



COMMODITY SPECIFIC FOOD SAFETY GUIDELINES

FOR THE FRESH TOMATO SUPPLY CHAIN

Third Edition | September 2018

Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain

Tomato Guidelines, 3rd Edition

User's Note

These guidelines provide recommended food safety practices that are intended to minimize the microbiological hazards associated with fresh and fresh-cut tomato products. The intent of drafting this document is to provide currently available information on food safety and handling in a manner consistent with existing applicable regulations, standards and guidelines. The information provided herein is offered in good faith and believed to be reliable, but is made without warranty, express or implied, as to merchantability, fitness for a particular purpose, or any other matter. These recommended guidelines were not designed to apply to any specific operation. It is the responsibility of the user of this document to verify that these guidelines are appropriate for its operation. The publishing trade associations, their members and contributors do not assume any responsibility for compliance with applicable laws and regulations, and recommend that users consult with their own legal and technical advisers to be sure that their own procedures meet with applicable requirements.

Foreword

The North American Tomato Trade Work Group (NATTWG) published in 2006 the first edition of Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain (“Guidelines”). Within two years of publication, several initiatives resulted in significant new learnings about potential risks and control measures at all points in the fresh tomato supply chain. Some of those initiatives include the FDA Tomato Safety Initiative, voluntary efforts by the Florida Tomato Exchange and the California Tomato Farmers to develop USDA-verified audit criteria and programs for tomato production and harvest practices in those states, and several retail and foodservice buyer initiatives to further define tomato safe growing and handling practices. Members of NATTWG and United Fresh Produce Association initiated a second edition, published in 2008, to capture those learnings and to include the perspectives of a wider scope of contributors.

The Guidelines led to the development of the “Tomato Metrics”, an industry effort inclusive of many associations, agencies, companies and individuals with expertise in food safety practices for one or more steps in the fresh tomato supply chain which provided food safety standards and auditable criteria for tomato handling during open field production, harvesting, greenhouse, and packinghouse/repackers. The Tomato Metrics, in turn, paved the way for development of the Produce GAPs Harmonized Food Safety Standards (“Harmonized Standards”), which can be applied to production, harvesting, packing and holding of any whole fresh produce commodity.

In 2015, FDA published a final rule on *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (“Produce Safety rule”; 21 CFR part 112), which covers fresh tomato production, harvesting and packing of whole tomatoes on farm operations. FDA also published a final rule on *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food* (“Preventive Controls rule”; 21 CFR part 117), which covers non-farm packing and repacking operations and all fresh-cut processors except retail and foodservice operations. In 2016, FDA published a final rule on *Sanitary Transportation of Human and Animal Food* (“Sanitary Transportation rule”; 21 CFR part 1, subpart O), which covers whole and fresh-cut tomatoes shipped from non-farm operations by motor or rail vehicle for sale in the US. The evolution of scientific knowledge, regulatory requirements, and the general food safety landscape prompted the reevaluation of the Guidelines and associated Tomato Metrics.

The guidelines presented in this edition represent a current understanding of conditions and controls that should be considered by every company in the tomato supply chain for their respective operations. In some cases, a company may need to consider the guidelines in more than one module. For example, companies involved in Field Packing should also consider the recommendations in the Open Field Production module, and companies involved in Repacking should also consider the recommendations in the Packinghouse module.

Like previous versions, all perspectives were considered in the 2018 update. Under the leadership of the editors identified in the acknowledgments, over 40 contributors collaborated to develop this 3rd edition of the Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain.

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Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain

I. Introduction

In 1998, the U.S. Food and Drug Administration (FDA) issued its “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables.” The practices outlined in this and other documents are collectively known as Good Agricultural Practices or GAPs. GAPs provide general food safety guidance on critical production steps where food safety might be compromised during the growing, harvesting, transportation, cooling, packing and storage of fresh produce. More specifically, GAP guidance alerts the entire supply chain, including fruit and vegetable growers, shippers, handlers, packers, processors and buyers, to the potential microbiological hazards associated with various aspects of the production chain including: land history, adjacent land use, water quality, worker hygiene, pesticide and fertilizer use, equipment sanitation and product transportation. The vast majority of the fresh tomato industry has adopted GAPs as part of normal production operations. Indeed, the majority of fresh tomato producers undergo either internal or external third-party GAP audits on a regular basis to monitor and verify adherence to their GAPs programs. These audit results are often shared with customers as verification of the producer’s commitment to food safety and GAPs. While the produce industry has an admirable record of providing the general public with safe, nutritious fruits and vegetables, it remains committed to continuous improvement with regard to food safety.

In 2004, the FDA published a food safety action plan that specifically requested produce industry leadership in developing the next generation of food safety guidance for fresh fruits and vegetables. These new commodity-specific guidelines focus on providing guidance that enhances the safe growing, processing, distribution and handling of commodities from the field to the end user. Prior to this, the focus of food safety efforts had been on the farm, initial cooling and distribution points and value-added processing operations. Fruit and vegetable processing operations have developed sophisticated food safety programs largely centered on current Good Manufacturing Practices (GMPs) and the principles of Hazard Analysis Critical Control Point (HACCP) programs. Food safety programs for fresh-cut and value-added produce were supplemented by FDA’s 2008 “Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables”. As a greater understanding of food safety issues relative to the full spectrum of supply and distribution channels for fruits and vegetables evolved, it became clear that the next generation of food safety guidance needed to encompass the entire supply chain. United Fresh Produce Association assembled a diverse group of tomato industry experts representing all aspects of the supply chain to develop the 2nd edition of Commodity Specific Guidelines for the Fresh Tomato Supply Chain in 2008. This was immediately followed by the publication of Food Safety Programs and Auditing Protocol for the Fresh Tomato Supply Chain, more commonly known as Tomato Metrics. The Metrics, including associated checklists, were updated in 2010 and published in 2011. The Tomato Metrics laid the foundation for a broader industry initiative to harmonize a diversity of audit schemes, with the aim of “One audit by any credible third party, acceptable to all buyers.” To achieve this goal, the Initiative used the Tomato Metrics as a guide to develop food safety Good Agricultural Practices standards and audit checklists for pre-harvest and post-harvest operations, applicable to all fresh produce commodities, all sizes of on-farm operations and all regions in the U.S., and has made them available for use by any operation or audit organization at no cost. These are collectively known as the “Harmonized Standards”. GLOBALG.A.P. successfully benchmarked the Harmonized Standards, along with their Harmonized Produce Safety Standard (HPSS) process, against the Global Food Safety Initiative (GFSI) Guidance Document in summer 2016. Other licensees of

the Harmonized Standards are also expecting to complete benchmarking in the near future, so that the Harmonized Standards will be accepted as a GFSI-benchmarked scheme available through a number of different entities.

Directed by the Food Safety Modernization Act, in November 2015 FDA published a final rule on Produce Safety that sets standards for growing, harvesting, packing and holding of produce. The publication of the rule prompted a re-evaluation and update of the Harmonized Standards, completed in early 2017, to ensure operations compliant with the Harmonized Standards would also be compliant with the Produce Safety rule.

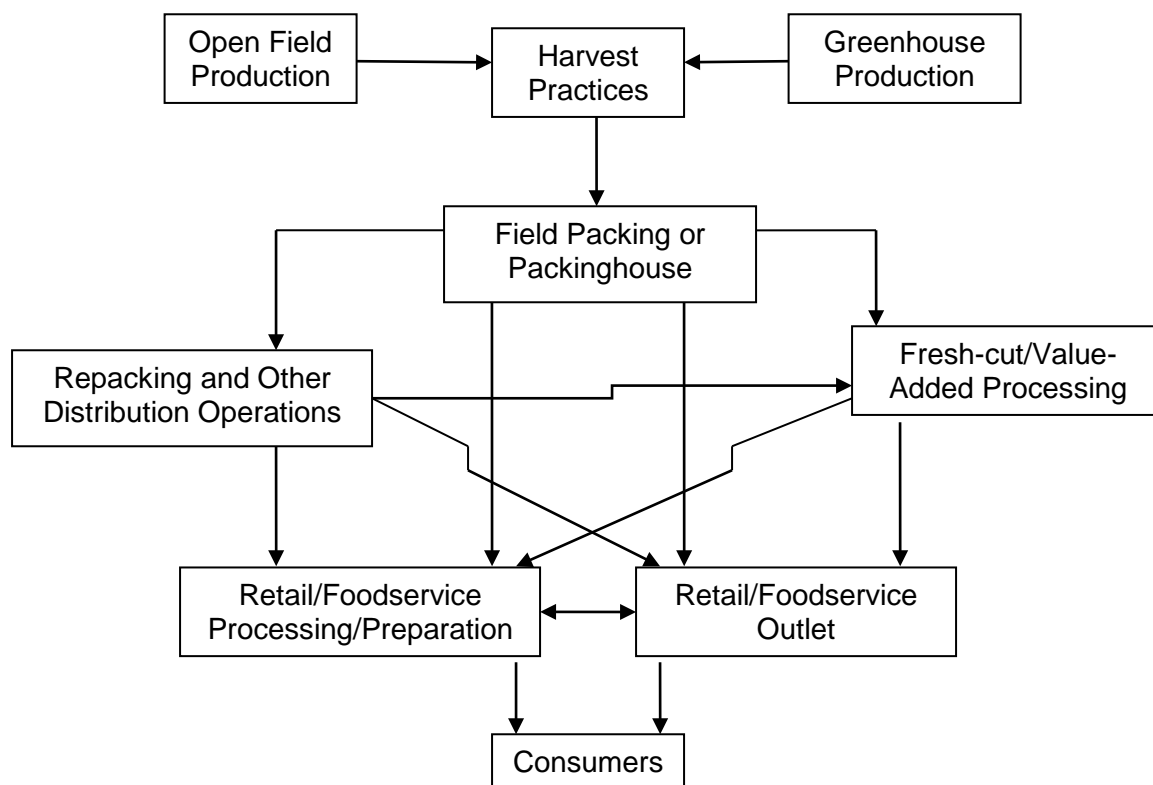
Tomatoes and the tomato supply chain have unique characteristics that warrant tomato-centric guidance. While commodity-specific guidance focused on leafy greens, cantaloupes, etc. contain valuable insight for those commodities, they are not always applicable to tomatoes. In March 2017 the Tomato Metrics group reconvened and discussed the best path forward in light of the Harmonized Standards, Produce Safety rule, and current industry landscape. The group decided that a 3rd edition of the Guidelines was warranted, to include updated science, practices and regulatory requirements. In addition to reviewing each section of the original Guidelines, workgroups were also established to evaluate the science around two specific issues: antimicrobials in wash water, and the potential for internalization of pathogens via wash water. The group also debated the relevance of *Listeria monocytogenes* and other environmental pathogens in tomato packing and processing operations.

These Guidelines are not intended to replace other food safety programs, but are meant to be used in conjunction with them to address food safety hazards known to affect the tomato supply chain. The guidelines are intended to serve any member of the fresh tomato supply chain regardless of whether they are audited and which audit standard they use.

II. Scope and Use of Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain

The scope of this document pertains only to fresh and fresh-cut tomato products, and does not include cooked tomato products, tomato juice, or tomatoes intended to be cooked. This document does not include considerations for products commingled with non-produce ingredients (e.g. salad kits which may contain meat, cheese, and/or dressings), although the tomatoes used in such products should be produced, harvested and otherwise handled in a manner consistent with the recommendations in this document. The distribution chain for fresh tomatoes can be complex, in that tomatoes may be sold direct or indirect to the buyer. Tomatoes are often subject to repacking for size and/or quality. As a result, there is no single distribution chain. The distribution chain may be simple or very complex, with tomatoes being handled by a number of entities prior to being offered for sale to the consumer. The model distribution chain for the purpose of this document provides an overview of only a few of the many paths a fresh tomato can take prior to the end user. It is the intent of this document to cover all significant aspects of the tomato supply chain, from production to delivery to the consumer.

Figure 1. General Supply Chain Flow for Fresh Tomatoes



Safe production, packing, processing, distribution and handling of fresh and fresh-cut tomatoes depend upon a myriad of factors and the diligent efforts and food safety commitment of all parties throughout the distribution chain. No single resource document can anticipate every food safety issue or provide answers to all food safety questions.

These guidelines are not intended to replace other food safety programs, but are meant to be used in conjunction with them to address food safety hazards known to affect the tomato supply chain. These guidelines focus on minimizing the microbial food safety hazards by providing actions, based on the best available science, that have been shown to effectively reduce, control or eliminate microbial contamination of tomatoes in the field-to-fork supply chain. Because of sub-commodity, regional and operational practice differences, not all of these actions will be applicable to all tomato handling operations. However, it is suggested that all companies involved in the fresh tomato farm to table supply chain consider the recommendations and regulatory requirements contained within these guidelines in developing their company-specific food safety program. Every effort to provide food safety education to supply chain partners should be made as well, to ensure that opportunities to prevent contamination are not lost as tomatoes pass from one point of the supply chain to the next. Together with the commitment of each party along the supply chain to review and implement these guidelines, the fresh produce industry is doing its part to provide a consistent, safe supply of produce to the market.

