

Food Safety Programs and Auditing Protocol for the Fresh Tomato Supply Chain



2011

Repacking and Distribution



Food Safety Programs and Auditing Protocol for the Fresh Tomato Supply Chain, 2011

Forward

Work on *Food Safety Programs and Auditing Protocol for the Fresh Tomato Supply Chain* (“Tomato Food Safety Protocol”) was initiated shortly after the successful completion of the *Commodity Specific Guidelines for the Fresh Tomato Supply Chain, 2nd Edition* (“2nd edition”), at the request of fresh tomato supply chain stakeholders who were concerned that the 2nd edition did not provide sufficiently auditable standards or “metrics”. The general omission of metrics from the 2nd edition was intentional, as the contributors believed that operations should establish food safety requirements for themselves, based on the considerations described in the 2nd edition. Nevertheless, both buyers and suppliers in the tomato supply chain expressed concern that they were unsure of what constituted “compliance”. Buyers were concerned that operations might interpret the considerations in the 2nd edition too loosely, allowing food safety risks to go uncontrolled. Suppliers were concerned that auditor interpretations of the 2nd edition would result in an unending spiral of ever increasing audit expectations, resulting in additional costs without improving food safety. Thus, the Tomato Food Safety Protocol was initiated in October 2008 in an effort to harmonize food safety audit standards for the fresh tomato supply chain.

To prevent the Tomato Food Safety Protocol from becoming just another standard, in addition to rather than replacing others, a critical mass of fresh tomato “buyers” (e.g., processors, foodservice and retail) were asked to participate and, if successful, be prepared to accept audits of their suppliers using this standard. In this way, the goal was ultimately to replace the multitude of similar but different audit standards with this one.

The Tomato Food Safety Protocol was developed during a series of open meetings. Invitations were extended to all participants in the 2nd edition – from industry, government and academia, Mexico and Canada – and additional participants welcomed as they were identified. In an effort to assure transparency, no one who asked to participate was excluded. The individuals and organizations participating in development of the Tomato Food Safety Protocol are listed below.

The Tomato Food Safety Protocol began with the 2nd edition as a basis, endeavoring to establish “requirements” that were as specific as possible, but keeping in consideration different needs based on region, sub-commodity (e.g., round vs. Roma vs. grape or cherry tomatoes), operation size and equivalent growing or handling practices. Every effort was made to base these requirements on current science, but the participants accepted that these requirements would likely change as future research provides better information.

Although the initial intention was to establish mandatory metrics (e.g., how often, how many, how far), the participants were, frankly, surprised to find that current science provided little basis for universal numerical standards. Consequently, requirements more often became performance expectations rather than numerical measurements.

The entire fresh tomato supply chain was considered in this effort, but the participants recognized that the goal of replacing other, existing audit standards with the Tomato Food Safety Protocol would only be successful in operations that are primarily handling tomatoes; e.g., open field operations, harvesting, field packing, greenhouses, packinghouses, tomato repackers, tomato distributors and warehouses. Other operations in the tomato supply chain, i.e., fresh-cut processors, retailers, and foodservice operations, while handling tomatoes, would also be handling a far greater diversity of foods. The participants considered tomato-specific standards for those operations but, since tomato-specific standards would not replace existing audit standards for such operations, ultimately decided not to establish stand-alone audits. Therefore, while the Tomato Food Safety Protocol may be informative to all operations that handle tomatoes, it is specifically targeted to operations that undergo tomato-specific audits.

Format of the Tomato Food Safety Protocol and Checklists and Their Use

Four sets of Tomato Food Safety Protocols were developed for use by operations and auditors: Open Field Production, Harvest and Field Packing; Greenhouse; Packinghouse; and Repacking and Distribution. Each set contains auditable requirements – “Items” – that the participants concluded should be attainable and in place for any North America fresh tomato operation, regardless of region, size, growing practice (e.g., organic) or sub-commodity handled. As appropriate to the type of operation, the Items were further divided into sections that the participants considered critical for a food safety program, such as management responsibility, facility and environmental assessment, raw materials and inputs including water, pest control and pesticide usage, tomato cleaning operations, sanitation, food contact containers, food contact tools and equipment, employee health and hygiene, education and training, and traceback and recall programs.

For each Item, the Tomato Food Safety Protocol contains a simply-stated Requirement, and a Procedure that restates the requirement in other words, in an effort to minimize misunderstanding. The Requirement and Procedure are instructions to the operation to clearly describe the programs that are expected to be in place and maintained, and that will be audited. Each Item also includes a Verification and Corrective Action/Disposition. The Verification is provided as instruction to the auditor how to verify whether the operation has complied with the Requirement. The Corrective Action/Disposition is provided as instruction to the operation if the audit determines that compliance has not been achieved. While each of these is not necessarily binding on the operation or the auditor – equivalent procedures and actions that meet the intent of

the Item are acceptable or, in some cases, not applicable – they are provided in an effort to minimize “standards creep”, which has led to the multitude of disparate and often conflicting standards.

Each of the four Tomato Food Safety Protocols is accompanied by a Checklist, which provides an audit format that auditors can use to assess and record compliance. Each Checklist begins with a cover page that provides information about the auditor, the audited operation and the audit. That is followed by an Audit Summary in which the auditor will indicate the number of Items rated as C, CAN, IAR and NA (see below) as well as listing the Item numbers requiring corrective action; i.e., judged as CAN or IAR. The participants intentionally chose not to “score” the audit, indicating that audit scores tend to distract from auditor observations and judgments.

The body of the Checklist mirrors the associated Tomato Food Safety Protocol, with all of the Items and Requirements listed. The Checklist also includes, for each Item, an opportunity for the auditor to indicate the level of compliance observed. The possible “judgments” were left generally broad and include the following: C, Compliant with requirement; CAN, Corrective Action Needed to be compliant; IAR, Immediate Action Required because of imminent food safety risk; and NA, not applicable or not needed. A judgment of C or NA is self-explanatory. A judgment of CAN, Corrective Action Needed to be compliant, is expected when the operation has clearly not complied with the intent of the Item, but that noncompliance is not reasonably likely to result in a food safety issue. A judgment of IAR, Immediate Action Required because of imminent food safety risk, is expected when a noncompliance may reasonably and directly result in an unacceptable food safety risk, and requires immediate corrective action to prevent the risk from continuing. IAR was not provided as a possible judgment for audit Items that the participants could not conceive of a noncompliance resulting in a food safety risk; e.g., Item 1.5 in the Greenhouse checklist, *Operation has a written procedure and timelines for implementing and documenting corrective actions*. The Checklist also has a space at each Item in which the auditor can provide Comments to explain the judgment. An Auditor Comment is required for all CAN and IAR judgments.

It was the intention in the development of these Tomato Food Safety Protocols for the *Commodity Specific Guidelines for the Fresh Tomato Supply Chain*, 2nd edition, to serve as a prerequisite reference to the use of this document. Each of the four Tomato Food Safety Protocols and their associated Checklists are intended for discrete segments of the fresh tomato supply chain, and it is the responsibility of the user to utilize the appropriate document. Throughout the documents, the term “shall” is used to indicate an action mandatory for compliance, while “should” indicates a recommended action that may not be necessary for some operations. In an operation’s food safety program that is compliant with the Tomato Food Safety Protocol, standard operating procedures (SOPs) may be designed to cover more than one requirement.

