction and are they inspected for pitting, pin holes (in plate heat exchangers), gasket integrity, and other visible wear on a regular, predetermined frequency?</p> <p>Are heat exchangers cleaned and sanitized prior to use following a written procedure using a clean-in-place (CIP) system of appropriate size, pressure and volume as recommended by the manufacture and a reputable detergent supplier?</p>
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<p>Many couplings, fittings, and other parts associated with extractors, pumps, and heat exchangers must be disassembled for cleaning.</p> <p>Plates and gaskets in plate-type heat exchangers can become uncleanable through wear and pitting. Worn plates can also allow leaks and potential contamination of juice with the cooling medium.</p>	<p>Are pumps, juice holding reservoirs or chill tanks involved in juice cooling and handling of a cleanable design, fabrication and construction, and are they disassembled, cleaned and sanitized prior to use following recommended and written procedures?</p> <p>Are cleaning and sanitizing procedures used for extractors, heat exchangers, pumps, and juice cooling or storage tanks validated as to effectiveness on a regular, predetermined frequency?</p>
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Table 31. Juice Filling and Packaging

<p>Extra care should be taken to prevent contamination during juice filling and packaging.</p>	<p><i>Evaluate juice filling and packaging operations.</i></p> <p>Is the filling equipment housed in a clean room which is constructed to minimize exposure to airborne contaminants and separated from raw fruit operations?</p> <p>Is the time period between juice extraction and filling minimized?</p> <p>If blending of juice is done, is it done in a sanitary manner?</p> <p>Is filling equipment so designed, constructed, and located to prevent overhead or splash contamination?</p> <p>Is filling equipment of cleanable design, fabrication and constructed and located to facilitate cleaning and sanitizing?</p> <p>Are fillers, heads and other parts inspected for wear on a regular, predetermined frequency, and are worn, uncleanable parts replaced as needed?</p> <p>Is filling equipment disassembled, cleaned and sanitized prior to use following recommended and written procedures?</p> <p>Are bottles or packages manufactured from approved food grade materials and are they brand new, dust free, and stored in a sanitary manner?</p> <p>Are bottles or packages handled with care so as not to contaminate them during filling?</p> <p>Is hand contact of interior surfaces of bottles or packages avoided in hand filling operations?</p> <p>Are bottles or packages coded at the time of filling so as to ensure traceability and facilitate recall?</p> <p>Is filling done in a sanitary manner which avoids excess juice on the outside of containers?</p>
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Are packages for off-site consumption labeled with appropriate consumer handling information such as "Keep Refrigerated"?

Table 32. Juice Casing, Storage, and Warehousing

Storage and warehousing time should be minimized.

Evaluate juice storage and warehousing operations.

Upon filling, are containers rapidly transferred into an adequate cold storage facility?

Inventory management is critical.

Are secondary packages (i.e. cases, crates, overwraps) clean and handled in a sanitary manner?

Is a written inventory management system in place?

Are refrigerated storage cases maintained and inspected on a regular, predetermined frequency?

Table 33. Transportation and Distribution

Maintaining the integrity of the cold chain is necessary to ensure quality and safety of a fresh juice product.

Evaluate any transportation and other distribution operations.

If packaged juice is transported to another facility (i.e. retail store), is it done in clean, sanitary, refrigerated trucks?

Are retail outlets periodically inspected for appropriate handling of your product?

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Current Good Manufacturing Practice In Manufacturing, Packing, Or Holding Human Food, 21 CFR 110; <http://vm.cfsan.fda.gov/~lrd/part110t.html>

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