For the purposes of this guidance, the tomato supply chain has been divided into eight primary modules:

- open field production (including shadehouse production),
- harvest practices,
- field packing,
- greenhouse production (including high tunnel production),
- packinghouse,
- repacking and other distribution operations,
- fresh-cut processing (value-added), and
- foodservice and retail.

Multiple modules will apply to many users of these guidelines. Users should not assume that a single module will cover their entire tomato operation.

Each of these modules contains key considerations for potential sources of pathogen contamination that may be reasonably likely to occur in the absence of control. Each module also references key requirements in the Produce Safety (21 CFR Part 112), Preventive Controls (21 CFR Part 117) or Sanitary Transportation (21 CFR Part 1, subpart O) rules (noted with either a PS§, PC§ or ST§ citation, respectively), with the assumption that the operation is subject to the respective rules and is neither exempt nor subject to modified requirements. Links to the rules and other resources that may be useful are provided in the Appendix.

Throughout this document, the words “must” and “shall” are used to designate practices, policies and procedures that are required by regulation or by general agreement within the fresh tomato industry. The word “should” is used to designate best practice recommendations which operations should consider using, but are not required.

III. Open Field Production

The development of good agricultural practices for field tomato production must consider all the elements of the field production system; field site, prior land use, land preparation practices, standard establishment practices, adjacent land use, agricultural inputs (e.g., irrigation water, fertilizers), workers and production practices, and single or multiple harvests. Microbial contamination can occur from a number of sources; evaluation of these risks, and their management, are essential to proper food safety procedures in the production of fresh tomatoes.

1. Field Management

Field producers must give consideration to the control of microbial contamination in the selection and management of production sites.

- a.** Tomato growers should determine previous usage of land if at all possible and should assess and mitigate conditions that may pose a food safety risk in and near production fields as a function of specific production and crop management practices.
- b.** Tomato growers must conduct a land use assessment including topography, land history, risk of flooding, adjacent land use and domestic animal and wildlife presence.
 - i.** Routinely review field environments and maintain records of assessments and any corrective actions.

- ii. Consider the potential for flooding to create conditions that may pose a food safety risk. Flooding is the uncontrolled introduction of large amounts of water from off-field sources into the production area. While flooding creates a risk of pathogen contamination from off-field sources, the risk of chemical contamination from those sources should also be considered. All growers should refer to [FDA's guidance on how to assess flooded fields](#) for safety, from both a microbiological and chemical standpoint. Of particular relevance to tomatoes is how they are grown, and the proximity of the fruit to the ground. Ground / bush type tomatoes versus staked may have different corrective actions in response to a flood event. As stated in the FDA guidance "If the edible portion of a crop is exposed to flood waters, it is considered adulterated".
- c. Tomato fields should not be located in any area that can receive runoff or drainage from an animal operation or any other source of contamination. If unavoidable, steps shall be taken to avoid, prevent or mitigate runoff into the field from any animal operation or other conditions that may pose a food safety risk.
- d. Areas of tomato fields that have been contaminated by runoff to a field or crop management water source from an animal operation shall not be harvested for fresh or fresh-cut consumption.
- e. Procedures used to mitigate risks shall be documented.

2. Adjacent Land Use

- a. Adjacent land must be assessed for activities or conditions that may pose a risk to tomato safety. These may include, but are not limited to, runoff from animal operations or other sources of contamination, domesticated animals, wildlife, landfills, sewage treatment, chemical plants, or other conditions that pose a food safety risk.
- b. Appropriate measures shall be taken to mitigate any identified food safety risks. These measures may include berms, fences, ditches, buffer zones or other strategies to effectively mitigate any risks.

3. Personnel Qualifications and Training

- a. PS§ 21 requires that all personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce (i.e., tomatoes) or food contact surfaces must have the education, training and/or experience necessary to perform the person's assigned duties in a manner that ensures compliance with requirements in the Produce Safety rule.
- b. PS§ 21 requires that all personnel receive adequate training, as appropriate to the person's duties, upon hiring, repeated as necessary if observations or information indicate that personnel are not meeting standards, and at least once annually. That training must be conducted in a manner that is easily understood by those being trained.
- c. PS§ 22 requires the training to include, at minimum:
 - i. Principles of food hygiene and food safety;
 - ii. The importance of health and personal hygiene for all personnel and visitors, including recognizing symptoms of a health condition that is reasonably likely to result in contamination of covered produce or food contact surfaces with pathogens; and
 - iii. The requirements of the Produce Safety rule that are applicable to the employee's job responsibilities.

- d. PS§ 22 requires at least one supervisor or responsible party for the farm to have successfully completed food safety training at least equivalent to that received under the standardized curriculum recognized as adequate by FDA. At this writing, training developed by the Produce Safety Alliance is the only curriculum recognized as adequate by FDA.
- e. Training should be relevant to tomato production and harvest operations management.
- f. PS§ 30 requires training to be documented, including what training is required for personnel and, for training sessions, the date of training, topics covered, and the person(s) trained. Records should also be kept of the trainer's qualifications.
- g. PS§ 33 requires that operations make visitors aware of policies and procedures to protect tomatoes and food contact surfaces from contamination by people and take all steps reasonably necessary to ensure that visitors comply with such policies and procedures.

4. Health and Hygiene Practices

a. Health

- i. PS§ 31 requires operations to take measures to prevent contamination of covered produce and food contact surfaces with pathogens from any person with an applicable health condition (such as communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting or diarrhea).
- ii. PS§ 31 requires employees, visitors and other field personnel with symptoms of diarrhea, fever, vomiting or other symptoms of foodborne illness to be restricted from working with or in the vicinity of tomatoes or tomato contact surfaces until the person's health condition no longer presents a risk to public health.
- iii. PS§ 31 requires operations to instruct personnel to notify their supervisor(s) (or a responsible party) if they have, or if there is a reasonable possibility that they have such a health condition.
- iv. The supervisor shall determine if an effective measure (e.g., bandage and non-permeable covering) can be employed such that the employee may be allowed to work with or in the vicinity of tomatoes or tomato contact surfaces.

b. Hygiene

- i. There shall be a policy prohibiting eating, drinking, chewing gum, and using tobacco in fields and tomato handling areas except in clearly designated areas. PS§ 33 prohibits eating, chewing gum, or using tobacco products in an area used for a covered activity; however, PS§ 33 permits drinking beverages in designated areas.
- ii. There shall be a policy restricting jewelry in the field and tomato handling areas. PS§ 33 requires removing or covering hand jewelry that cannot be adequately cleaned and sanitized during periods in which covered produce is manipulated by hand.
- iii. Employees, visitors and other field personnel shall wear clean and suitable outer garments. Consider, as appropriate to the operation, hair restraints, plastic aprons and sleeves, and restricting uncovered nail polish or false nails.
- iv. PS§ 33 requires maintaining adequate personal cleanliness to protect against contamination of tomatoes and food contact surfaces.
- v. PS§ 33 requires washing hands thoroughly, including scrubbing with soap (or other effective surfactant) and running water that satisfies the requirements of PS§ 44(a) (see Water Use, below), and drying hands thoroughly using single-

service towels, sanitary towel service, electric hand dryers, or other adequate hand drying devices. Hands must be washed at any time when they may have become contaminated and likely to lead to contamination of tomatoes, including before starting work, before putting on gloves, after using the toilet, upon return to the work station, after any break or other absence from the work station, and as soon as practical after touching animals (including livestock and working animals) or any waste of animal origin.

- vi. Other good food handling techniques shall be developed as appropriate to the specific operation to prevent contamination.
- c. Sanitary facilities
 - i. Toilet facilities shall be designed, located, operated and serviced in a manner that does not pose a source of contamination of the field. PS§ 129 requires operations to provide personnel with adequate, readily accessible toilet facilities, including toilet facilities readily accessible to growing areas during harvesting activities. Toilet facilities must be designed, located, and maintained to:
 1. Prevent contamination of tomatoes, food contact surfaces, areas used for a covered activity, water sources, and water distribution systems with human waste;
 2. Be directly accessible for servicing, be serviced and cleaned at a frequency sufficient to ensure suitability of use, and be kept supplied with toilet paper; and
 3. Provide for the sanitary disposal of waste and toilet paper.
 - ii. Restroom cleaning equipment shall be labeled and segregated so as not to pose a risk of contamination.
 - iii. Sanitary facilities shall be provided for all field workers during planting, harvesting or other field activities. Toilet facilities shall be provided with a minimum of one per twenty employees and be readily accessible within walking distance, located not more than ¼ (0.25) mile or 5 minute drive (if available) of all employees, or as required by prevailing regulation.
 - iv. PS§ 33 requires that toilet and handwashing facilities be made accessible to visitors.
 - v. PS§ 129 requires that, during growing activities that take place in a fully-enclosed building, and during covered harvesting, packing, or holding activities, operations provide a hand-washing station in sufficiently close proximity to toilet facilities to make it practical for persons who use the toilet facility to wash their hands.
 - vi. Toilet facilities shall have appropriate hand washing stations, including collection of gray water, shall be maintained in a clean and sanitary condition and properly stocked with soap, water for handwashing, single use towels and toilet paper, and a written record of cleaning shall be kept. PS§ 130 requires that operations provide personnel with adequate, readily accessible handwashing facilities during growing activities that take place during tomato harvest, packing, or holding activities. Hand-washing facilities must be furnished with soap (or other effective surfactant), running water that satisfies the microbiological requirements of PS§ 44(a) (*i.e.*, no untreated surface water and no detectable generic *Escherichia coli* (*E. coli*) in 100 milliliters (mL) of water) and adequate drying devices (such as single service towels, sanitary towel service, or electric hand dryers).
 - vii. PS§ 130 requires that operations provide for appropriate disposal of waste associated with a hand-washing facility (*e.g.*, waste water and used single-service towels) and take appropriate measures to prevent waste water from a handwashing facility from contaminating tomatoes, food contact surfaces, areas

used for tomato growing and handling, agricultural water sources, and agricultural water distribution systems.

- viii. PS§ 130 prohibits use of antiseptic hand rubs as a substitute for soap (or other effective surfactant) and water.

5. **Glove Use**

- a. If gloves are utilized, a procedure for glove use must be documented and followed so that glove use does not become a source of contamination. PS§ 33 requires that, if gloves are used in handling tomatoes or food contact surfaces, gloves are maintained in an intact and sanitary condition and replaced when no longer able to do so.
- b. Hands shall be washed and dried before putting on gloves.
- c. Hand sanitizers may be used, but not as a substitute for proper washing of hands.
- d. Gloves must be changed when they have become torn or contaminated, and at any time when hands would need to be washed.
- e. Gloves not in use should be stored appropriately to avoid contamination.
- f. Reusable gloves
 - i. Reusable gloves must be made of materials that can be cleaned and sanitized.
 - ii. It is the responsibility of the operation to ensure that gloves are cleaned, sanitized and dried daily or more often as needed. Gloves shall not be permitted to be taken home by workers.
 - iii. Appropriately cleaned and sanitized gloves shall be issued each day and at such times as needed during the day. Reusable gloves must not be worn during break times, smoking, using toilet facilities, or any process not involving handling of tomatoes. Gloves must be changed when the gloves have become torn or contaminated.

6. **Agricultural Water Use in the Field**

- a. PS§ 41 requires that all agricultural water be safe and of adequate sanitary quality for its intended use. At this writing, FDA [has delayed compliance dates](#) for all requirements in PS§ 41-50 until at least 2022.
- b. Water Source
 - i. Source(s) and distribution of water for each field and agricultural use (e.g., foliar or drip irrigation, crop protection spray) must be documented.
 - ii. PS§ 42 requires, at the beginning of a growing season, as appropriate, but at least once annually, operations must inspect all of their agricultural water systems, to the extent they are under the operation's control (including water sources, water distribution systems, facilities, and equipment), to identify conditions that are reasonably likely to contaminate tomatoes or food contact surfaces, including consideration of the nature of each agricultural water source (for example, ground water or surface water), the extent of the operation's control over each agricultural water source, the degree of protection of each agricultural water source, the use of adjacent and nearby land, and the likelihood of introduction of hazards by another user of agricultural water before the water reaches the operation. Results of the inspection must be documented.
 - iii. Any well used must be properly designed, located, constructed and maintained in such a way as to prevent contamination. PS§ 42 requires operations to adequately maintain all agricultural water sources to the extent they are under the operation's control. Such maintenance includes regularly inspecting each

source to identify any conditions that are reasonably likely to introduce hazards into or onto tomatoes or food contact surfaces, correcting any significant deficiencies (e.g., repairs to well cap, well casing, sanitary seals, piping tanks and treatment equipment, and control of cross-connections), and keeping the source free of debris, trash, domesticated animals, and other possible sources of contamination of tomatoes to the extent practicable and appropriate under the circumstances.