Performance of an audit to verify compliance with the Tomato Food Safety Protocol is expected to include reviews of pertinent policies and SOPs, official records demonstrating compliance, and visual observations of the operation to determine the current level of compliance. In order to demonstrate compliance, all required documentation shall be kept on file and made available for review by the auditor. Lot-specific records shall be retained for two (2) years or as required by prevailing laws or regulations. Observation of incomplete or otherwise noncompliant records required for compliance shall require a corrective action, such as retraining of the responsible individuals. The operation shall assess whether the noncompliant records indicate a potential food safety risk. Where training is required, it is expected that employees sign their training records, indicating that they understand and agree to follow the policy or procedure that is the subject of the training. Observations of noncompliances that may result in a risk of contamination of public health concern shall require an immediate corrective action and an assessment of the actual noncompliance and, if contamination is reasonably likely to have occurred, a corrective action shall be taken to prevent the affected product from being harvested or distributed into commerce. Such corrective actions shall be documented and those records shall be available for regulatory review, in compliance with prevailing laws and regulations. It is a violation of federal law (i.e., Federal Food, Drug and Cosmetic Act) to introduce or deliver for introduction into interstate commerce any food that is adulterated or misbranded. Foods, including fresh tomatoes, that are discovered to be adulterated and have been released into commerce should be recalled and the prevailing regulatory authorities notified.

2011 Revision

In late 2010, the tomato industry reconvened to review the performance of the Tomato Food Safety Protocol, and recommended several changes. In this Repacking and Distribution document, the auditor Verification for items 7.2 and 7.4 were clarified and the changed sections are displayed in red. There were no changes to the Checklist that accompanies this document, and so the 2009 Repacking and Distribution Checklist remains current.

Food Safety Programs and Auditing Protocol for the Fresh Tomato Supply Chain, 2011

Repacking and Distribution*

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

1. Management Responsibility				
Item#	Requirement	Procedure	Verification	Corrective Action/ Disposition
1.1	Operation has designated an individual responsible for food safety.	Operation prepares an organizational chart or other documentation that designates the responsible individual. Individual can be a dedicated employee or part-time contracted.	Auditor reviews the organizational chart or other document for the designated food safety individual.	Operation designates who is responsible for food safety. Organizational chart or other documentation is developed or revised.
1.2	Responsible individual has evidence of training in food safety relevant to tomatoes.	The point person for food safety demonstrates knowledge of food safety principles. Food safety designate has completed at least one formal food safety course/workshop or by job experience.	Auditor reviews the evidence of the individual's training relevant to tomato food safety, such as a degree or course certificate or receipt, or attendance at a relevant food safety meeting, or company training record. If the operation passes the food safety audit, then the auditor will judge the food safety individual's training to be adequate.	Individual must obtain demonstrable food safety training.
1.3	Operation has current copies of the <i>Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain, Food Safety Programs and Auditing Protocol for the Fresh Tomato Supply Chain</i> and additional food safety documents as required by state and/or federal regulation.	Operation has a current copy of the Guidelines, this audit document and all other required documents.	Auditor observes the current copies at the operation.	Operation obtains current copies.

1.4	Operation has been registered or permitted as a food handling establishment as required by state or federal regulation.	Operation demonstrates knowledge of prevailing requirements and has a copy of required permit(s) or registration.	Auditor reviews copies at the operation to verify they are current and complete.	Operation applies for or renews required permits or registration.
1.5	Operation has procedures for conducting self-audits, and conducts self-audits to verify compliance with established internal policies and procedures.	Operation has a self-audit procedure and performs documented self-audits, with corrective actions, preventive measures, documentation and follow-up as needed, at a prescribed frequency sufficient to ensure compliance with established internal policies and procedures, the <i>Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain</i> , this audit document and additional food safety documents as required by state and/or federal regulation.	Auditor reviews the self-audit procedures, and records of self-audits to verify compliance with the procedures.	Operation develops and maintains self-audit program, with corrective actions preventive measures, documentation and follow-up.
1.6	Operation has a written procedure and timelines for implementing and documenting corrective actions.	Operation has a written procedure to implement and document corrective actions, including timelines and sign-off by a responsible individual.	Auditor observes that the written procedure includes assignment, timeline and sign-off. Auditor observes evidence that the procedure has been followed.	Operation develops, revises or implements the written procedure.
1.7	Operation has a “zero tolerance” policy for controllable practices and conditions that result in immediate food safety risks.	Policy establishes consequences for employees who violate established policies or procedures, resulting in an immediate food safety risk.	Auditor reviews policy, observes evidence that the policy has been followed, and interviews employees for knowledge of the policy.	Operation develops a written policy and provides training.

2. Packinghouse Condition and Equipment

A. General Building				
Item#	Requirement	Procedure	Verification	Corrective Action/Disposition
2.1	Grounds are reasonably free of litter, debris and standing water.	Operation maintains grounds to prevent accumulation of litter, debris, and other potential sources of contamination or pest attractants. Areas of standing water that may contribute contamination to food by seepage, footborne filth, or providing a breeding place for pests are adequately drained.	Auditor inspects grounds and observes for compliance	Non-compliances are corrected on site. Retraining is performed.
2.2	Facility is constructed/arranged to allow separation of incoming, in-process and finished products.	Facilities or processes assure separation and positioning of incoming raw materials so as not to become a source of contamination of in-process and finished product.	Auditor observes placement of incoming raw materials, in-process and finished products for opportunities for cross-contamination.	Procedures are developed or revised. Non-compliances are corrected on site. Retraining is performed.
2.3	System for removing waste materials from product handling area works efficiently.	Procedures for handling waste materials, from creation to departure from packinghouse property, are sufficient so as not to create a contamination risk.	Auditor observes waste handling procedure and practices.	Procedures are developed or revised. Non-compliances are corrected on site. Retraining is performed.
2.4	Outside garbage receptacles/dumpsters are covered or are located away from facility entrances, and areas around such sites are reasonably clean.	Garbage receptacles are positioned and maintained in a manner so as not to create a contamination risk or pest attraction.	Auditor observes location and condition of garbage receptacles/dumpsters and surrounding area for evidence of contamination risk or pest activity	Procedures are developed or revised. Non-compliances are corrected on site. Retraining is performed.

2.5	Proper maintenance of roof is done.	Roof maintenance is sufficient so as not to create an opportunity for contamination of product.	Auditor visually observes that ceiling is in good condition and that there is no evidence of roof leaks, holes or other damage that may pose a risk of contamination to produce below.	Roof, ceiling and other overhead fixtures are repaired as needed.
2.6	Operation has procedures that minimize the accumulation of standing water.	If floor drains exist, they are adequate, functional, free of obstruction and are properly maintained and cleaned sufficient to prevent them from becoming sources of contamination. If standing water exists, it is removed from floors and floors cleaned in a manner and at a frequency sufficient to prevent creation of a source of contamination.	Auditor observes floor drains and evidence of standing water for compliance with procedures.	Floor drains are installed, repaired or maintained, or procedures are modified, to prevent standing water from becoming a potential source of contamination.
2.7	Floors are in good repair and easily cleaned.	Floor design, construction and maintenance are sufficient so as not to create an opportunity for contamination of product.	Auditor visually observes that floor is in good condition and that there is no evidence of damage that may pose a risk of contamination to produce.	Floor is repaired as needed.
B. Facility and Equipment				
Item#	Requirement	Procedure	Verification	Corrective Action/ Disposition

2.8	All food contact surfaces are made of material and designed to be easily cleaned and sanitized, and are maintained in good condition.	All tomato contact surfaces and equipment are made of materials, designed or constructed to be easily cleaned and sanitized, all food contact surfaces are free of rust or corrosion, and seams between food contact surfaces are smooth or accessible for cleaning.	Auditor observes product contact surfaces and equipment and their use for evidence of non-compliance.	Non-compliances are corrected or replaced. Operation makes a commitment for phasing out non-conforming tomato contact surfaces and equipment, in a reasonable timeline. Retraining is performed.
2.9	Wood is not used as a food contact surface.	Operation has eliminated, or has a plan to eliminate, use of wooden items as food contact surfaces	Auditor inspects facility for evidence of wooden food contact surfaces.	Operation that still utilizes wood as a food contact surface has a plan to phase out such surfaces, and is in compliance with the plan.
2.10	Glass and brittle plastic items are excluded to the extent practical from and/or protected in tomato handling or packing areas. Lights have shatterproof bulbs or covers in all areas where tomatoes or packaging are handled or held.	Written policy minimizes unprotected glass or brittle plastic in all areas where tomatoes are handled or stored. All remaining glass (e.g., glass thermometers) and brittle plastic is listed in a glass and brittle plastic register and is periodically inspected. Written procedure requires investigation of all glass or brittle plastic breakages to ensure potentially adulterated product has been identified and destroyed.	Auditor reviews policy and procedures, visually inspects facility for glass and brittle plastic and its condition, verifies accuracy of glass and brittle plastic register if used, and reviews records of glass and brittle plastic corrective actions.	Policy or procedures are developed or revised. Non-compliances are corrected. Retraining is performed.
2.11	Where workers walk over product contact surfaces, those walkways are protected by kick plates, catch trays, product covers or other barriers.	Catwalks and other walkways that traverse product flow zones are designed and maintained to prevent potential contamination of product.	Auditor observes walkways over product flow zones for compliance.	Walkways are redesigned or repaired to be compliant, removed or replaced.