- iv. Appropriate backflow prevention devices for wells (e.g., air gaps, backflow valves) shall be used to protect water quality.
 - v. Water source(s) shall be protected from contamination from fertilizers, pesticides, etc.
 - vi. Allow for appropriate water treatment methods and/or identify alternate water sources to ensure water quality is consistent with appropriate standards.
 - vii. PS§ 42 requires operations to adequately maintain all agricultural water distribution systems to the extent they are under the operation's control as necessary and appropriate to prevent the water distribution system from being a source of contamination to tomatoes, food contact surfaces, areas used for a covered activity, or water sources, including by regularly inspecting and adequately storing all equipment used in the system.
 - viii. PS§ 42 requires operations to implement measures reasonably necessary to reduce the potential for contamination of tomatoes as a result of contact of tomatoes with pooled water. For example, such measures may include using protective barriers or staking to keep tomatoes from touching the ground or using an alternative irrigation method.
- c. Water Use
- i. While not required by the Produce Safety rule, any foliar application of water to tomatoes (e.g., irrigation or crop protection sprays) shall meet the microbial standards contained in PS§ 44(a), i.e., no detectable generic *Escherichia coli* (*E. coli*) in 100 milliliters (mL) of agricultural water.
 - ii. While not required by the Produce Safety rule, any water used for drip irrigation or non-contact uses shall meet the standard for *E. coli* levels in PS§ 44(b), i.e., (1) A geometric mean (GM) of 126 or less colony forming units (CFU) of generic *E. coli* per 100 mL of water and (2) a statistical threshold value (STV) of 410 or less CFU of generic *E. coli* per 100 mL of water.
- d. Microbial Monitoring
- i. Records of testing of agricultural waters must be analyzed and maintained. PS§ 46 does not require operations to test agricultural water when:
 - 1. Water is provided by a Public Water System, as defined under the Safe Drinking Water Act (SDWA) regulations, 40 CFR part 141, that furnishes water that meets the microbial requirements under those regulations or under the regulations of a State (as defined in 40 CFR 141.2) approved to administer the SDWA public water supply program. Public Water System results or certificates of compliance that demonstrate that the water meets that requirement are required.
 - 2. Water is provided by a public water supply that furnishes water that meets the microbial quality requirement described in PS§ 44(a). Results or certificates of compliance from the public water system are required that demonstrate that the water meets the required standards.
 - 3. Water is treated by a method effective to make the water consistently safe and of adequate sanitary quality for its intended use and/or to meet the required standards. If treated, the treatment must be monitored at a

frequency adequate to ensure that the water is consistently safe and of adequate sanitary quality for its intended use.

- ii. Each agricultural water source not tested or treated as above must be microbiologically monitored at a frequency not less than defined in PS§ 46(b), to create and maintain a water quality profile of initial samples and annual samples collected as close in time as practicable to, but prior to, harvest.
- iii. PS§ 47 permits testing of agricultural water source(s) by the operation, or by a person or entity acting on the operation's behalf, or to use data collected by one or more third parties, provided the water source(s) sampled by the third parties adequately represent the operation's agricultural water source(s) and all other applicable requirements are met.
- iv. Agricultural water samples must be aseptically collected and tested using a method described in PS§ 151 or in FDA guidance on [Equivalent Testing Methodology for Agricultural Water](#) published in 2017.
- v. Corrective actions shall be established and taken if standards are not met. PS§ 45 requires that, if testing demonstrates the water source is no longer in compliance with the required standards, immediately discontinue that use(s), and either (1) re-inspect the entire affected agricultural water system to the extent it is under the operation's control, identify any conditions that are reasonably likely to introduce hazards into or onto tomatoes or food contact surfaces, make necessary changes, and take adequate measures to determine if changes were effective and, as applicable, adequately ensure that agricultural water meets the microbial quality criterion in PS§ 44(a); or (2) treat the water as described above.

7. Soil Amendments and Crop Production Practices

Assess risk of all production inputs to reduce contamination risk.

- a. Chemical Fertilizers
 - i. Manufacturer's instructions for usage and storage must be followed.
 - ii. Fertilizer mixing areas shall not present a contamination hazard to tomatoes.
- b. Fertilizers Containing Manures, Composts or Biosolids
 - i. While permitted by the Produce Safety rule under specific conditions (PS§ 53), biosolids are not allowed for use in tomato fields.
 - ii. FDA considers a "biological soil amendment of animal origin" to be treated if it has been processed to completion to adequately reduce microorganisms of public health significance in accordance with the requirements of PS§ 54. FDA considers it to be untreated if it has not been processed to completion in accordance with the requirements of PS§ 54, or it has become contaminated after treatment, or it has been recombined with an untreated biological soil amendment of animal origin, or contains a component that is untreated waste that is likely contaminated with a hazard that has been associated with foodborne illness; or is an agricultural tea made with untreated biological materials of animal origin or with water that does not meet the microbial quality requirement described in PS§ 44(a).
 - iii. Compost applications shall be no less than 45 days prior to harvest. . While PS§ 56 permits untreated manure to be applied to fields if applied in a manner that does not contact tomatoes during or after application, if fertilizers containing manures or composts are used, only properly treated (composted or heat treated) manures are allowed for use in fields.
 - iv. PS§ 52 requires operations to handle, convey and store any biological soil amendment of animal origin in a manner and location such that it does not

become a potential source of contamination to tomatoes, food contact surfaces, areas used for a covered activity, water sources, water distribution systems, and other soil amendments. Agricultural teas that are biological soil amendments of animal origin may be used in water distribution systems provided that all other requirements of this rule are met.

- v. If treated manures are used, the following must be documented: composition, dates of treatment, methods utilized, application dates and test results or process verification data demonstrating compliance with microbial standards.
- c. Pesticides (Crop Protection Treatments)
 - i. Pesticides must be appropriately registered for such use and must be used in accordance with label directions. Pesticide uses shall be documented.
 - ii. Pesticides for foliar application shall only be mixed with water that meets the microbial standard for agricultural water contained in PS§ 44(a) (*i.e.*, no detectable generic *E. coli* in 100 mL of water).
 - iii. Loading, diluting, mixing, etc. of pesticides shall not be done in a manner that will potentially contaminate the water source.
 - iv. Cleaning of pesticide equipment shall not be done in a manner that will potentially contaminate the water source.
- d. Chemicals Used on Product
Chemicals used on tomatoes that are not registered pesticides may be permitted if allowed by prevailing regulations.

8. Animal Exclusion

- a. Measures shall be taken to exclude domesticated animals and livestock from tomato fields.
- b. PS§ 33 requires avoiding contact with animals other than working animals, and taking appropriate steps to minimize the likelihood of contamination of tomatoes when in direct contact with working animals.
- c. An assessment of resident wildlife activity, which may be a potential source of contamination, must be conducted seasonally.
- d. Measures shall be taken to minimize wildlife presence. These measures may include the use of barriers or other deterrents, minimizing wildlife attractants and opportunities for harborage, redirecting wildlife to non-sensitive areas and/or other methods identified by wildlife experts.
- e. If animal intrusion is detected, measures shall be taken to remove or prevent the harvest of any potentially contaminated tomatoes.
- f. PS§ 83 requires operations to assess the areas used for growing and handling tomatoes for evidence of potential contamination of tomatoes as needed during the growing season and, if significant evidence of potential contamination is found (such as observation of animals, animal excreta or crop destruction), evaluate whether the covered produce can be harvested and take measures reasonably necessary during growing to assist later during harvest to identify, and not harvest, tomatoes that are reasonably likely to be contaminated.

9. Equipment, Containers and Utensils

- e. Any surfaces or equipment intended to touch fresh produce is a food contact surface and must be cleaned and sanitized at a frequency sufficient to prevent the surfaces from becoming a source of contamination.

- f. Reusable containers, food contact equipment and utensils shall be designed and constructed of materials that can be easily cleaned and sanitized.
- g. The food safety impact of any process or equipment changes shall be considered prior to implementation.
- h. Harvest containers should remain under the oversight of farm management.
- i. PS§ 123 requires operations to use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained. Equipment and tools must be installed and maintained as to facilitate cleaning and stored and maintained to protect tomatoes from being contaminated and to prevent the equipment and tools from attracting and harboring pests.
- j. PS§ 123 requires seams on food contact surfaces of equipment and tools to be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms.
- k. PS§ 123 requires operations to inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of tomatoes.

10. Record Keeping

Appropriate record keeping provides evidence of operating conditions and practices and facilitates periodic review and evaluation of those practices.

- a. PS§ 161 requires records required by the Produce Safety rule to include, as applicable:
 - i. The name and location of the operation;
 - ii. Actual values and observations obtained during monitoring;
 - iii. An adequate description (such as the commodity name, or the specific variety or brand name of a commodity, and, when available, any lot number or other identifier) of covered produce applicable to the record;
 - iv. The location of a growing area (for example, a specific field) or other area (for example, a specific packing shed) applicable to the record; and
 - v. The date and time of the activity documented;
- b. PS§ 161 requires records to be created at the time an activity is performed or observed; be accurate, legible, and indelible; and be dated, and signed or initialed by the person who performed the activity documented.
- c. PS§ 161 requires the following records to be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party:
 - i. Required training,
 - ii. Results of all required analytical tests or treatment monitoring conducted on agricultural water,
 - iii. Treatment conditions and testing performed on manures treated by the operation, and
 - iv. Documentation of the date and method of cleaning and sanitizing of equipment used in harvesting, packing, or holding activities.
- d. PS§ 164 requires all records required by the Produce Safety rule to be retained for at least two (2) years beyond the date the record was created or when its use was discontinued.
- e. PS§ 166 requires all records required by the Produce Safety rule to be readily available and accessible for inspection and copying by FDA upon oral or written

request, except that operations have 24 hours to obtain records kept offsite. Electronic records are considered to be on-site if they are accessible from an on-site location. Records must be provided to FDA in a format in which they are accessible (e.g., electronic records) and legible. If the operation is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to the operation within 24 hours for official review upon request.

IV. Harvest Practices

Tomatoes for harvest shall have been produced according to the Produce Safety Rule or prevailing regulation, and the recommendations described in the prior section on Open Field Production, or subsequent section on Greenhouse Production, as appropriate. Refer to recommendations and Produce Safety rule requirements in the Open Field Production section for Health and Hygiene Practices, Glove Use, and Record Keeping.

1. Personnel Qualifications and Training

- a. Refer to recommendations and Produce Safety rule requirements in the Open Field Production section.
- b. PS§ 22 requires persons who conduct harvest activities to also receive training that includes all of the following:
 - i. Recognizing tomatoes that must not be harvested, including tomatoes that may be contaminated;
 - ii. Inspecting harvest containers and equipment to ensure that they are functioning properly, clean, and maintained so as not to become a source of contamination of tomatoes; and
 - iii. Correcting problems with harvest containers or equipment, or reporting such problems to the supervisor (or other responsible party), as appropriate to the person's job responsibilities.

2. Preharvest Assessment

A preharvest assessment provides a last opportunity to evaluate any safety risks that may impact the potential for the tomatoes to be contaminated.

- a. The harvest supervisor or other responsible person shall ensure that an assessment is performed as close as practical prior to the beginning of harvest, but not more than 5 days prior to the beginning of harvest.
- b. The land use assessment must be reviewed for changes that may affect product safety, such as adjacent land use and animal intrusion.
- c. If tomatoes are harvested at multiple times, fields should be assessed sufficiently to assure that new risk factors have not emerged.

3. Agricultural Water Use in the Field

- a. Refer to recommendations and Produce Safety rule requirements in the Open Field Production section for Agricultural Water Use in the Field.
- b. PS§ 44(a) requires agricultural water that directly contacts tomatoes or food contact surfaces during or after harvest activities (for example, water that is used for washing hands or is applied to tomatoes for washing or cooling activities), including when

used to make ice that directly contacts tomatoes or food contact surfaces, to meet the microbiological standard of no detectable generic *Escherichia coli* (*E. coli*) in 100 milliliters (mL) of agricultural water. PS§ 44 prohibits the use of untreated surface water for any of these purposes.

4. Equipment, Containers and Utensils

- a. Refer to recommendations and Produce Safety rule requirements in the Open Field Production section for Equipment, Containers and Utensils.
- b. PS§ 123 requires operations to maintain and clean all non-food-contact surfaces of equipment and tools used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of tomatoes.
- c. PS§ 123 requires equipment such as pallets, forklifts, tractors, and vehicles that are intended to, or likely to, contact tomatoes to be used in a manner that minimizes the potential for contamination of tomatoes or food contact surfaces.

5. Tomato or Equipment Sanitizing Agents Used During Harvest

- a. EPA considers any chemical making an antimicrobial claim, including those used to sanitize equipment and tomatoes, to be a pesticide.
- b. Sanitizing chemicals used must comply with all requirements of EPA registration and any federal, state or local regulations.
- c. Sanitizing chemicals must be appropriately registered for such use and must be used in accordance with label directions. Sanitizing chemicals uses shall be documented.

6. Debris Removal

Dirt, stems and leaves should be removed from tomatoes to the degree practical in the field, in a manner that does not pose a risk of contamination.