2.12	Motors and gear boxes above food handling areas have drip pans under them and use food grade lubricants.	Motors, gear boxes and other lubricated equipment in tomato handling or storage areas, that are reasonably likely to drip lubricant which may contact tomatoes or food contact surfaces, shall be fitted with easily accessible and cleanable drip pans or shields so as not to be a source of contaminating product. All such motors will use only food grade lubricants.	Auditor observes motors and gear boxes above tomato handling or storage areas for protection from leakage, evidence of lubricant leakage, and reviews evidence that only food grade lubricants are used for this equipment.	Drip pans or shields are repaired or installed. Procedures are established or reinforced requiring use of food grade lubricants.
2.13	Goods in all storage areas are kept off the floor and away from walls to allow cleaning and inspection for pest activity.	Product shall be palletized to avoid direct contact with the floor. A minimum 18 inch perimeter between pallets and walls shall be maintained to facilitate cleaning, pest control and visual inspection. If a perimeter less than 18 inches is used, facility shall have a written procedure to enable inspection and cleaning behind and between stored materials.	Auditor verifies palletization of stored product, compliance with 18 inch perimeter, or compliance with written procedure.	Procedures are developed or revised. Non-compliances are corrected on site. Retraining is performed.

C. Cooling Systems

Item#	Requirement	Procedure	Verification	Corrective Action/Disposition
2.14	Evaporators, cooling coils, drip pans, drains, drain lines and reservoirs are cleaned and sanitized on a scheduled basis.	Evaporators, cooling coils, drip pans, drains, drain lines and reservoirs are included in Master Cleaning and Sanitation Schedule.	Auditor verifies that cooling system equipment are included in Master Cleaning and Sanitation Schedule.	Operation revises Master Cleaning and Sanitation Schedule.

2.15	Water from refrigeration drip pans is drained and disposed of away from product and product contact surfaces.	Drip pans and drains are designed and maintained to assure condensate does not become a potential source of contamination.	Auditor visually inspects cooling equipment for adequate drainage of condensate.	At risk product is moved until equipment is redesigned or repaired.
2.16	Operation has a program to maintain and monitor temperature in process and storage rooms where temperature control is required.	Facilities have a program to monitor the temperature in temperature-controlled rooms. Temperatures should be monitored to be within facility-specified control ranges at a frequency defined by the operation.	Auditor reviews records to verify that the operation is monitoring temperature according to its program, and verifies that temperature controlled rooms are within the facility-specified temperature ranges at the time of the audit.	Establish monitoring procedures for rooms requiring temperature control.

3. Pest Control

Item#	Requirement	Procedure	Verification	Corrective Action/ Disposition
3.1	Operation has a written pest control program, performed by a trained pest control operator. Pest control operators are licensed where required by prevailing regulation or law.	Operation has a written program covering all locations of the operation where pest activity may pose a contamination risk (e.g., packaging material storage areas), with up to date records. Program activities are performed at prescribed frequency.	Auditor reviews program, records and, where appropriate, copy of operator's license or qualifications. If there is no evidence of pest issues within the facility, auditor shall determine that the pest control program is adequate.	Program is developed or revised. Deficiencies in compliance with program are corrected; retraining is performed.
3.2	There is a clear area surrounding the facility to deter pest infestation.	Perimeter surrounding facility is maintained so as not to provide pest harborage. Operation has a policy regarding outside storage of equipment or other potential pest harborage.	Auditor reviews policy and observes perimeter outside of operation for pest harborages and pest infestation, and compliance with outside storage and perimeter policy.	Policy is developed or revised. Operation removes potential pest harborages. Non-compliances are corrected on site. Retraining is performed.

3.3	There is no evidence of significant pest populations (birds, rodents, insects) reasonably likely to contaminate tomatoes.	Operation monitors on ongoing basis for presence of pests that may pose contamination risks.	Auditor observes facility and surrounding areas for significant pest populations and potential for product contamination.	Operation removes problem and establishes procedures to prevent recurrence or minimize risk.
3.4	There are no bait stations containing toxic baits inside the facility.	Bait stations containing toxic baits shall all be outside packinghouse facilities and located where they are not reasonably likely to contaminate products or equipment.	Auditor verifies that bait stations are located and maintained in compliance with pest control program.	Program is developed or revised. Non-compliances are corrected on site. Retraining is performed.
3.5	Traps do not contain toxic bait and are placed at the interval and location recommended by the pest control operator. Traps must be labeled with a number or other identifier and their locations are documented on a map.	Only non-toxic baits are permitted in traps inside facilities. Trap intervals are defined in pest control program, and locations are identified on a facility map.	Auditor observes facilities for proper type, location and maintenance of traps, and evidence of pest control.	Program is developed or revised. Non-compliances are corrected on site. Retraining is performed.
3.6	Bug zappers and insect attractant devices, if used, are not placed in a location where product or food handling equipment or food packaging materials may become adulterated.	Insect electrocuters or attractants that may disperse insect fragments are not permitted in tomato handling areas. This restriction does not apply to glue boards or other instruments that do not disperse insect fragments.	Auditor observes location of insect control devices for compliance with pest control program and the potential to contaminate product.	Program is developed or revised. Non-compliances are corrected on site. Retraining is performed.

3.7	Operation has a written policy prohibiting domestic animals in the packinghouse.	There is no evidence of domestic animals in the packing facility.	Auditor observes operation for evidence of non-compliance.	Policy is developed or revised. Non-compliances are corrected on site. Retraining is performed.
4. General Sanitation				
Item#	Requirement	Procedure	Verification	Corrective Action/Disposition
4.1	A Master Cleaning and Sanitation Schedule for the facility is in place for daily, weekly, monthly and seasonal/yearly cleaning and maintenance tasks including all areas.	Operation develops, maintains and follows a prescribed schedule for all facility and equipment maintenance, cleaning and sanitizing activities. The Master Cleaning and Sanitation Schedule should include activities performed by third parties. A written cleaning crew checklist is current for the facility. Records demonstrating compliance are maintained.	Auditor reviews schedule for completeness, reviews records for compliance, and visually observes facility and equipment for adequacy of activities.	Schedule is developed or revised. Non-compliances are corrected on site. Retraining is performed.
4.2	All compounds used to clean and sanitize finished product containers, food contact surfaces, or food contact tools are approved for that use by the US EPA, FDA or appropriate agency and used according to label instructions.	Operation maintains labels for all cleaning and sanitation compounds. Procedures require use of compounds in accordance with label instructions.	Auditor reviews procedures and labels, and observes use of compounds for compliance.	Non-compliances are corrected on site. Unapproved cleaning compounds are removed from use and replaced with approved compounds. If unapproved compounds are used, operation shall assess potential for product adulteration. Procedures are developed or revised. Retraining is performed.
4.3	All chemicals, cleaning compounds and solvents are stored in a secure and locked location.	Operation has a written policy for the storage and security of cleaning compounds and solvents.	Auditor reviews policy, observes the storage area and production area for evidence of compliance.	Policy is developed or revised. Secure, locked storage area is designated. Non-compliances are corrected on site. Retraining is performed.

4.4	There are written cleaning and sanitation procedures for all food contact surfaces (SSOPs).	Operation has written SSOPs for all food contact equipment, utensils and other surfaces. SSOPs shall include chemicals approved for use and concentrations for use; frequencies; instructions for cleaning, sanitizing and, where necessary, rinsing; what records are required; verification procedures (e.g., visual, ATP, microbial); acceptance criteria; and responsibilities.	Auditor reviews SSOPs for completeness, interviews responsible employees for knowledge, and reviews records for compliance with SSOPs.	Procedures are developed or revised. Non-compliances are corrected on site. Retraining is performed.
4.5	There are written cleaning and, if required, sanitizing procedures for all non-food contact surfaces and areas of the facility including floors, drains, walls, ceilings and other surfaces that may pose a source of product contamination.	Operation has written cleaning SOPs for all non-food contact equipment, utensils and other surfaces in all production and storage areas, including loading docks and ripening rooms. Procedures shall include chemicals approved for use and concentrations for use; frequencies; instructions for cleaning; what records are required; acceptance criteria; and responsibilities.	Auditor reviews SOPs for completeness, interviews responsible employees for knowledge, and reviews records for compliance with SOPs.	Procedures are developed or revised. Non-compliances are corrected on site. Retraining is performed.
4.6	Cleaning equipment and tools are clean, in working order and stored properly away from food handling areas.	Operation has procedure for maintenance and storage of cleaning equipment and tools, including materials used to clean tomatoes. Storage area is segregated from food handling areas and food contact surfaces.	Auditor reviews procedures and observes cleaning equipment and tools, and storage area, for compliance with procedures.	Procedures are developed or revised. Non-compliances are corrected on site. Retraining is performed.

5. Raw Material Sourcing

Item#	Requirement	Procedure	Verification	Corrective Action/ Disposition
5.1	Operation has an Approved Supplier program for all incoming materials, including packaging.	Operation has and maintains a current list of approved raw material suppliers. Approved Supplier program includes a procedure for accepting materials from alternate sources.	Auditor verifies a list of raw material suppliers is maintained and current. Auditor verifies that all materials received from alternate sources has followed established procedure.	Operation develops an Approved Supplier program and maintains current list. Operation develops a procedure for accepting materials from alternate sources. Operation ceases accepting or shipping materials from non-compliant suppliers.
5.2	The operation has a policy and takes affirmative steps to ensure that all fresh tomatoes that are packed or stored in the facility are grown following requirements in <i>Tomato Metrics Audit - Open Field Production, Harvest and Field Packing</i> .	The packinghouse requires all raw product suppliers to provide evidence of food safety/GAP programs and compliance. Such evidence must include sufficient documentation to demonstrate that the supplier complies with the requirements in <i>Tomato Metrics Audit - Open Field Production, Harvest and Field Packing</i> .	Auditor reviews policy and verifies that operation's evidence of supplier compliance with food safety/GAP programs is in compliance with the operation's policy.	Operation obtains required documentation. Operation ceases accepting or shipping product from non-approved suppliers, until sufficient documentation demonstrating compliance is received by the operation.
5.3	Operation has procedures to ensure that the tomato staging area and staging practices do not pose a risk of tomato contamination.	The packinghouse staging area is designed so that overhead areas do not pose a contamination risk of uncovered tomatoes, or that tomatoes are protected during staging to prevent contamination.	Auditor reviews procedures and inspects staging area for potential sources of contamination.	Operation develops procedures and/or redesigns staging area or staging practices to prevent reasonably likely to occur opportunities for contamination. Tomatoes that have become contaminated are discarded.

6. Produce Containers and Packaging Materials

Item#	Requirement	Procedure	Verification	Corrective Action/ Disposition
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6.1	Tomato-contact bulk bins, gondolas, totes and trays shall be constructed of impervious materials that can be easily cleaned and sanitized.	Written SOP requires that all food contact containers are made of materials that can be sanitized, or clean and sanitary liners are used. Wood is not an appropriate food contact surface. Procedures require damaged containers that are no longer easily cleanable or sanitary shall be removed from service of food contact purposes.	Auditor reviews SOP, visually observes product bins, trays and containers and their use for evidence of non-compliance.	Policy is developed or revised. Non-compliances are corrected. Operation removes non-conforming product containers from food contact purposes. Retraining is performed. Operation develops a plan to phase out wooden bins, and demonstrates compliance with the plan.
6.2	Bulk bins, gondolas, totes and trays are stored and maintained in designated locations.	Locations are designated for bins, totes and trays to be staged and stored in a manner to minimize contamination and opportunity for pest harborage. Procedures are in place to inspect and clean and make sanitary bins, totes or trays, if contamination is observed.	Auditor observes locations for staging and storing of bins, totes and trays for compliance and evidence of overt contamination or pest activity.	Re-evaluate designated storage location to minimize contamination. Bins, totes and trays not in designated area are moved to designated area. Bins, totes and trays reasonably concluded to be contaminated are cleaned and made sanitary before use.
6.3	The operation has written procedures for cleaning and sanitizing of produce food contact containers, requiring that bulk bins, gondolas, totes and trays are cleaned and sanitized periodically and is documented.	Written SOP is established to ensure that bulk bins, gondolas, totes, trays and other food contact containers and implements are adequately cleaned and sanitized at a frequency sufficient to maintain clean and sanitary food contact surfaces, and documentation of compliance is maintained.	Auditor reviews SOP, cleaning logs and records, interviews responsible individuals for knowledge of the SOP and observes containers, employees and records for evidence of compliance.	Policy is developed or revised. Non-compliances are corrected on site. Retraining is performed.

6.4	Bins, totes and cartons intended for product are not used for any other purposes.	A system shall be in place to clearly identify bins, totes and containers to their intended use. Bins, totes and containers intended for product contact shall be used only for that purpose. Bins, totes and containers used for alternate purposes are clearly identified and not used for product contact.	Auditor visually observes bins, totes and containers for evidence of non-compliance.	Use bins, totes and containers only for appropriate uses. Re-evaluate use identification procedure. Retraining is performed. Bins, totes and containers used inappropriately are identified for non-product use, or are cleaned and made sanitary before use, as appropriate.
6.5	Packaging materials and finished product containers are stored in a clean and orderly manner and prohibited from direct contact with the floor. Pallets, slip sheets, and supports used to keep product containers off the floor are clean and in good condition.	Locations are designated for packaging materials to be staged and stored in a manner to prevent contamination and opportunity for pest harborage. Operation has a policy prohibiting finished product containers in direct contact with the floor, and that pallets, slip sheets, and supports used to keep product containers off the floor are maintained so as not to be a source of contamination.	Auditor reviews policy and examines staging and storage areas for compliance with the policy. Auditor observes areas for evidence of overt contamination or pest activity.	Operation creates or revises policy. Re-evaluate designated storage location to prevent contamination. Packaging materials not in designated area are moved to designated area. Packaging materials reasonably concluded to be contaminated are discarded. Non-compliances are corrected on site. Retraining is performed.

7. Primary Packaging Boxes

Item#	Requirement	Procedure	Verification	Corrective Action/ Disposition
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7.1	The repacker must label the container as being repacked. The box contains information on the commodity, repacker identification and provides lot identification.	Operation shall ensure that all product containers containing repacked tomatoes are labeled as repacked. The container shall also include the commodity, repacker identification, and repacker lot identification.	Auditor observes repacked product boxes for compliance.	Procedure is developed or revised. Retraining is performed.
7.2	Operation has a process to ensure that inaccurate information on previously used boxes is obliterated, or otherwise made clear that original information no longer applies, to prevent misidentification.	Boxes shall not be reused if prohibited by prevailing regulation or law.	Auditor observes one or more repacked lots and repacking documentation for those lots using reused cartons to verify that only the cartons from the original lot(s) are used to repack reworked tomatoes and a positive effort has been made to obliterate (mark out by any means) inaccurate information; OR a label that clearly states the information on the box is no longer valid has been affixed and has the proper lot information on the label.	Operation ceases using boxes inappropriately. Procedure is developed or revised. Retraining is performed.
7.3	Primary packaging boxes are clean and sanitary.	Operation has a box inspection process to prohibit packing into any visibly wet, stained or dirty boxes.	Auditor reviews box inspection process and observes boxes in use for evidence of compliance.	Operation ceases using visibly wet, stained or dirty boxes. Procedure is developed or revised. Retraining is performed.