7. Exclusion from Harvest

- a. PS§ 112 requires operations to take all measures reasonably necessary to identify, and not harvest, tomatoes that are reasonably likely to be contaminated, including steps to identify and not harvest tomatoes that are visibly contaminated with animal excreta. At a minimum, identifying and not harvesting contaminated tomatoes requires a visual assessment of the growing area and all tomatoes to be harvested, regardless of the harvest method used.
- b. PS§ 114 prohibits harvesting tomatoes that have fallen from the plant to the ground (*i.e.*, “drops”). Tomatoes that have grown in contact with the ground or plastic are not considered drops and are permitted to be harvested.
- c. Tomatoes contacted by any fecal material shall not be harvested.
- d. If animal intrusion is detected, measures shall be taken to remove or prevent the harvest of any potentially contaminated product.
- e. Damaged, soft or decayed tomatoes should be excluded, to the degree possible, because they are more susceptible to pathogen growth.

8. Traceability

- a.** Traceability practices should be utilized to ensure that all tomatoes are traceable to their origin (e.g., field and harvest date) and to their immediate destination, if different than the growing operation.
- b.** Traceability records shall be readily available.

9. Transportation of Harvested Tomatoes

- a.** Transportation vehicles must be inspected for cleanliness, odors, visible dirt and debris before loading. If needed, the vehicle shall be cleaned or cleaned and sanitized by a documented procedure prior to loading.
- b.** PS§ 125 requires equipment used to transport tomatoes to be adequate for its use and adequately clean before use.

10. Recall Program

A documented recall program, including a traceability system to track tomatoes forward to customers, shall be developed and tested at least annually. A record of this test shall be maintained and be available.

V. Field Packing

Field packing of tomatoes, where permitted by prevailing regulation, includes any practices to grade, sort, size, clean, pack or palletize tomatoes in the field into containers for commerce. Field packing might not include cleaning and is not likely to include washing of tomatoes. Tomatoes packed in the field using a mobile packing unit (“mule train”) should refer to recommendations in the Packinghouse section. Field packed tomatoes are not usually transferred to a packinghouse for further handling.

1. Prerequisites for Field Packing Whole Tomatoes

Packing of tomatoes in the field must meet all requirements in the Produce Safety rule and recommendations included in this document in the Open Field Production and Harvest Practices sections, in addition to requirements further detailed in this section on Field Packing.

- a.** Refer to the Open Field Production and Harvest Practice sections for recommendations and Produce Safety rule requirements for Personnel Qualifications and Training.
- b.** Refer to the Open Field Production section for recommendations and Produce Safety rule requirements for Health and Hygiene Practices, Glove Use and Record Keeping.
- c.** Refer to the Harvest Practice section for recommendations and Produce Safety rule requirements for Preharvest Assessment, Tomato or Equipment Sanitizing Agents Used during Harvest, Debris Removal, Exclusion from Harvest, Traceability, Transportation of Harvested Tomatoes and Recall Program.
- d.** If washing is performed in the field, refer to Packinghouse section for Postharvest Washing of Fresh Tomatoes.

2. Cleaning Materials

The marketplace demands that dirt and debris be removed from a final packing of tomatoes. The manner in which tomatoes packed in the field are cleaned is of major importance and can be a source of contamination with potentially harmful microorganisms. If cleaning materials (cloths, paper towels, etc.) are used repeatedly for cleaning tomatoes, special steps shall be taken to ensure they do not become a source of contamination.

- a. Operations must have a procedure for the appropriate use of cleaning materials used for cleaning tomatoes.
- b. Materials used for cleaning tomatoes shall have no other purpose, and be kept separate from materials used for other purposes.
- c. Cleaning materials shall be maintained dry unless specified by the procedure.
- d. If cleaning materials are moistened to facilitate tomato cleaning, materials shall be moistened with single use potable water or with an approved sanitizer maintained at an established concentration.
- e. Cleaning materials shall not be taken home by workers.
- f. Operations must have a procedure for when to discontinue using or change a cleaning material.
- g. Operations must establish and document a worker-training program, including appropriate use of cleaning materials, their cleaning and sanitation, and when to discontinue use. Documentation of the training of workers in appropriate use of cleaning materials must be available.

3. Containers for Field Packing Tomatoes

- a. Packaging material shall be inspected upon arrival.
- b. All containers shall be stored in a manner to prevent contamination.
- c. Reuse of single use containers (*e.g.*, corrugated) for the field packing of tomatoes is prohibited.
- d. Reusable containers, such as reusable plastic containers (“RPCs”), shall be cleaned and sanitized by a documented procedure before reuse, and shall be properly labeled for current use.
- e. Containers shall be protected from direct contact with the ground.
- f. Cartons or other primary packaging shall be labeled accurately and shall clearly communicate that tomatoes were packaged in the field.
- g. PS§ 116 requires food-packing material to be adequate for its intended use, which includes being cleanable or designed for single use, and unlikely to support growth or transfer of bacteria. If food-packing material is reused, adequate steps must be taken to ensure that food contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner.

4. Storage

Any area used to collect or store tomatoes packed in the field must be maintained in a clean and sanitary manner.

5. Traceability and Labeling

All tomatoes shall be traceable at least one step forward and one step back. This shall include appropriate labeling of each case.

- a.** Traceability practices should be utilized to ensure that all tomatoes are traceable to their origin (e.g., field and harvest date) and to their immediate destination.
- b.** Containers shall be accurately labeled with commodity name, field packer firm name and information sufficient to allow for identification of grower, field location, and date of harvest/field pack.
- c.** Consumer-ready containers shall be labeled to identify when the product has been packed without washing.
- d.** Labels on re-used containers (e.g., RPCs) that originate from a prior use or are inaccurate shall be removed or concealed prior to packing.

6. Recall Program

A documented recall program, including a traceability system to track tomatoes forward to customers, shall be developed and tested at least annually. A record of this test shall be maintained and be available.

VI. Greenhouse Production

Greenhouses whose primary purpose is the growing and harvesting of fresh produce are considered by FDA to be farms and therefore subject to the Produce Safety rule. For the purposes of this guidance, a greenhouse is presumed to be capable of being fully enclosed with a controlled environment. As such, greenhouse practices will include recommendations from Open Field Production, Harvest Practices, Field Packing and Packinghouse sections. Note that this section does not apply to shade houses or other open structure, which shall follow all recommendations and Produce Safety rule requirements for Open Field production.

1. Personnel Qualifications and Training

Refer to recommendations and Produce Safety rule requirements in the Open Field Production section for Personnel Qualifications and Training.

2. Greenhouse

- a.** The greenhouse shall be enclosed and access shall be limited to double-entry or rotating plenum or other protected entry method.
- b.** Entryways should have foot dip stations or other mechanism to minimize risk of foot-borne pathogens.
- c.** Glass containers shall not be allowed in the greenhouse. A glass clean up procedure shall be developed and employees trained accordingly.
- d.** Refer to recommendations and Produce Safety rule requirements in the Packinghouse section for Grounds, Building, General Maintenance, Water Supply and Plumbing, and Trash and Tomato Waste Disposal.

3. Animals and Pest Control

- a. Refer to recommendations and Produce Safety rule requirements in the Packinghouse section for Animals and Pest Control.
- b. Pesticides used in the greenhouse must be labeled for use in greenhouses or have a field label that does not preclude greenhouse use.

4. Health and Hygiene Practices

- a. Refer to recommendations and Produce Safety rule requirements in the Open Field Production and Packinghouse sections for Health and Hygiene Practices.
- b. Restrooms that do open directly into greenhouse production areas should be equipped with self-closing mechanisms or have a maze-type entrance/exit.

5. Glove Use

Refer to recommendations and Produce Safety rule requirements in the Open Field Production section for Glove Use.

6. Preharvest Agricultural Water

Refer to recommendations and Produce Safety rule requirements in the Open Field Production section for Agricultural Water Use in the Field.

7. Fertilizers and Substrates

- a. Risk of all production inputs shall be assessed to reduce contamination risk. Refer to recommendations and Produce Safety rule requirements in the Open Field Production section for Soil Amendments and Crop Production Practices.
- b. Inert substrates shall be treated in such a way as not to pose a risk of contamination.

8. Tomato or Equipment Sanitizing Agents Used During Harvest

Refer to recommendations and Produce Safety rule requirements in the Harvest Practices section for Tomato or Equipment Sanitizing Agents Used during Harvest.

9. Equipment, Containers and Utensils

Refer to recommendations and Produce Safety rule requirements in the Harvest Practices section for Equipment, Containers and Utensils.

10. Cleaning Materials

Refer to recommendations in the Field Packing section for Cleaning Materials.

11. Postharvest Washing of Fresh Tomatoes

Refer to recommendations and Produce Safety rule requirements in the Packinghouse section for Postharvest Washing of Fresh Tomatoes.

12. Packaging Materials

Refer to recommendations and Produce Safety rule requirements in the Packinghouse section for Packaging Materials.

13. Transportation of Harvested Tomatoes

- a. Refer to recommendations and Produce Safety rule requirements in the Open Field Production section for Transportation of Harvested Tomatoes
- b. Transportation vehicles such as picking carts, scissor lifts, scaffolds, etc. should be made of material that can be sufficiently cleaned so as not to be a source of contamination.
- c. If non-dedicated vehicles are used for transportation, verify records of prior loads. Should there be any doubt as to previous loads transported or a potential risk from microbial contamination, the vehicle shall be cleaned and sanitized by a documented procedure prior to use.

14. Traceability and Labeling

Refer to recommendations and Produce Safety rule requirements in the Field Packing section for Traceability and Labeling.

15. Recall Program

A documented recall program, including a traceability system to track tomatoes forward to customers, shall be developed and tested at least annually. Traceability is expected to achieve 100% reconciliation of product to recipients. A record of this test shall be maintained and be available.

16. Record Keeping

Refer to recommendations and Produce Safety rule requirements in the Field Packing section for Record Keeping.

VII. Packinghouse

A well designed and managed packinghouse and food safety program can greatly reduce the risk of chemical, physical and microbial contamination but the risk can never be totally eliminated. Poor or inconsistent food safety practices can greatly increase this risk. Sanitary conditions and proper food safety practices are critical to product safety.

The needs of each packinghouse may vary due to location, environment, the volume of tomatoes handled, the type of tomatoes handled, local regulations and many other variables but the overall goal of any effective packinghouse food safety program is to minimize risk of contamination from equipment and the environment as well as cross contamination between

tomatoes. There may be multiple strategies for effectively dealing with individual hazards.

The general requirements for the packing of fresh tomatoes are that operations shall meet the requirements for good manufacturing practices as required under Produce Safety rule subparts K and L (PS§ 111 through 140). This shall extend to all aspects of the packinghouse, including ripening and holding rooms. PS§ 122 requires compliance by any fully- or partially-enclosed building used for covered activities, including minimal structures that have a roof but do not have any walls, and storage sheds, buildings, or other structures used to store food contact surfaces (such as harvest containers and food-packing materials).

Tomato handling operations that are required to register with FDA are subject to the Preventive Controls rule. PC§ 8 allows that compliance with the Good Manufacturing Practices requirements of that rule (PC§ subpart B) by operations that only package, pack or hold raw agricultural commodities may be achieved by complying with the applicable requirements for packing and holding in the Produce Safety rule. At this writing, FDA has opined that “discretionary enforcement” will be used if such operations are not in full compliance with the Preventive Controls rule but are in compliance with the Produce Safety rule.

1. Personnel Qualifications and Training

Refer to recommendations and Produce Safety rule requirements in the Open Field Production section for Personnel Qualifications and Training.

2. Grounds

- a.** The grounds about a packinghouse under the control of the operator shall be kept in a condition that will protect against contamination of tomatoes. The methods for adequate maintenance of grounds include, but are not limited to:
 - i.** Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.
 - ii.** Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where tomatoes are exposed.
 - iii.** Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.
 - iv.** Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where tomatoes are exposed.
- b.** If the packinghouse grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a) (i) through (iv) of this section, care shall be exercised in the packinghouse by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.
- c.** It is recommended that the land adjacent to the packinghouse should not be a significant source of contamination. Hazards may include but not be limited to livestock, wildlife, landfills, chemical plants, etc.
- d.** Appropriate measures shall be taken to minimize any food safety hazards from surrounding land use or environment. These measures may include berms, fences,

ditches, buffer zones or other strategies to effectively mitigate any hazards. Records shall be kept of the measures used.

3. Buildings

- a.** PS§ 126 requires that buildings must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards. Buildings must:
 - i.** Provide sufficient space for placement of equipment and storage of materials; and
 - ii.** Permit proper precautions to be taken to reduce the potential for contamination of covered produce, food contact surfaces, or packing materials with known or reasonably foreseeable hazards. The potential for contamination must be reduced by effective design including the separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, enclosed systems, or other effective means;
 - iii.** Provide adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building.
- b.** PS§ 126 requires that operations implement measures to prevent contamination of tomatoes and food contact surfaces in buildings, as appropriate, considering the potential for such contamination through floors, walls, ceilings, fixtures, ducts, or pipes, and drip or condensate.

4. General Maintenance

- a.** Buildings, fixtures, food contact surfaces and other physical facilities of the packinghouse shall be maintained in a clean and sanitary condition and shall be kept in repair sufficient to prevent tomatoes from becoming adulterated.
- b.** PS§ 124 requires that instruments or controls used to measure, regulate, or record temperatures, pH, sanitizer efficacy or other conditions, in order to control or prevent the growth of pathogens, must be accurate (*i.e.*, calibrated) and precise as necessary and appropriate in keeping with their purpose, adequately maintained, and adequate in number for their designated uses.
- c.** Pallets used to keep finished product off the floor must be visually clean.
- d.** Bins, trays, and pallets shall be maintained in clean operational condition according to SSOPs, and stored in a secure, clean location.
- e.** Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of tomatoes, food contact surfaces or packaging materials.
- f.** Sanitation Standard Operating Procedures (SSOPs) related to the general cleaning and sanitation of the facility, including maintenance of dump tanks, bump pads, brush rollers, sponge rollers, and other equipment to minimize damage to fruit, shall be established. While a cleaning schedule is part of SSOPs, the volume of tomatoes handled may require more frequent attention to cleaning. Minor surface injuries such as abrasions that might not result in the culling of a tomato have been shown to promote survival of pathogens, especially in combination with fruit waxes.
- g.** Cleaning compounds, sanitizers, pesticides and all other chemicals shall be labeled, handled, and stored in a manner that does not pose a risk of contamination to tomatoes, food contact surfaces, or food packaging materials. Food-grade and non-

- food grade chemicals shall be kept separate in order to minimize the risk of accidentally substituting one for the other. These products shall be used in accordance with manufacturers' label instructions and all federal, state, and local regulations shall be followed.
- h.** All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned and sanitized in keeping with an established, documented sanitation standard operating procedure (SSOP) to protect against contamination of food.
 - i.** Non-food-contact surfaces shall be cleaned and sanitized in accordance to the facility's SSOP or more frequently if necessary to protect tomatoes from contamination.
 - ii.** Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.
 - iii.** Sanitizing products shall be registered for their intended use and cleaning and sanitizing products used according to manufacturers' label instructions.
 - i.** Cleaned and sanitized utensils and portable equipment with food-contact surfaces should be stored in a location and manner that protects food-contact surfaces from contamination.

5. Water Supply and Plumbing

- a.** The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts food or food-contact surfaces, intended or unintended, shall meet the microbial standards as set forth in PS§ 44(a), *i.e.*, no untreated surface water and no detectable generic *Escherichia coli* (*E. coli*) in 100 milliliters (mL) of water.
- b.** Running water shall be available at suitable temperature, pressure and volume where it is needed for packing, cleaning, sanitation, and employee hygiene.
- c.** PS§ 133 requires plumbing to be of adequate size and design and adequately installed and maintained to:
 - i.** Supply sufficient quantities of water under pressure as needed, to required locations throughout the packinghouse.
 - ii.** Properly convey sewage and liquid disposable waste from the packinghouse in a manner that does not pose a risk of contamination to food, water supplies, equipment, or utensils or create an unsanitary condition.
 - iii.** Protect against backflow from, or cross-connection between, piping systems that discharge wastewater or sewage and piping systems that carry water for food or food manufacturing. Appropriate backflow prevention devices (*e.g.*, air gaps, backflow valves) shall be used to protect water quality at the source and during distribution and use.
- d.** Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.
- e.** PS§ 131 requires that sewage be properly disposed into appropriate sewer, septic or alternative systems that do not pose a risk of contamination. Operations must maintain sewage and septic systems, and manage leakages or spills of human waste, in a manner that prevents contamination of tomatoes, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems.

- f. After a significant event (such as flooding or an earthquake) that could negatively impact a sewage or septic system, PS§ 131 requires that operations take appropriate steps to ensure that sewage and septic systems continue to operate in a manner that does not contaminate tomatoes, food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.

6. Animals and Pest Control

- a. No animals are permitted in areas where tomatoes are packed, handled or stored. PS§ 127 requires operations to exclude domesticated animals from fully-enclosed buildings where tomatoes, food contact surfaces, or food packing material is exposed; or separating domesticated animals in a fully enclosed building from an area where a covered activity is conducted on tomatoes by location, time, or partition. PS§ 127 permits guard or guide dogs to be allowed in some areas of a fully enclosed building if the presence of the dogs is unlikely to result in contamination of tomatoes, food contact surfaces, or food packing materials.
- b. A pest control program shall be in place to protect the packinghouse from rodents, birds, amphibians (e.g., tree frogs), reptiles and other facility pests. PS§ 128 requires operations to take those measures reasonably necessary to protect tomatoes, food contact surfaces, and food packing materials from contamination by pests in buildings, including routine monitoring for pests as necessary and appropriate. Operations must take measures to exclude pests from fully-enclosed buildings and to prevent pests from becoming established in partially-enclosed buildings (such as by use of screens or by monitoring for the presence of pests and removing them when present).
- c. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of tomatoes, food-contact surfaces, and food-packaging materials. Generally, only non-toxic traps and pest control devices are used inside the packinghouse.

7. Health and Hygiene Practices

- a. Refer to recommendations and Produce Safety rule requirements in the Open Field Production section for Health and Hygiene Practices.
- b. Restrooms that do open directly into tomato handling areas should be equipped with self-closing mechanisms or have a maze-type entrance/exit.
- c. A written record of cleaning of restrooms shall be kept.
- d. Handwashing signs shall be posted in restrooms. Signs should be multilingual or pictorial, as appropriate to the workforce.
- e. Hot water, where available, should be provided for handwashing.
- f. Sanitizers may not be used in lieu of proper handwashing, but may be used in addition to handwashing.
- g. Refuse receptacles must be constructed and maintained in a manner that protects against contamination of tomatoes.

8. Glove Use

Refer to recommendations and Produce Safety rule requirements in the Open Field Production section for Glove Use.

9. Trash and Tomato Waste Disposal

- a.** Trash and tomato waste shall be handled, stored and disposed in a manner that minimizes odors, minimizes the potential for attracting or harboring pests, and minimizes the risk of contamination of tomatoes, food and non-food contact surfaces, and water supplies. Operation has a culling procedure to remove damaged and decayed tomatoes to the extent practical. Workers are trained to recognize and remove damaged or decayed tomatoes.
- b.** PS§ 132 requires that trash, litter and waste be conveyed, stored, and disposed of in a manner that minimizes the potential to attract or harbor pests and protects against contamination of tomatoes, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems. Systems for waste treatment and disposal must be adequately operated so that they do not constitute a potential source of contamination in areas used for a covered activity.
- c.** Culls and tomato waste that are destined for animal feed must comply with the following Good Manufacturing Practices described in the Preventive Controls rule (PC§ 95):
 - i.** Human food by-products held for distribution as animal food without additional manufacturing or processing by the human food processor must be held under conditions that will protect against contamination, including the following:
 - 1.** Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;
 - 2.** Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and
 - 3.** During holding, human food by-products for use as animal food must be accurately identified.
 - ii.** Labeling that identifies the by-product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed.
 - iii.** Shipping containers (*e.g.*, totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against contamination of the human food by-products for use as animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.

10. Storage, Ripening Rooms and Distribution Facilities

- a.** Storage ripening rooms and distribution facilities shall be kept clean and sanitary, with debris minimized. All walls, floors, ceilings and other surfaces shall be systematically and periodically cleaned and sanitized to avoid the build-up of mold or other potential contaminants.

- b. Product shall be palletized to avoid direct contact with the floor, with a minimum 18 inch perimeter between pallets and walls maintained to facilitate cleaning, pest control and visual inspection. If a perimeter less than 18 inches is used, the operation shall have a procedure to enable inspection and cleaning behind and between stored materials.
- c. Product on hold or rejected shall be clearly identified and segregated from other product. The operation shall have a procedure to clearly identify and segregate product on hold.
- d. There shall be no storage of trash or waste in the storage or ripening rooms.

11. Receiving Tomatoes

- a. Ensure tomatoes are from suppliers in compliance with the Produce Safety rule and these guidelines.
- b. A procedure shall be established for inspecting, accepting or rejecting incoming loads.
- c. The staging area shall be designed so that overhead areas do not pose a contamination risk of uncovered tomatoes, or that tomatoes are protected during staging to prevent contamination.
- d. Ensure that incoming documentation provides sufficient information to facilitate traceability to the source.
- e. Records of incoming inspections shall be maintained.

12. Postharvest Washing of Fresh Tomatoes

When tomatoes are washed, the quality of postharvest water that contacts fresh produce during postharvest flume transport, cleaning, grading, and surface treatment application is widely recognized as an essential pathogen control point to limit cross contamination of fresh produce. While the use of antimicrobials in wash water does not constitute a “kill step”, levels must be monitored so that the treated water adequately limits cross contamination.

Because no point in the tomato supply chain applies a validated kill step, wash water is but one hurdle in the continuum of safe practices that needs to be implemented; it does not compensate for poor production and/or handling practices prior or subsequent to washing.

- a. Water Quality Regulatory Requirements
 - i. The Produce Safety rule considers water used during washing, rinsing, and transport as “agricultural water”, with requirements detailed in PS§ 41-50. Notably, these include requirements to establish and follow water-change schedules for recirculated water, visually monitor the quality of water for buildup of organic material, and monitor the temperature of the water to minimize the potential for infiltration of microorganisms. PS§ 44(a) prohibits untreated surface waters for any uses in packinghouses or other postharvest contact, and agricultural water that will contact tomatoes or food contact surfaces must meet the microbial requirement of no detectable *E. coli* in 100 ml water.
 - ii. Florida tomatoes are subject to mandatory state inspection and audit for handling, production, and packing. [Tomato GAPs and Best Management](#)

Practices were adopted as state regulations effective July 1, 2008.

- b. Temperature of Water Supplies Used in Postharvest Applications.
 - i. Internalization of bacteria into the fruit has been demonstrated with tomatoes submerged in water without a sanitizer. Water adequately treated with sanitizer is the most effective method of controlling internalization of pathogens due to cross-contamination.
 - ii. Cold water immersion as a cooling technique shall not be done.
 - iii. While PS§ 48 requires operations to maintain and monitor the temperature of water in which tomatoes are submerged at a temperature that is appropriate for the commodity and operation (considering the time and depth of submersion) and is adequate to minimize the potential for infiltration of microorganisms of public health significance into covered produce, studies indicate that the temperature differential between wash water and tomato pulp temperature may not be as influential as previously thought. Residence time and product depth are influential and may be difficult to strictly control. Therefore, it is prudent for water temperature in dump tanks to be maintained at least 10°F warmer than the pulp temperature of the tomato.
 - 1. Monitor water temperature and pulp temperature at least hourly.
 - 2. Pulp temperature is the average of at least 5 tomatoes.
 - iv. Temperature control of water, and the risk of internalization, does not apply to spray bar or other processes in which tomatoes are not submerged.
- c. Antimicrobials in Postharvest Wash Water
 - i. The objective of using antimicrobials in wash water is to prevent cross contamination between tomatoes that may have been contaminated in the field and other tomatoes in the dump tank or flume.
 - 1. Every effort should be made to limit contamination on incoming tomatoes by following the recommendations for production and harvesting.
 - 2. Antimicrobials in wash water are not “sanitizers” or “disinfectants” for the tomatoes and cannot be relied upon to render previously contaminated tomatoes safe.
 - 3. If antimicrobial levels drop to levels too low to prevent cross contamination (*i.e.*, below the critical limit established by the operation), the safety of the tomatoes may have been compromised and they **must be discarded since, as noted in (2), if tomatoes are contaminated, re-washing is not an appropriate corrective action.**
 - ii. Different types of wash systems (*e.g.*, dump tanks, flumes and spray bars) influence the types and levels of antimicrobials that are appropriate.
 - 1. Only antimicrobials registered with EPA and labeled for food use are permitted in tomato wash systems.
 - 2. Chlorine and peracetic acid (PAA) are the two most commonly used antimicrobials in dump tanks and flumes. Antimicrobial levels and their efficacy can fluctuate dramatically with changes in the organic load, especially when chlorine is used.
 - 3. Water used in postharvest operations must be changed as necessary for the given operation. The dump tank shall be cleaned and the water changed daily and more often as needed; water used in the first dump tank may need to be changed more frequently than water used in subsequent processes.