7.4	Used boxes may be used as secondary shipping containers, provided that the original identification information on the box has been obliterated or otherwise made clear that it is no longer accurate.	Operation may reuse tomato boxes as secondary (no product contact) shipping containers. Operation has a process to ensure that inaccurate information is obliterated, or otherwise made clear that original information no longer applies, to prevent misidentification.	If used boxes are used as secondary shipping containers, auditor observes one or more repacked lots and repacking documentation for those lots using reused cartons to verify that a positive effort has been made to obliterate (mark out by any means) inaccurate information; OR a label that clearly states the information on the box is no longer valid has been affixed and has the proper lot information on the label.	Operation relabels mislabeled boxes. Procedure is developed or revised. Retraining is performed.
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8. Produce Cleaning and Produce Wash Water

A. Cleaning Materials Including Cloths

Item#	Requirement	Procedure	Verification	Corrective Action/Disposition
8.1	Operation shall have a policy that cloths, towels, or other cleaning materials shall not be used to wipe tomatoes.	Employees are trained that wiping tomatoes with cloths or other multiple use materials may pose a risk of cross-contamination and are prohibited.	Auditor reviews policy, interviews employees for knowledge of the policy and observes harvest area and employees for evidence of non-compliance.	Policy is developed or revised. Non-compliances are corrected on-site. Retraining is performed.

B. Debris Removal and Removal of Injured Tomatoes

Item#	Requirement	Procedure	Verification	Corrective Action/Disposition
8.2	Debris is not allowed to collect in wash areas/dump tanks.	Wash areas/dump tanks are equipped (e.g., screens, chains, designated personnel) to remove debris to the extent practical.	Auditor observes wash areas/dump tanks for debris removal procedure or equipment and effectiveness.	Operation retrofits or replaces equipment or procedure to improve debris removal.

8.3	Damaged tomatoes are removed to the degree possible.	Operation has a culling operation to remove damaged and decayed tomatoes to the extent practical. Workers are instructed about the importance to recognize and remove damaged or decayed tomatoes.	Auditor observes the culling process, inspects for effectiveness of process to remove damaged and decayed tomatoes, and interviews employees for knowledge of the importance of culling.	Operation takes steps to improve effectiveness of the culling operation. Retraining is performed.
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C. Water Quality Management

Item#	Requirement	Procedure	Verification	Corrective Action/Disposition
8.4	Only water that meets the microbial standards for potable water is used in the packinghouse for handwashing, food or food contact surface use.	Water used for handwashing or to contact food or food contact surfaces is from a source known to meet the microbial standards for potable water. Documentation of test results, demonstrating the water source meets the microbial standards for potable water, is available for review. One sample per water source shall be tested at the closest practical point of use, at a minimum according to the relative risk of the water source; e.g., annual testing of municipal water, wells and other sources that historically have demonstrated compliance with the microbial standard; monthly testing of treated surface water or sources that historically have demonstrated non-compliance with the microbial standard.	Auditor verifies that all water that may be used for handwashing or to contact food and food contact surfaces is from an appropriate source. Auditor reviews documentation of test results.	Operation performs testing or obtains documentation of test results. If water does not meet standards, cease using the water source until corrected and confirmed by testing.

8.5	Cross connections between water that may contact food and food contact surfaces and non-potable water systems are prohibited.	Plumbing schematics are maintained and available for review. Water lines that carry water that does not meet the microbial standards for potable water are clearly identified. Water system that carries water that may contact food and food contact surfaces is designed and installed without direct connection to non-potable water systems.	Auditor inspects water lines for cross connections.	Unused piping and prohibited cross connections are removed.
8.6	All water lines are protected against back flow siphonage.	All water lines susceptible to contamination from back flow are equipped or designed with back flow prevention. Employees are trained to avoid practices that may result in back flow (e.g., proper use of hoses).	Auditor inspects water lines for back flow prevention devices and practices, and inspects records of device functionality.	Water lines are redesigned or retrofitted with back flow prevention. Retraining is performed.
8.7	All water lines and fixtures are in proper repair.	Water lines, particularly waste water, are maintained so as not to become a source of contamination	Auditor observes water lines for evidence of leaks or conditions that may pose a potential source of contamination.	Leaks are repaired. Potential contamination risks are evaluated and corrective actions are implemented as necessary.

D. Product Wash Water Management

Item#	Requirement	Procedure	Verification	Corrective Action/Disposition
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8.8	Only sanitizers or sanitizer systems registered or approved by EPA or the prevailing regulatory agency for their specific intended use may be used in the dump tank wash water, on the spray line or other food contact purposes.	Operation maintains a current list of approved products (e.g., sanitizers, acids, surfactants) that may contact tomatoes and are approved for food contact use in the facility.	Auditor reviews chemical list and observes inventory of water treatment chemicals for compliance. Auditor reviews labels or other manufacturer documents that demonstrate sanitizers being used are registered for the specific intended use.	Non-compliances are corrected on site. Unapproved chemicals are removed from use and replaced with approved chemicals. Procedures are developed or revised. Retraining is performed. If unapproved chemicals are used, or approved chemicals are used in an unapproved manner, operation shall assess potential for product adulteration. Tomatoes that have contacted sanitizer used in an unapproved manner are adulterated.
8.9	Wash water sanitizer, used in dump, flume or other multi-pass wash system, is used in accordance with operational procedure, manufacturer instructions, and regulatory requirements. Records are kept.	Operation shall have a procedure that includes minimum limits for sanitizer in wash water for food safety. Non-recirculating spray systems do not require sanitizer for food safety. Procedure shall include how to control, monitor and record use of wash water sanitizer as needed to assure continuous compliance with minimum limits. Operation shall have a procedure as to what corrective actions are taken if criteria are not met.	Auditor shall review the procedure and shall review records of sanitizer use, verification of treatment levels and monitoring records. Auditor reviews records for deviations and their disposition.	Procedure is developed or revised. Retraining is performed. Tomatoes exposed to sanitizer in excess of label limits are treated by an approved method to bring tomatoes into compliance or are discarded. Tomatoes exposed to sanitizer below established minimum limits shall be discarded back to the last evidence of compliance.

8.10	<p>In systems where tomatoes are submerged or dwell in water, water temperature is monitored and controlled. Water temperature should be at least 10°F above highest measured pulp temperature of tomatoes when entering the water. If operation can demonstrate retention times are never more than two minutes and water submersion does not exceed 1 ft, water temperature shall be controlled to be not less than highest measured pulp temperature.</p>	<p>Operation shall have methods for determining pulp temperature, a procedure for control of water temperature, shall monitor temperature at a prescribed frequency sufficient to assure continuous compliance and shall maintain records of water temperature. If water is maintained at less than 10°F above pulp temperatures, the operation shall maintain records substantiating that dwell time and depth standards have been met, and tomatoes have not been washed in water at temperatures less than the highest measured pulp temperature. Operation shall have a procedure as to what corrective actions are taken if criteria are not met. Water spray or shower systems, wherein tomatoes are not submerged or dwell do not require temperature control.</p>	<p>Auditor shall review the procedure and shall review records of temperature monitoring. Auditor observes process including the operation's sampling of pulp and water temperatures. Auditor reviews records for deviations and their disposition.</p>	<p>Procedure is developed or revised. Retraining is performed. Tomatoes washed in water at temperatures less than the highest measured pulp temperature shall be discarded back to the last evidence of compliance.</p>
8.11	<p>Operations utilizing spray systems in place of whole tomato immersion shall design the line so that the entire tomato surface is rinsed.</p>	<p>Spray systems shall be designed such that rinse water contacts all surfaces of the tomato.</p>	<p>Auditor observes spray system for compliance.</p>	<p>Equipment or process is redesigned or retrofitted to ensure all surfaces of tomato are contacted.</p>

8.12	Re-circulated and re-used water is changed at least daily, and records of changes are kept.	Operation shall maintain records to demonstrate water changes. Water may be used for longer than daily if a validated regeneration system (e.g., a water pasteurization/ filtration system) is being used.	Auditor reviews records to verify at least daily changes of all wash water.	Procedure is developed or revised. Retraining is performed.
8.13	If water quality is based upon a chlorine-based sanitizer and Oxidation Reduction Potential (ORP), the process shall be targeted to be at least 800 mV. ORP levels shall not be less than 650 mV, measured at the exit of the product from the water system, unless validation data are available to demonstrate a lower ORP is effective under operating conditions.	Operation shall have a procedure to manage ORP levels, shall establish process adjustments for when the ORP drops below 800 mV, and shall maintain records to verify proper management of levels.	Auditor shall review the procedure and shall review records of ORP measurement and appropriate management. Auditor reviews records for deviations and their disposition.	Procedure is developed or revised. Retraining is performed. Tomatoes washed in water at ORP less than 650 mV shall be discarded back to the last evidence of compliance.
8.14	If an ORP system is used, an independent measurement is used to verify compliance.	Operation shall have a procedure and shall maintain records to measure ORP by a secondary method to ensure primary measurement is accurate.	Auditor shall review the procedure and shall review records of secondary ORP measurement.	Procedure is developed or revised. Retraining is performed.

8.15	If water quality is based upon an aqueous chlorine dioxide sanitizer, chlorine dioxide levels shall not be less than 1 ppm, measured at the exit of the product from the water system, unless validation data are available to demonstrate a lower level is effective under operating conditions.	Operation shall have a procedure to manage aqueous chlorine dioxide levels, shall establish process targets so as not to drop below the minimum ppm, shall establish adjustments for when the chlorine dioxide drops below the target ppm, and shall maintain records to verify proper management of levels.	Auditor shall review the procedure and shall review records of aqueous chlorine dioxide measurement and appropriate management. Auditor reviews records for deviations and their disposition.	Procedure is developed or revised. Retraining is performed. Tomatoes washed in water at less than 1 ppm aqueous chlorine dioxide shall be discarded back to the last evidence of compliance.
8.16	If water quality is based upon a peroxyacetic, peracetic or peracid system, levels shall not be less than 30 ppm, measured at the exit of the product from the water system, unless validation data are available to demonstrate a lower level is effective under operating conditions.	Operation shall have a procedure to manage peracid levels, shall establish process targets so as not to drop below the minimum ppm, shall establish adjustments for when the peracid level drops below the target ppm, and shall maintain records to verify proper management of levels.	Auditor shall review the procedure and shall review records of peracetic measurement and appropriate management. Auditor reviews records for deviations and their disposition.	Procedure is developed or revised. Retraining is performed. Tomatoes washed in water at less than 30 ppm peracetic shall be discarded back to the last evidence of compliance.

8.17	If a sanitizer system other than aqueous chlorine dioxide, peracid, or hypochlorous and ORP is used, the system shall be operated and controlled to levels of equivalent efficacy of pathogen cross-contamination control in tomato wash systems.	Operation shall have a procedure to manage sanitizer levels, shall have established target and minimum levels, shall establish process adjustments for when the sanitizer level drops below target level, shall establish procedures to independently verify measurements of sanitizer and shall maintain records to verify proper management of levels.	Auditor shall review the procedure and shall review records of sanitizer measurement and appropriate management. Auditor reviews records for deviations and their disposition.	Procedure is developed or revised. Retraining is performed. Tomatoes washed in water at sanitizer levels less than established minimum shall be discarded back to the last evidence of compliance.
8.18	All instruments used to measure temperature, pH, sanitizer levels and or other important devices used to monitor requirements in this section shall be calibrated at a frequency sufficient to assure continuous accuracy.	Operation has procedures to calibrate thermometers and other measuring devices at the manufacturer's recommended frequency, or more often as needed. Operation shall maintain records of all calibrations.	Auditor shall review the procedure and the records of calibration of each device used in monitoring the system. Auditor verifies that measuring instruments in use are within established calibration period.	Procedure is developed or revised. Retraining is performed. Instruments out of calibration shall be recalibrated or replaced. Tomatoes handled while instruments are out of calibration shall be assessed for food safety risk and dispositioned appropriately.
8.19	Instruments, test methods or test strips used to monitor requirements shall be appropriate to their use and sufficiently sensitive to their intended purpose.	Operation shall use appropriate instruments or test methods to monitor or verify sanitizer concentration, pH and other analytical measurements as required in this section. Test strips shall have sufficient resolution relative to the operating and corrective action limits to assure accurate determination of compliance.	Auditor shall reviews methods for the use of instruments, test methods and test strips and interviews employees using these instruments, methods and test strips to verify knowledge of their use. Auditor verifies test strips have not exceeded their expiration date.	Procedures are developed or revised. Appropriate analytical tools are obtained. Retraining is performed. Tomatoes handled while instruments have not been used appropriately shall be assessed for food safety risk and dispositioned appropriately.

9. Facility Supplies and Equipment

Item#	Requirement	Procedure	Verification	Corrective Action/ Disposition
9.1	MSDS are on file for all chemicals used in the facility, and readily accessible.	Operation maintains a list of all chemicals approved for use in facility, and maintains MSDS for all. MSDS are in a location easily accessible by employees.	Auditor reviews MSDS binder and observes chemicals in facility for evidence of compliance.	Obtain missing MSDS. Relocate MSDS.
9.2	All waxes, coatings and other chemicals applied to product are approved by the US EPA, FDA or prevailing authority for their designated use and used according to label instructions.	Operation maintains a current list of approved products and their intended application.	Auditor reviews chemical list and observes inventory of waxes, coatings and other food contact chemicals for compliance.	Non-compliances are corrected on site. Unapproved compounds are removed from use and replaced with approved compounds. If unapproved compounds are used, operation shall assess potential for product adulteration. Procedures are developed or revised. Retraining is performed.

10. Quarantine or On-hold Materials

Item#	Requirement	Procedure	Verification	Corrective Action/ Disposition
10.1	Materials placed on hold, quarantined or rejected are clearly identified and segregated from other products and packaging materials.	Operation has a written procedure to clearly identify and segregate on-hold, quarantined and rejected materials, to prevent commingling with other products or adulteration of products, production area or packaging materials.	Auditor reviews procedure, reviews logs and observes all currently on-hold, quarantined and rejected materials for compliance with procedure.	Non-compliances are corrected on site. If on-hold, quarantined or rejected materials are not segregated according to procedure, operation shall assess potential for product adulteration. Procedures are developed or revised. Retraining is performed.

11. Transportation

Item#	Requirement	Procedure	Verification	Corrective Action/ Disposition
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11.1	Shipping unit is clean, functional and free of objectionable odors before loading. A responsible individual signs the completed checklist.	Operation has a procedure and checklist to verify cleanliness and functionality of shipping units (e.g., trailer). The procedure requires that personnel responsible for loading and unloading of produce inspect the vehicle before loading and after unloading for cleanliness, odors, obvious dirt, debris, fecal material or pest activity that may serve as a source of microbial contamination. Results of these inspections, and any corrective actions, are documented.	Auditor reviews procedure, past and current records for evidence of compliance, and observes performance of shipping unit inspection.	Procedures are developed or revised. Retraining is performed.
11.2	Vehicles and containers used to transport produce shall not be used to transport trash, animal carcasses or raw animal products that may be a source of microbial contamination unless cleaned and sanitized by a procedure sufficient to ensure that microbial contamination of produce does not occur.	Checklist includes prohibition of animal or animal product transport, or other materials that may be a source of contamination with pathogens. Unless dedicated vehicles are used, procedure requires transport history for immediate past 3 loads, or that trailer must first be cleaned and sanitized and accompanied by a wash ticket.	Auditor reviews checklist and recent shipping records for evidence of compliance.	Procedures are developed or revised. Retraining is performed.