4. Although the risk of cross contamination in a single pass spray bar system is lower than in a dump tank or flume, antimicrobial use (e.g., chlorine, PAA or chlorine dioxide) is still required so that a hostile environment on equipment is maintained that limits cross contamination, biofilm formation, and the establishment of environmental pathogens.
- iii. Operations should target antimicrobial levels that exceed the levels required to prevent cross contamination (the critical limits). Operational limits should be higher than critical limits to ensure that fluctuations in antimicrobial levels do not result in potentially unsafe conditions (Zhou et al., 2014).
- iv. Types of antimicrobials
 1. Chlorine (hypochlorous acid)
 - a. *Total chlorine measurements do not accurately represent antimicrobial effectiveness. Free* chlorine levels must be monitored and maintained.
 - b. Achieving an effective free chlorine level is dependent on several factors. Gombas et al. (2017) describe factors to consider during the validation of antimicrobials in leafy greens operation, and the concepts are generally applicable to tomatoes. Each operation should assess the following factors to determine the appropriate free chlorine level needed to consistently prevent cross contamination:
 - i. Quality of incoming tomatoes: in lay terms, the dirtier the tomatoes, the more difficult it will be to maintain effective levels of free chlorine, because chlorine is quenched by organic material. Maintaining clean water either through the control of debris on incoming tomatoes or through frequent water changes will make it easier to maintain effective chlorine levels.
 - ii. pH: There are several chemical forms of chlorine (*i.e.*, hypochlorous acid, which is the effective antimicrobial form, and hypochlorite, which is less effective), and their ratios vary based on pH. While the lower the pH, the greater the antimicrobial efficacy, the optimal pH range is 6.0-7.5.
 - iii. Throughput rate: the higher the throughput rate, the more tomatoes are washed in a given time, meaning that more chlorine may be needed to maintain an effective antimicrobial level.
 - iv. Characteristics of the water: other characteristics of the water, *e.g.*, hardness and temperature, may have an effect on chlorine efficacy, although to a lesser level.
 - c. Much of the tomato industry aims to maintain 150 ppm free chlorine. This is the level required by Florida regulation.
 - d. Research (Sreedharan et al., 2017 [J. Food Protection 80:1436-1442]) shows that below 100 ppm free chlorine, cross contamination is possible if water is of poor quality (*i.e.*, high turbidity) due to incoming product and associated debris.
 - e. Lower critical limits of free chlorine may be justified if water quality is controlled and should be scientifically determined, generally requiring the expertise of a food microbiologist experienced in conducting validation studies. Studies should be based on the operation's worst case conditions of acceptable water quality, highest pH, and highest

- throughput rate.
- f. Oxidation reduction potential (ORP) is not directly correlated to free chlorine measurements in typical tomato dump tanks. Preliminary studies suggest that potential for cross contamination does not correlate well with ORP levels. Operations using free chlorine as the wash water antimicrobial should not rely solely on ORP readings to manage chlorine levels. Rather, free chlorine levels in such systems should be verified by a method such as chemical titration.
- 2. PAA
 - a. There are limited published data on PAA efficacy in tomato wash systems. Until such data are available, peracetic acid should be used according to manufacturer's label directions.
 - b. Although its efficacy is less pH dependent than chlorine, it should still be used in systems where the pH is maintained below 8.0 (because it dissociates to a less active form at pH levels above 8.2).
 - 3. Chlorine dioxide
 - a. Chlorine dioxide should not be used in dump tanks because permitted concentrations are very difficult to maintain (Tomas-Callejas et al., 2012 [JFP 75:304-313]).
 - b. When used in spray bars, operations should consider 3 ppm as a practical operating level because commercial test strips are available for 1, 3, 5 and 10 ppm and the use of 1 ppm chlorine dioxide will not be adequate under many commercial conditions.
 - c. The EPA Safe Water Drinking Water Act permits up to 0.8 ppm chlorine dioxide as a finishing rinse.
 - 4. Other antimicrobials
 - a. Other water antimicrobials may be used, but must be registered with U.S. EPA for its intended purposes. If prevention of cross contamination is based on other water treatments, follow manufacturer recommendations for monitoring and limits, considering realistic worst case conditions relative to water quality, turbidity, etc.
 - v. Monitoring antimicrobial levels
 - 1. Monitoring microbial levels in wash water is not a useful method of verifying water quality or potential for cross contamination.
 - 2. Operations should establish and implement monitoring antimicrobial levels at an appropriate frequency to maintain sanitary conditions in consideration of product volume and product condition
 - 3. Probes should be located, and/or water samples should be taken from areas expected to have the lowest reading (e.g., worst case conditions, farthest from the antimicrobial injection site, etc.).
 - 4. Electronic monitoring devices (e.g., free chlorine sensors) shall be calibrated at a frequency at least consistent with the manufacturer's technical specifications, and checked periodically during daily operation using a titration procedure.
 - 5. Measuring devices must have sufficient precision to ensure levels are within established limits, and accuracy should be verified periodically to ensure that

measurements, particularly those close to the established threshold, are reliable.

- a. Free, not total, chlorine should be measured
 - i. Because levels of free chlorine fluctuate, ideally, levels should be monitored continuously. Equipment with which to monitor free chlorine continuously is expected to become available in the future.
 - ii. If water quality maintenance is based on *manually* monitoring chlorine levels, then free chlorine and pH must be monitored at start-up and at least hourly thereafter, and recorded, unless the operation has data that indicate that levels are maintained for longer intervals (based on worst case conditions of product volume and condition).
 - b. When PAA is used in wash water systems, levels should be monitored at least hourly.
6. When monitoring antimicrobial levels or ORP electronically, the monitoring should be verified with a chemical test that measures antimicrobial levels (and pH where applicable) at start-up and at a frequency sufficient to demonstrate accuracy of the electronic measurements, and recorded.
 7. Chlorine “wheels” and test strips can provide directional information but generally do not have the precision or accuracy for chlorine measurements near the critical limits. In such operating ranges, facilities should use calibrated free chlorine probes or titration procedures, rather than test strips, to monitor or verify free chlorine levels. If an operation chooses to rely on test strips, only use them within the precision level of the test strips.

13. Packaging Materials

- a. Packaging material shall be inspected upon arrival. The goal is to ensure that packaging material is free from contamination upon arrival and that materials are stored in a manner as to prevent contamination.
- b. Containers shall be protected from direct contact with the ground or floor.
- c. Finished product containers shall be distinguished from those serving other purposes.
- d. The firm must have a policy prohibiting the re-use of single use bins, trays and boxes made of corrugated cardboard or fiberboard for product contact purpose unless used to pack the same lot of tomatoes.
- e. Resorting of tomatoes into a corrugated cardboard container that contained the same lot of tomatoes is acceptable, provided that the container is clean, sanitary and properly labeled. Refer to recommendations regarding reuse of containers in the Repacking and Other Distribution Operations section for Traceability and Lot Identification.

14. Transportation

- a. PS§ 125 requires equipment used to transport tomatoes to be adequate for its use and adequately clean before use.
- b. Inspect transportation vehicles for cleanliness, odors, visible dirt and debris before loading. If needed, the vehicle shall be cleaned or cleaned and sanitized by a documented procedure prior to loading.

- c. If non-dedicated vehicles are used for transportation, verify records of prior loads. Should there be any doubt as to previous loads transported or a potential risk from microbial contamination, such as from raw animal proteins, garbage or other refuse, then the vehicle shall be cleaned and sanitized by a documented procedure prior to use.
- d. Whole tomatoes do not require temperature control for safety. If shipped in temperature controlled vehicles, product temperature is typically maintained in the range of 55°F to 70°F.
- e. Non-farm operations that ship whole tomatoes by rail or motor vehicle for sale in the US are subject to FDA's *Sanitary Transportation of Human and Animal Food* rule. Requirements particularly relevant to tomato packinghouse operations include the following:
 - i. ST§ 1.906 requires that all transportation operations be conducted under such conditions and controls necessary to prevent the food from becoming unsafe during transportation operations including taking effective measures such as segregation, isolation, or the use of packaging to protect food from contamination by raw foods and nonfood items in the same load.
 - ii. A shipper must develop and implement written procedures adequate to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food, *i.e.*, will prevent the food from becoming unsafe during the transportation operation. Measures to implement these procedures may be accomplished by the shipper or by the carrier or another party covered by this subpart under a written agreement.
 - iii. Before loading food not completely enclosed by a container onto a vehicle or into transportation equipment the loader must determine, considering, as appropriate, specifications provided by the shipper that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food, *e.g.*, it is in adequate physical condition, and free of visible evidence of pest infestation and previous cargo that could cause the food to become unsafe during transportation. This may be accomplished by any appropriate means.

15. Traceability and Labeling

All levels of the tomato supply chain shall maintain adequate traceability to a minimum of one step forward (immediate next recipient) and one step back (immediate previous supplier) in compliance with FDA recordkeeping requirements.

- a. Documentation maintained by the packinghouse shall include sufficient information about the source (*i.e.*, field packer firm name, identification of grower, field location, and date of harvest/field pack) as well as the customer receiving the product to allow for the appropriate tracing of product.
- b. The packer shall have established procedures to ensure that traceability information about the source is retained with tomatoes as they move through the packinghouse processes to shipping, including during resorting.
- c. Corrugated containers shall be new and accurately labeled with commodity name, packinghouse firm name, and lot identification sufficient to allow for accurate traceability.
- d. Only containers able to be cleaned and sanitized (*e.g.*, reusable plastic containers, "RPCs") may be reused. If using reusable containers, they shall be cleaned and sanitized before reuse. Labels that originate from a prior use or are inaccurate shall be removed or concealed prior to packing.

16. Recall Program

- a.** A documented recall program, including a traceability system to track tomatoes forward to customers, shall be developed and tested at least annually. Traceability is expected to achieve 100% reconciliation of product to recipients. A record of this test shall be maintained and be available.
- b.** Operations subject to the Preventive Controls rule are required to have a written recall plan. PC§ 139 requires the plan to include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility:
 - i.** Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food;
 - ii.** Notify the public about any hazard presented by the food when appropriate to protect public health;
 - iii.** Conduct effectiveness checks to verify that the recall is carried out; and
 - iv.** Appropriately dispose of recalled food; *e.g.*, through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food.

17. Record Keeping

Refer to recommendations and Produce Safety rule requirements in the Open Field Production section for Record Keeping.

VIII. Repacking and Other Distribution Operations

Everyone in the supply chain that handles tomatoes, including repackers, terminal markets and other facilities, has a responsibility to ensure and maintain the safety and traceability of the product. Repacking and distribution operations that package, pack or hold raw agricultural commodities and are not farms are subject to the Preventive Controls rule. PC§ 8 allows that compliance with the Good Manufacturing Practices requirements of that rule (PC§ subpart B) by such operations may be achieved by complying with the applicable requirements for packing and holding in the Produce Safety rule. At this writing, FDA has opined that “discretionary enforcement” will be used if such operations are not in full compliance with the Preventive Controls rule but are in compliance with the Produce Safety rule.

1. Prerequisites for Repacking of Tomatoes

Repacking of tomatoes must meet all recommendations and Produce Safety rule requirements included in the Packinghouse section, including Personnel Qualifications and Training, Grounds, Buildings, General Maintenance, Water Supply and Plumbing, Animals and Pest Control, Health and Hygiene Practices, Glove Use, Trash and Tomato Waste Disposal, Storage, Ripening Rooms and Distribution Facilities, Receiving Tomatoes, Postharvest Washing of Fresh Tomatoes, Packaging Materials, Transportation, Recall Program, and Record Keeping, in addition to the requirements further detailed in this section on Repacking.

2. Traceability and Lot Identification

All levels of the tomato supply chain shall maintain adequate traceability to a minimum of

one step forward (immediate next recipient) and one step back (immediate previous supplier) in compliance with FDA recordkeeping requirements.

- a. Documentation maintained by the repacker for each lot received shall include sufficient information about the source (*i.e.*, production location, supplier identification, lot identification) as well as the customer receiving the product to allow for the appropriate tracing of product.
- b. The packer shall have established procedures to ensure that traceability information about the source is retained with tomatoes as they move through the repacking processes to shipping, including during resorting or rerunning.
- c. It is preferred that incoming lots are not mixed/commingled during repacking. However, if incoming lots are mixed/commingled, then documentation shall be maintained to identify all included sources.
- d. Only containers that are clean and sanitary (sanitized, if possible) may be reused. Labels that originate from a prior use or are inaccurate shall be removed or concealed prior to packing. Only containers designed to be reused (*e.g.*, reusable plastic containers, "RPCs") may be reused when none of the tomatoes to be packed were originally packed in that container.
- e. If tomato lots are not mixed/commingled, then tomatoes may be repacked into their original containers. When original containers of a packinghouse supplier are to be reused, and the tomatoes are removed and resorted, and returned to that clean and sanitary container, the repacker must label the container as being repacked, and include the commodity, repacker name and provide lot identification.
- f. If tomato lots are commingled, then tomatoes should be repacked into new or used containers where the original label matches at least one tomato in the commingled lot. Reused containers shall be clean and sanitary, and accurately labeled with the repacker's information and lot identification that maintains the integrity of traceability information to all the included lots. In the event of a recall, all lots in the commingled lot are affected.
- g. Used containers may be used as secondary packaging, provided that the original identification information on the container has been removed, concealed or otherwise made clear that it is no longer accurate.

3. Cleaning Materials

Refer to recommendations in the Field Packing section for Cleaning Materials.