12. Employee Hygiene

A. Toilet Facilities

Item#	Requirement	Procedure	Verification	Corrective Action/ Disposition
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12.1	Clean and sanitary toilet facilities are provided for all employees and toilets are made from cleanable materials and are cleaned and sanitized daily or sufficiently often to be maintained in a clean and sanitary manner.	Written SOPs and logs that the sanitary facilities are maintained at a frequency appropriate to the operation and the level of use. Records shall provide sufficient information to document that the SOP is being followed, including the recent dates of service.	Auditor reviews service records for compliance with the SOP and visually observes the condition of the facilities.	Non-compliances are corrected on site. Operation develops a written procedure and provides training.
12.2	The number of toilet facilities meets state and federal requirements.	The operation will have verification that the number of toilet facilities meets the more stringent federal or state regulations. The relevant OSHA regulation: 29 CFR part 1928.110, specifies one gender-specific toilet facility per 20 employees	Auditor verifies that the number of available toilet facilities is compliant for the number of employees.	Operation obtains a sufficient number of toilet facilities to be compliant.
12.3	Toilets are located within a five minute walk of work areas.	Toilet facilities shall be easily accessible.	Auditor visually verifies that the toilet facilities are located at an appropriate distance from employees.	Toilet facilities shall be moved to a compliant location.
12.4	All toilet facilities contain toilet paper.	Toilet facilities shall be stocked with toilet paper, positioned and stored in a sanitary manner. Toilet facility servicing shall be sufficiently frequent to assure compliance.	Auditor verifies toilet facilities are equipped with toilet paper positioned in a compliant manner.	Responsible party restocks the toilet facility with toilet paper.
12.5	There is a program for the sanitary disposal of used toilet paper.	Training programs shall include procedures for sanitary disposal of used toilet paper, in a manner compliant with prevailing standards.	Auditor verifies the training program and observes the toilet facilities for evidence of non-compliance.	Non-compliances are corrected on site. Retraining is performed.

12.6	Hand washing facilities, with soap, water and disposable hand-drying towels, or air blowers, and refuse containers are provided.	Hand washing facilities must be sufficient in number so as not to be limiting for the number of employees, easily accessible and adequately stocked. Water for handwashing shall meet the microbial standard for potable water (including hot water where available). Refuse receptacles are constructed and maintained in a manner that protects against contamination of tomatoes.	Auditor visually observes the hand washing facilities for compliance.	Restock and maintain, or provide, to compliance.
12.7	If permanent handwashing facilities are not used, gray water is captured and disposed of away from the packing area..	Waste water from hand washing facilities shall be captured and disposed in a manner so as not to become a source of contamination.	Auditor visually verifies that hand washing facilities have adequate mechanism for capture and disposal.	Hand washing facility shall be repaired, redesigned or replaced to compliance.
12.8	If portable hand wash water tanks are used, they are cleaned and sanitized and the water is changed periodically.	Water tanks used to provide hand wash water shall be maintained at a prescribed frequency in a clean and sanitary manner.	Auditor reviews cleaning and sanitizing protocol and service logs, and visually observes condition of water tanks for signs of non-compliance.	Clean and sanitize the tank, replace water to compliance.
12.9	The source of water used to fill hand washing tanks meets the microbial standard for potable water and is documented.	Water used for hand washing tanks is from a source that meets microbial standards for potable water (40 CFR Part 141.63), or has been treated to be compliant. Documentation of the quality of the source is maintained.	Auditor reviews documentation of water quality.	Replace water source or treat to achieve compliance. Obtain documentation demonstrating compliance.

12.10	Toilet and hand washing facilities are inspected by a designated individual at a sufficient frequency during use to assure cleanliness, condition and adequate supplies.	The operation designates a trained individual to routinely inspect the toilet and hand washing facilities for compliance. Records are maintained.	Auditor reviews inspection records and interviews the designated individuals for knowledge.	Retrain or replace the designated individuals.
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B. First Aid Policies

Item#	Requirement	Procedure	Verification	Corrective Action/Disposition
12.11	There is a written policy describing procedures which specify handling/disposition of produce or treatment of food contact surfaces that have come into contact with blood or other bodily fluids.	A written policy or procedure shall require designation and disposal of any produce and cleaning/sanitization of food contact surfaces that may have come into contact with blood or other bodily fluids.	Auditor verifies existence of the policy and interviews the responsible person for knowledge.	Operation prepares or edits the policy. Retrain or replace the responsible person.
12.12	There is a written policy instructing workers to seek prompt treatment for cuts, abrasions and other injuries and first aid supplies are provided.	Written policies and training programs shall require employees to report and seek treatment for cuts, abrasions and other injuries. Operation shall have and provide adequate first aid supplies.	Auditor verifies existence of the policy, training program and observes the first aid supplies. Auditor questions employees for knowledge of policy and observes employees for evidence of non-compliance.	Policy or training program is developed or revised. Non-compliances are corrected on site. Retraining is performed.

C. Habits and Conditions

Item#	Requirement	Procedure	Verification	Corrective Action/Disposition
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12.13	There is a written Hygiene Practices policy including, but not limited to, policies and procedures on hand washing, toilet use, and requiring handwashing at beginning of shift and prior to returning to production line, for all employees and visitors.	A written Hygiene Practices policy shall apply to employees, outside contractors, inspectors, and visitors.	Auditor verifies existence of the policy, questions employees for knowledge of policy, and observes employees and visitors for evidence of non-compliance.	Policy or training program is developed or revised. Non-compliances are corrected on site. Retraining is performed.
12.14	Policies shall require hand washing with soap and potable water at the appropriate time, such as before starting work, after use of toilet facilities, after breaks and when hands may have become contaminated. Policy shall apply to employees, outside contractors, inspectors, and visitors. Compliance is emphasized by management.	Operation shall have a written SOP regarding hand washing practices. Operation management reinforces importance of and compliance with handwashing policy. Sanitizers may not be used in lieu of soap and water hand washing, but may be used to supplement. If gloves are used when contacting tomatoes or food contact surfaces, policies will clearly communicate that gloves are not a replacement for good handwashing practices.	Auditor observes handwashing practices of employees and visitors for compliance. If handwashing practices are observed to be compliant, auditor will judge management emphasis to be sufficient.	SOP is developed or revised. Retraining is performed. Management increases frequency of or approach to reinforcing hand washing policy.
12.15	There are signs, either in the appropriate language or pictorially, reminding workers to wash their hands after using the toilet.	Easily understandable hand washing signs are posted near all handwashing and toilet facilities.	Auditor visually verifies placement and content of signs.	Appropriate signage is posted.