4. Cross-docking and Terminal Markets

Tomato handling at facilities that primarily redistribute tomatoes, whether or not they repack, sort or otherwise change the contents in the container, are also required to follow the recommendations and regulatory requirements in these guidelines, as appropriate to their specific operation.

IX. Fresh-cut Processing (Value-Added)

Processing fresh tomatoes into fresh-cut products increases the risk of bacterial growth and contamination by breaking the natural exterior barrier of the tomato. The release of plant cellular fluids when tomatoes are cut provides a nutritive medium in which pathogens, if present, can survive or grow. The processing of fresh tomatoes without proper sanitation procedures in the processing environment increases the potential for contamination by pathogens. 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.

Unless exempt, facilities processing tomatoes must comply with 21 CFR Part 117, the *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food* rule (the Preventive Controls or PC rule). In general, facilities operating under the PC rule must comply with Good Manufacturing Practices (GMP) described in subpart B of the rule (PC§ 10 through 110), and also comply with subparts C and G of the rule (PC§ 126 through 190 and PC§ 301 through 475), which require conducting a hazard analysis and implementing process, allergen, sanitation and supply chain preventive controls as appropriate to the facility and products produced to significantly minimize or prevent any identified hazards requiring preventive controls. Facilities must also comply with the verification, validation, and record keeping procedures along with a recall plan. While a basic description of those requirements, as they apply to fresh-cut tomatoes, are provided in this section, there may be exceptions depending on the supplier, transporter, and types of fresh-cut tomato products produced. See the Preventive Controls rule for further details.

1. Personnel Qualifications and Training

PC§ 4 identifies the following requirements:

- a. Each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof shall be a qualified individual, *i.e.*, to have the education, training, or experience (or a combination thereof) necessary to perform the individual's assigned duties.
- b. Each individual shall receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties. Records of this training must be established and maintained.
- c. Supervisors responsible for ensuring compliance by individuals must have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food.
- d. The operation shall have designated a Preventive Controls Qualified Individual (PCQI), *i.e.*, a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system. The PCQI does not need to be a full time employee of the operation, but is responsible for performing several activities, as noted in the sections below.
- e. PC§ 180 identifies the following responsibilities of the PCQI:
 - i. Preparation of the food safety plan;
 - ii. Validation of process preventive controls;
 - iii. Review of monitoring and corrective action records, records of calibration, testing (*e.g.*, product testing, environmental monitoring), supplier and supply-chain verification activities, and other verification activities; and
 - iv. Reanalysis of the food safety plan.

2. Grounds, Buildings and General Maintenance

While these requirements are covered under subpart B of the Preventive Controls rule, operations can refer to the Packinghouse section for recommendations and requirements for Grounds, Buildings and General Maintenance.

3. Facility Sanitation, Pest Control

Comprehensive sanitation programs, with trained sanitation personnel, reduces the risk of product microbial contamination from equipment, floors and drains. Improper use of chemicals may lead to inadequately cleaned equipment or chemical contamination of equipment. A written pest control program will reduce the risk of rodent, insect or bird infestations of the facility, which could otherwise lead to product contamination. GMP requirements are described in subpart B of the Preventive Controls rule, particularly PC§ 35.

- a. Raw, processing and finished product segregation shall be addressed by using physical barriers or other adequate control separating these areas and the use of disinfectant foam/dip at the entrance to processing area.
- b. A documented sanitation program shall be in place that meets regulatory requirements and ensures the cleanliness of product handling equipment and facility, including storage, processing and other rooms.
- c. Facilities shall define and maintain cleaning frequencies: include peripherals (walls, ceilings, light fixtures, cooling units, etc.).
- d. Chemicals shall be registered with U.S. EPA and used in accordance with label instructions for time, temperature, concentration and application.
- e. Facilities should establish a sampling program for incoming chemicals at a given frequency that verifies the suppliers' Certificates of Analysis (COA).
- f. A written program shall be implemented that monitors adequacy and compliance of the sanitation program.
- g. The results of the verification program shall be documented and monitored to identify areas of opportunity for continuous improvement.
- h. A program (e.g., color coding) shall be in place to readily identify and segregate food contact vs. non-food contact equipment and utensils used in the sanitation program.
- i. Hands shall be cleaned and sanitized prior to handling clean equipment.
- j. Product shall be protected or removed during cleaning and sanitizing operations to reduce the potential for cross contamination.
- k. Sanitation personnel shall not spray floors or drains with high-pressure hoses (resulting aerosol may contaminate product surfaces).
- l. Sanitation personnel shall remove excess water from cleaned equipment.
- m. Sanitation personnel shall not place product contact equipment directly onto the floor.
- n. Facilities shall properly identify and segregate equipment used to clean drains and floors and shall not use equipment aids with wooden or hollow handles.
- o. A program shall be in place that minimizes or eliminates the potential for environmental pathogens. Environmental swabs should be used to verify the effectiveness of the program.
- p. A preventive maintenance program shall be in place that identifies areas of opportunities for continuous improvement; e.g., use only food grade lubricants when possible, avoid over-lubricating and wipe off excess, welds should be smooth and sanitary, catch pans shall be placed under motors and bearings which are located over product zones or traffic areas, equipment should be free of rust.

- q. Facilities shall develop and implement a written pest control program to include a licensed pest control technician, adequate monitoring frequencies and pest control devices to control the infiltration of rodents and insect monitoring/ control. Pesticides shall be EPA approved for the methods, target pests, and locations where they are used.

4. Water Supply and Plumbing

While GMP requirements are covered under subpart B of the Preventive Controls rule, particularly PC§ 37, operations can refer to the Packinghouse section for recommendations and requirements for Water Supply and Plumbing.

5. Health and Hygiene Practices, Glove Use

- a. While GMP requirements are covered under subpart B of the Preventive Controls rule, particularly PC§ 10, operations can refer to the Open Field Production and Packinghouse sections for recommendations and requirements for Health and Hygiene Practices and Glove Use.
- b. Operations that handle food allergens shall follow requirements for allergen awareness and control in PC§ 10.

6. Equipment and Utensils

GMP requirements are covered under subpart B of the Preventive Controls rule, particularly PC§ 40. Requirements particularly relevant to fresh-cut tomato operations include the following:

- a. All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be adequately cleanable, and must be adequately maintained to protect against allergen cross-contact and contamination.
- b. Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.
- c. Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.
- d. Food-contact surfaces must be corrosion-resistant when in contact with food.
- e. Food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.
- f. Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated by any source, including unlawful indirect food additives.
- g. Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.
- h. Equipment that is in areas where food is manufactured, processed, packed, or held and that does not come into contact with food must be so constructed that it can be kept in a clean and sanitary condition.

- i. Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate clean and sanitary condition.
- j. Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment.
- k. Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food must be accurate, precise, adequately maintained, and adequate in number for their designated uses.
- l. Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives.

7. Processes and Controls

GMP requirements are covered under subpart B of the Preventive Controls rule, particularly PC§ 80. Requirements particularly relevant to fresh-cut tomato operations include the following:

- a. All operations in the manufacturing, processing, packing, and holding of food (including operations directed to receiving, inspecting, transporting, and segregating) must be conducted in accordance with adequate sanitation principles.
- b. Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.
- c. Overall sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function.
- d. Adequate precautions must be taken to ensure that production procedures do not contribute to allergen cross-contact and to contamination from any source.
- e. Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination.
- f. All food that has become contaminated to the extent that it is adulterated must be rejected, or if appropriate, treated or processed to eliminate the contamination.
- g. Raw materials and other ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration.
- h. Raw materials must be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not cause allergen cross-contact or increase the level of contamination of the food.
- i. Material scheduled for rework must be identified as such. Work-in-process and rework must be handled in a manner that protects against allergen cross-contact, contamination, and growth of undesirable microorganisms.
- j. Raw materials and other ingredients that are food allergens, and rework that contains food allergens, must be identified and held in a manner that prevents allergen cross-contact.

- k. Equipment and utensils and food containers must be maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment must be taken apart for thorough cleaning.
- l. All food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.
- m. Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding.
- n. Effective measures must be taken to protect finished food from allergen cross-contact and from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in allergen cross-contact or contaminated food. Food transported by conveyor must be protected against allergen cross-contact and against contamination as necessary.
- o. Equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients, work-in-process, rework, or other food must be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and against contamination.
- p. Adequate measures must be taken to protect against the inclusion of metal or other extraneous material in food.
- q. Food, raw materials, and other ingredients that are adulterated must be disposed of in a manner that protects against the contamination of other food.
- r. Steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying must be performed so as to protect food against allergen cross-contact and against contamination. Food must be protected from contaminants that may drip, drain, or be drawn into the food.
- s. Filling, assembling, packaging, and other operations must be performed in such a way that the food is protected against allergen cross-contact, contamination and growth of undesirable microorganisms.
- t. When ice is used in contact with food, it must be made from water that is safe and of adequate sanitary quality and must be used only if it has been manufactured in accordance with current GMP.

8. Food Safety Plan

- a. PC§ 126 requires operations to prepare, or have prepared, and implement a written food safety plan.
- b. The food safety plan must be prepared, or its preparation overseen, by one or more PCQIs.
- c. The written food safety plan must include a hazard analysis, preventive controls for all identified hazards, a supply-chain program, a recall plan, procedures for monitoring the implementation of the preventive controls, corrective action procedures that must be taken if preventive controls are not properly implemented, and procedures to verify the implementation and effectiveness of the plan.

9. Hazard Analysis

- a. PC§ 130 requires the food safety plan to include a written hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility to determine whether there are any hazards requiring a preventive control.
- b. The hazard analysis must consider known or reasonably foreseeable hazards that include biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens; chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and physical hazards such as stones, glass, and metal fragments).
- c. The hazard analysis must include an evaluation of the hazards to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls. The hazard evaluation must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.
- d. FDA and the tomato industry recognize that *Salmonella* is a known or reasonably foreseeable biological hazard in whole and fresh-cut tomatoes. Operations should consider the potential for other biological hazards, such as viruses and parasites, and the potential for physical hazards and chemical hazards to occur at levels reasonably likely to cause illness or injury if consumed, considering what is known about the growing and handling of the tomatoes, other ingredients and primary packaging prior to receipt at the operation.
- e. The hazard analysis shall also consider the potential for conditions at receipt, within the facility and in outgoing transportation to introduce or amplify biological, chemical or physical hazards. FDA and the tomato industry recognize that cross-contamination of tomatoes with *Salmonella* or other biological hazards during immersion washing is a known or reasonably foreseeable hazard. Operations should consider the potential for environmental or cross-contamination with biological, chemical or physical hazards from other food contact surfaces, considering the likelihood of occurrence of such hazards under the operation's existing GMPs.
- f. While *Listeria monocytogenes* is a recognized risk in produce processing facilities, resulting from the environmental conditions that may be present in many operations, its risk to public health on fresh-cut tomatoes has not been well established. Nevertheless, a well designed environmental monitoring program has proven to be an effective tool in minimizing or preventing the contamination of ready-to-eat foods with *L. monocytogenes* whenever such food is exposed to the environment prior to packaging. "[Guidance on Environmental Monitoring and Control of Listeria for the Fresh Produce Industry](#)" is available for free download from United Fresh, as is the FDA draft guidance for industry titled "[Control of Listeria monocytogenes in Ready-to-Eat Foods](#)." Refer to these documents for further details.

10. Preventive Controls

- a. FDA (PC§ 3) defines preventive controls as those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.
- b. PC§ 135 requires operations to identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the food manufactured, processed, packed, or held by the facility will not be adulterated.
- c. The Preventive Controls rule categorizes preventive controls as process, allergen, sanitation, and supply-chain.

11. Receiving

- a. Operations shall establish a written procedure for inspecting, accepting or rejecting incoming loads. PC§ 405 requires fresh-cut operations to establish and implement a written supply-chain program to ensure tomatoes are from suppliers who are compliant with the Produce Safety rule or Preventive Controls rule, as appropriate to the supplier, and are following these guidelines. Note that, in the Preventive Controls rule, FDA identifies the “supplier” as the farm where the tomatoes were grown.
- b. PC§ 410 requires the supply-chain program to include determining, conducting and documenting the performance of appropriate supplier verification activities, and performing those activities prior to approving, and receiving tomatoes from, any fresh tomato supplier.
 - i. PC§ 430 states that for fresh tomatoes, as well as all fresh produce covered by the Produce Safety rule, the appropriate supplier verification activity is an onsite audit of the supplier (*i.e.*, the farm that grew and harvested the tomatoes), conducted prior to using tomatoes from the supplier and at least annually thereafter. Fresh-cut operations should consider if other entities in the tomato supply chain, subsequent to the farm and prior to receipt by the fresh-cut operation, should be included in the supply-chain verification activities.
 - ii. PC§ 430 allows that a supplier verification activity other than an annual onsite audit may be used if there is a written determination by the fresh-cut operation’s Preventive Controls Qualified Individual (PCQI) that other verification activities and/or less frequent onsite auditing of the supplier provides adequate assurance that the hazards are controlled.
 - iii. The onsite audit must be performed by a qualified auditor, and can be performed by the fresh-cut operation (second party audit) or by a third party. Supply-chain programs are prohibited from using self-audits, performed by the supplier, as the sole verification activity.
 - iv. The audit must demonstrate that the supplier is in compliance with the Produce Safety rule, or has implemented procedures that provide the same level of public health protection, to minimize the risk of contamination of the tomatoes with pathogens.
 - v. The audit results, and any corrective actions needed to bring the supplier into compliance with required food safety practices, must be reviewed by the fresh-

cut operation's PCQI. That review, and the PCQI's acceptance of the results as evidence supporting approval of the supplier, must be documented. Note that FDA does not require the fresh-cut operation to maintain a copy of the audit, but must retain records that include the name of the supplier subject to the onsite audit; documentation of the audit procedures; the dates the audit was conducted; the conclusions of the audit; corrective actions taken in response to significant deficiencies identified during the audit; and documentation that the audit was conducted by a qualified auditor. These records shall be retained for at least two years beyond the last use of the supplier, or two years beyond a new audit of the supplier, whichever is sooner.