12.16	If gloves are used, there must be a written SOP regarding their use.	If gloves are used for product or food contact purposes, operation shall have a written policy and SOP regarding their use, maintenance and disposal, including cleaning of reusable gloves, not taking gloves into restrooms or eating areas, replacing gloves that may be damaged or have become a source of contamination. The SOP should also address limitations of use of non-sanitary gloves (i.e., work gloves). The SOP will require that reusable gloves shall not be taken home by workers for cleaning and sanitizing, and the operation shall be responsible to ensure that reusable gloves are washed in water over 140°F and sanitized daily by a validated procedure.	If gloves are used, auditor reviews the SOP, records of SOP performance, and visually verifies that glove use is consistent with the SOP; i.e., gloves at the beginning of tomato handling activities are clean and not damaged; workers are observed to not take gloves into restrooms or eating areas; and that gloves are not taken into restrooms or eating areas.	SOP is developed or revised. Non-compliances are corrected on site. Retraining is performed.
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12.17	SOPs establishing the operation's illness policy provide that workers who show signs of illness (vomiting, jaundice, diarrhea) or open or exposed sores or lesions on their hands are not permitted to perform job duties where they will come in direct contact with raw product or food contact surfaces.	SOPs and documented employee training at least annually to report any active case of illness that may be transmissible by food, open sores or lesions to their supervisor, and that such employees are not permitted to work directly with food or food contact surfaces.	Auditor reviews the policy, reviews training records, interviews employees for knowledge of the policy and observes employees for evidence of non-compliance.	The policy and training are created or amended to be compliant. Retraining is performed and documented.
12.18	There is a written policy regarding the use of hair restraints.	Policy exists regarding the use of hair restraints by all employees and visitors in packinghouse. Operation provides hair restraints to all employees and visitors, as appropriate to policy.	Auditor reviews policy and visually observes compliance.	Policy is developed or revised. Non-compliances are corrected on site. Retraining is performed.
12.19	There is a written policy regarding jewelry, nail polish and false nails in the workplace.	Operation has a policy on acceptable and prohibited jewelry in the packinghouse. The policy shall restrict use of nail polish or false nails,	Auditor reviews policy and visually observes compliance.	Policy is developed or revised. Non-compliances are corrected on site. Retraining is performed.
12.20	Food and tobacco products are only in designated areas as specified in company SOP.	Operation has a written policy prohibiting food and tobacco products except in designated areas.	Auditor verifies existence of the policy, questions employees for knowledge of policy, and observes employees and visitors for evidence of non-compliance.	Policy or training program is developed or revised. Non-compliances are corrected on site. Retraining is performed.

12.21	Drinking water shall be provided in fountains or single use containers. Drinking water containers shall be handled in a manner that prevents them from becoming sources of contamination.	Operation has a written policy regarding drinking water, and water cups, containers or fountains that are clean and sanitary, and handled in a manner that prevents them from becoming sources of contamination	Auditor observes that drinking water containers are handled in a manner that prevents them from becoming sources of contamination.	Policy is developed or revised. Non-compliances are corrected on site. Retraining is performed.
12.22	There is a written policy prohibiting the storage and use of personal items outside of designated areas.	Operation has a policy to permit employee personal items (e.g. employee lunches, drinks, clothing) only in designated, non-production and non-product storage areas.	Auditor reviews policy and visually observes compliance.	Policy is developed or revised. Non-compliances are corrected on site. Retraining is performed.

13. Education and Training

Item#	Requirement	Procedure	Verification	Corrective Action/Disposition
13.1	Employees shall receive mandatory safe product handling and personal hygiene education at time of hire with reinforcements as detailed in company SOP.	Operation shall have a written SOP that outlines topics to be covered in training, with reference to authoritative sources of training information; dates, names and signatures of trainees; and prescribed frequencies of training, to be at least annually.	Auditor reviews SOP and training logs, interviews employees for knowledge of the training and observes employees for evidence of non-compliance.	Policy is developed or revised. Non-compliances are corrected on site. Retraining is performed.
13.2	Individuals shall be trained on all food safety requirements specific to their assigned duties.	Training programs shall be inclusive of all individuals' assigned responsibilities and operational requirements. Training records are available.	Auditor reviews training program and logs, interviews employees for knowledge of the training and observes employees for evidence of insufficient training for assigned duties.	Policy is developed or revised. Retraining is performed.

13.3	Workers are trained and follow the policy that product dropped on the floor is discarded.	Employees are trained that open or uncased product that has fallen to the floor shall be discarded.	Auditor reviews policy, performance criteria and training logs, interviews employees for knowledge of the training and observes production areas and employees for evidence of non-compliance.	Training program is revised. Retraining is performed.
13.4	Supervisors are trained to look for, recognize and react to symptoms of potentially infectious illness.	Supervisors are trained to look for and recognize symptoms such as diarrhea, vomiting or other signs of potentially infectious illness, and appropriate actions to be taken.	Auditor reviews training programs, training logs, and interviews supervisors for knowledge of illness symptoms and appropriate actions.	Training program is revised. Retraining is performed.

14. Product Traceability and Recall Procedures

Item#	Requirement	Procedure	Verification	Corrective Action/ Disposition
14.1	All levels of the tomato supply chain shall maintain adequate traceability to a minimum of immediate next recipient and immediate previous supplier.	Operation shall have a procedure to identify the sources of incoming product and recipients of outgoing product (including trash).	Auditor shall review procedure.	Procedure is developed or revised.
14.2	Establish procedures to maintain lot identity of tomatoes, including setbacks and primary containers, throughout the repacking process.	Operation shall have a procedure and maintain records to identify all outgoing product lots and shipments with all component tomato lots and prior lots in reused primary boxes, in both traceback and trace forward directions.	Auditor shall review procedure and review batch records for compliance. Auditor shall ask operation to traceback one, auditor-selected product lot to all supplier lots and primary boxes, and trace forward one supplier lot to all product lots and shipments.	Procedure is developed or revised. Retraining is performed.

14.3	Establish procedures for reconciliation of incoming tomato lots to usage.	Operation shall have a procedure and maintain records of tomato use and shrink to allow 100% reconciliation of tomato lots within 2 hrs.	Auditor reviews reconciliation procedure and asks operation to provide records to support one, auditor-selected reconciliation.	Procedure is developed or revised. Retraining is performed.
14.4	Documentation maintained for each lot received shall include sufficient information about the source to allow for the appropriate tracing of product.	Operation shall maintain lot identification records that include product description, shipper's identity and location, transporter's identity and location, product lot numbers, country of origin, quantity, pack size and date received.	Auditor reviews the procedure and receiving documents to verify compliance.	Procedure is developed or revised. Retraining is performed.
14.5	Documentation maintained for each lot shipped shall include sufficient information about the customer receiving the product to allow for the appropriate tracing of product.	Operation shall maintain lot identification records that include product description, customer's identity and location, transporter's identity and location, product lot numbers, country of origin, quantity, pack size and date shipped.	Auditor reviews the procedure and shipping documents to verify compliance.	Procedure is developed or revised. Retraining is performed.
14.6	Traceability records shall be readily available.	Operation shall maintain all records necessary to enable traceability of one material or product lot in a manner to be accessible upon request within 2 hours.	Auditor requests records to support either the traceback or trace forward, and verifies accessibility within 2 hours.	Procedure is developed or revised. Retraining is performed.
14.7	Effectiveness of these procedures shall be tested at least annually. A record of this test shall be kept on file.	Operation shall perform a trace exercise at least once per year. This may be performed during the audit or during a mock recall.	Auditor reviews records of the most recent trace exercise, if performed in the past 12 months.	Procedure is developed or revised. Retraining is performed.

14.8	A successful mock recall test has been performed in the last 12 months.	Operation shall test all recall procedures, in a mock process, at least annually.	Auditor reviews records of the most recent mock recall.	Procedures are developed or revised. Retraining is performed.
15. Food Defense Awareness				
Item#	Requirement	Procedure	Verification	Corrective Action/Disposition
15.1	The facility is registered with FDA as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.	If required by 21 CFR Part 1, Subpart H, facility is registered with FDA and registration is current.	Auditor asks whether facility is registered. Facility is not required to demonstrate registration to auditor.	Facility registers with FDA as required.
15.2	There are procedures in place that readily identify employees, and those with specific access privileges, e.g., to chemical storage, to the water system.	Operation has a written procedure for identifying current employees. Procedure also indicates which employees have access to restricted areas or materials, and how access is restricted.	Auditor reviews procedure, verifies list of special access employees, observes restricted areas and materials for evidence of compliance and interviews employees for knowledge of procedure.	Procedures are developed or revised. Retraining is performed.