- c. Records of incoming inspections shall be maintained. PC§ 420 requires that tomatoes are received only from approved suppliers. PC§ 475 requires that operations maintain records to demonstrate that tomatoes are received only from approved suppliers.
- d. PC§ 420 allows operations to receive tomatoes from unapproved suppliers on a temporary basis only if subjected to adequate verification activities before acceptance for use. Operations that occasionally may need to receive tomatoes from unapproved suppliers shall have a written procedure that will verify, and document, that such suppliers have adequately grown and handled such tomatoes in a manner that minimizes the risk of containing human pathogens like *Salmonella*. Operations shall implement the temporary approval procedure before permitting such tomatoes to be used in product.
- e. Incoming documentation must provide sufficient information to facilitate traceability to the source. Since FDA considers the supplier to be the operation that grew and harvested the tomatoes, fresh-cut operations are required to have evidence of their source.

12. Raw, Intact Product Storage

- a. Storage containers as well as storage facilities shall be designed with the proper materials and construction to facilitate cleaning.
- b. Containers and product shall be stored in a manner that minimizes the potential for contamination. This may include, but is not limited to, protecting stored containers and product with liners/covers and ensuring storage areas are clean and devoid of pests.
- c. Storage temperature of whole, intact tomatoes is critical to maintaining the quality of the product. Tomatoes stored at refrigeration temperatures for extended periods of time may result in decreased quality of raw product, increasing the likelihood of damaging the product during processing. Storage temperatures should also be maintained at sufficient temperatures to ensure required finished product temperatures are achieved.

13. Sorting

Use of damaged product or further damaging tomatoes with poor handling practices could provide openings for colonization and growth of pathogens. It is important to remove damaged or decayed raw material and maintain gentle handling practices to reduce the risk of contamination.

- a. Secondary containers used for packing sorted tomatoes shall be maintained in clean and sanitary condition.
- b. Tomatoes that show signs of physical damage such as skin breaks or decay shall be culled from processing. Culled tomatoes shall be disposed of properly so as not to serve as a contaminant.
- c. The sorting process shall be performed in a manner ensuring that further damage to the tomato is minimized.
- d. Lot identity shall be maintained throughout the sorting process.
- e. Preventive measures shall be implemented to remove foreign/extraneous materials.

14. Trash and Tomato Waste Disposal

Refer to recommendations and Produce Safety and Preventive Controls rule requirements in the Packinghouse section for Trash and Tomato Waste Disposal.

15. Whole Tomato Wash

- a. Tomatoes must be washed prior to processing by either the processing facility or by the supplier of the tomatoes.
- b. While the Preventive Controls rule has no specific requirements for tomato washing beyond GMPs, the potential for cross-contamination and infiltration of the tomatoes during immersion washing must be considered in the hazard analysis. If the hazard analysis concludes that cross-contamination or infiltration with a pathogen such as *Salmonella* is a hazard requiring a preventive control, the operation shall identify and implement a process preventive control to minimize the likelihood of the hazard.
- c. Refer to discussion and recommendations in the Packinghouse section for Postharvest Washing of Fresh Tomatoes.
- d. Cold water immersion, to firm tomatoes prior to cutting, shall not be done. Instead, tomatoes should be firmed by cold storage or cold air just prior to cutting.

16. Cutting

Blade condition relating to sharpness and damage should be monitored regularly. Improperly maintained blades can result in damaged and bruised tissue, which can make the product more susceptible to microbial growth during shelf life.

17. Cut Tomato Washing

- a. If fresh-cut tomatoes are washed after cutting, the potential for cross-contamination of the tomatoes during immersion washing must be considered in the hazard analysis. Refer to discussion and recommendations in the Packinghouse section for Postharvest Washing of Fresh Tomatoes.

- b. After cutting, the potential for infiltration, and the potential benefit of immersion in water warmer than the tomato, is much less. Instead, cut tomatoes should be washed with cold water to reduce product temperature.
- c. Wash water temperature shall be monitored to assure finished products do not exceed refrigerated temperatures ($\leq 41^{\circ}\text{F}$).
- d. If ice is used to chill the water, it must be made from water that is safe and of adequate sanitary quality and must be used only if it has been manufactured in accordance with current GMP.

18. Packaging

- a. An effective system shall be maintained to prevent the use of contaminated, damaged, or defective cartons, trays and totes in order to prevent microbial contamination of the fresh-cut tomatoes during packing operations.
- b. Packaging materials coming into direct contact with the fresh-cut tomatoes shall be appropriately identified, including traceability to their source.
- c. Packaging containers and cartons shall be used for their intended purpose only.
- d. Packaging materials shall be stored in a manner to protect them from contamination, such as away from pests, dirt, cleaning chemicals, and water condensation from overhead equipment and structures.
- e. Primary or secondary finished fresh-cut tomato product containers shall be labeled with recommended storage instructions (e.g., "Keep Refrigerated") and storage temperature to inform all persons handling the product of the recommended storage conditions.
- f. Primary and secondary packaging shall be coded to ensure traceability.

19. Storage Rooms and Distribution Facilities

- a. Finished products shall be stored at refrigerated temperatures not to exceed 41°F . For best quality, maintain storage room temperature as close to 32°F as possible without freezing the product.
- b. Storage rooms and distribution facilities shall be kept clean and sanitary, with debris minimized. All walls, floors, ceilings and other surfaces shall be systematically and periodically cleaned and sanitized to avoid the build-up of mold or other potential contaminants.
- c. Product shall be palletized to avoid direct contact with the floor.
- d. A perimeter between pallets and walls shall be maintained to facilitate visual inspection of pest control and sanitation.
- e. Product on hold or rejected shall be clearly identified and segregated from other product.
- f. There shall be no storage of trash or waste in the storage rooms.

20. Transportation

- a. Operations that ship fresh-cut tomatoes by rail or motor vehicle for sale in the US are subject to FDA's Sanitary Transportation rule. Refer to Sanitary Transportation rule requirements in the Packinghouse section for Transportation. Additional requirements in the rule particularly relevant to fresh-cut tomato operations include the following:

- i. ST§ 1.906 requires that all transportation operations be conducted under such conditions and controls necessary to prevent the food from becoming unsafe during transportation operations including taking effective measures to ensure that food that requires temperature control for safety is transported under adequate temperature control.
 - ii. The shipper of food that requires temperature control for safety under the conditions of shipment must develop and implement written procedures to ensure that the food is transported under adequate temperature control. Measures to ensure the safety of the food may be accomplished by the shipper or by the carrier or another party under a written agreement.
 - iii. Before loading food that requires temperature control for safety, the loader must verify, considering, as appropriate, specifications provided by the shipper, that each mechanically refrigerated cold storage compartment or container is adequately prepared for the transportation of such food, including that it has been properly pre-cooled, if necessary, and meets other sanitary conditions for food transportation.
 - iv. If a shipper, loader, receiver, or carrier becomes aware of an indication of a possible material failure of temperature control or other conditions that may render the food unsafe during transportation, the food shall not be sold or otherwise distributed, and these persons must take appropriate action including, as necessary, communication with other parties to ensure that the food is not sold or otherwise distributed unless a determination is made by a qualified individual that the temperature deviation or other condition did not render the food unsafe.
- b. Temperature controls must be implemented to maintain finished product temperature not to exceed 41°F throughout the supply chain including post-processing cooling, transport and storage. If product temperature exceeds 41°F for more than six (6) hours, the product should be discarded. Product temperatures are difficult to measure and track during transport since most transport containers only measure and track air temperature. Take care to ensure product temperature is below 41°F prior to loading as many customers will not accept product that has exceeded 41°F during transport.
- c. Finished tomatoes shall be transported in pre-cooled vehicles equipped with a calibrated temperature monitoring device.
- d. Transportation vehicles should be sufficiently clean so as not to be a source of contamination.
- e. Inspect transportation vehicles for cleanliness, odors, visible dirt and debris before loading. If needed, the vehicle shall be cleaned or cleaned and sanitized by a documented procedure prior to loading.
- f. If non-dedicated vehicles are used for transportation, verify records of prior loads. Should there be any doubt as to previous loads transported or a potential risk from microbial contamination, such as from raw animal proteins, garbage or other refuse, then the vehicle shall be cleaned and sanitized by a documented procedure prior to use.

21. Traceability and Labels

All levels of the tomato supply chain shall maintain adequate traceability to a minimum of one step forward (immediate next recipient) and one step back (immediate previous supplier).

- a. Documentation maintained by the processor shall include sufficient information about the source (e.g., production location, packer/repacker, lot identification, as appropriate to the source of tomatoes) as well as the customer receiving the product to allow for the appropriate tracing of product.
- b. The processor shall have established procedures to ensure that traceability information about the source is retained with tomatoes as they move through the processes to shipping.
- c. Primary and secondary containers shall be accurately labeled with commodity name, processor firm name or identification code, and lot identification sufficient to allow for accurate traceability.
- d. Traceability records shall be readily available.
- e. A documented recall program, including a traceability system to track tomatoes forward to customers, shall be developed and tested at least annually. Traceability is expected to achieve 100% reconciliation of product to recipients. A record of this test shall be kept on file.

22. Record Keeping

Food processors are required to keep records on file to verify processes.

- a. All processing, receiving and shipping records shall be maintained on file for a minimum of two years from processing.
- b. A document control program should be established to ensure customer confidentiality of specifications and proprietary documents.
- c. Copies of the operation's food safety plan, including hazard analysis, identification of preventive controls, and procedures to implement those controls, must be retained for at least two years beyond when they are in use.
- d. Records required by the Preventive Controls rule must be retained for at least 2 years after the date they were prepared, and include the following:
 - i. Records of employee training in the principles of food hygiene and food safety;
 - ii. Records that document the monitoring of preventive controls;
 - iii. Records that document corrective actions;
 - iv. Records that document verification, including, as applicable, those related to validation, verification of monitoring, verification of corrective actions, calibration of process monitoring and verification instruments, product testing (if performed as part of the food safety plan), environmental monitoring (if performed as part of the food safety plan), records review, and reanalysis;
 - v. Records that document the supply-chain program; and
 - vi. Records that document applicable training for the PCQI and the qualified auditor.
- e. ST§ 1.912 requires shippers to retain records that demonstrate that they provide specifications and operating temperatures to carriers as required by the Sanitary Transportation rule for a period of 12 months beyond when they are in use or the termination of the agreements with the carriers.
- f. While not required by FDA regulation, additional records to be maintained shall include, but not be limited to, the following:

- i. Sanitation records
- ii. Pest Control records
- iii. Maintenance records
- iv. Facility inspection records
- v. Employee training records beyond those required by PC§ 4
- vi. Customer complaint records
- vii. Incoming water quality records
- viii. Water treatment and monitoring records
- ix. Equipment calibration records beyond those required by PC§ 165
- x. Temperature control records
- xi. Finished product inspection records
- xii. Microbiological records (environmental, product) beyond those required by the food safety plan
- xiii. Distribution records

X. Foodservice and Retail

Foodservice and retail operators should follow their state and local requirements, which generally require adherence to the [FDA Model Food Code](#). United Fresh and the Food Marketing Institute (FMI) collaborated on a [document summarizing how the Food Code applies to fresh produce operations](#).

XI. References and Additional Resources

- A Notice to Growers, Food Manufacturers, Food Warehouse Managers, and Transporters of Food Products on How to Dispose of Contaminated Food. Updated September 7, 2006. <https://www.fda.gov/Food/RecallsOutbreaksEmergencies/Emergencies/ucm112717.htm>
- Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables. 2008. <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm064458.htm>
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- Suslow, Trevor V. Oxidation-Reduction Potential (ORP) for Water Disinfection Monitoring, Control, and Documentation. Univ. California Publication 8149. <http://postharvest.ucdavis.edu/datastorefiles/234-406.pdf>
- Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain, Edition 2.0. <https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM171708.pdf>
- Code of Federal Regulations. <http://www.gpoaccess.gov/cfr/index.html>
- FDA Produce Safety Rule <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>
- FDA Preventive Controls Rule <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm>

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